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Monday
November 4, 1996

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WASHINGTON, DC

WHEN: November 19, 1996 at 9:00 a.m.

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Contents

Federal Register

Vol. 61, No. 214

Monday, November 4, 1996

Separate Parts In This Issue

Reader Aids

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 61, No. 214
Monday, November 4, 1996

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 13

RIN 3150–AF57

Adjustment of Civil Monetary Penalties for Inflation; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; Correction.

SUMMARY: This document corrects a final rule appearing in the Federal Register on October 11, 1996 (61 FR 53554), that adjusts the maximum Civil Monetary Penalties under statutes within the jurisdiction of the NRC. This action is necessary to correct an erroneous Regulation Identifier Number (RIN).

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, telephone (301) 415–7163.

SUPPLEMENTARY INFORMATION: On page 53554, in the first column, in the heading, the fourth line from the top, the RIN number is corrected to read, ''RIN 3150–AF57''.

Dated at Rockville, Maryland, this 29th day of October 1996.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration.

[FR Doc. 96–28226 Filed 11–1–96; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–AWP–2]

Establishment of Class E Airspace; Murrieta/Temecula, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a Class E airspace area at Murrieta/Temecula, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 18 to French Valley Airport has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at French Valley Airport, Murrieta/Temecula, CA.

EFFECTIVE DATE: 0901 UTC January 30, 1997.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, Operations Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

History

On September 17, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing a Class E airspace area at Murrieta/Temecula, CA, (61 FR 48871). This action will provide adequate controlled airspace to accommodate a GPS SIAP to RWY 18 at French Valley Airport, Murrieta/Temecula, CA.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes a Class E airspace area at Murrieta/Temecula, CA. The development of a GPS SIAP to RWY 18 has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the GPS RWY 18 SIAP at French Valley Airport, Murrieta/Temecula, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air)

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Murrieta/Temecula, CA [New]

French Valley Airport, CA
(Lat. 33°34′34″N, long. 117°07′41″W)

* * * * *

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the French Valley Airport, excluding the Camp Pendleton, CA, 700-foot Class E airspace area and excluding the Riverside, CA, 700-foot Class E airspace area.

Issued in Los Angeles, California, on October 17, 1996.

George D. Williams,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–28283 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 96–AEA–07]

Establishment of Class E Airspace; Grundy, VA

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Grundy, VA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Grundy Municipal Airport, Grundy, VA has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Grundy Municipal Airport.

EFFECTIVE DATE: 0901 UTC, January 30, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Frances T. Jordan, Airspace Specialist, Operations Branch, AEA–530, Air Traffic Division, Eastern Region, Federal Aviation Administration, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430, telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

History

On August 15, 1996, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by establishing a Class E airspace area at Grundy Municipal Airport, Grundy, VA (61 FR 42397). The development of a GPS RWY 22 SIAP at Grundy Municipal Airport has made this action necessary.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace areas designations are published in paragraph 6005 of FAA Order 7400.9D, dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) establishes a Class E airspace area at Grundy, VA. The development of a GPS RWY 22 SIAP at Grundy Municipal Airport has made this action necessary. The intended effect of this action is to provide adequate Class E airspace for aircraft executing the GPS RWY 22 SIAP at the airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 10034, February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal.

Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996 and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA VA E5 Grundy, VA [New]

Grundy Municipal Airport, VA
(Lat. 37°13′56″N., Long. 82°07′30″ W.)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Grundy Municipal Airport.

* * * * *

Issued in Jamaica, New York; on October 21, 1996.

John S. Walker,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 96–28286 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3500

[Docket No. FR–3638–F–08]

RIN 2502–AG26

Amendments to Regulation X, the Real Estate Settlement Procedures Act: Withdrawal of Employer-Employee and Computer Loan Origination Systems (CLOs) Exemptions; Notice of Time Schedule for Establishing Effective Date of Rule

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice of time schedule for establishing effective date of rule.

SUMMARY: The Department published a notice on October 4, 1996, delaying until further notice the effective date of a final rule revising Regulation X, which implements the Real Estate Settlement Procedures Act of 1974 (RESPA), in light of recent legislation. The final rule was initially published on June 7, 1996, and it was corrected and revised on August 12, 1996. The October 4 notice announced that within 30 days, the Department would provide further notice of a time schedule for making effective the various provisions of the June 7, 1996 rule. Today's notice provides that time schedule.

FOR FURTHER INFORMATION CONTACT: David Williamson, Director, Office of Consumer and Regulatory Affairs, Room 9156, telephone (202) 708–6408; or, for legal questions, Kenneth A. Markison, Assistant General Counsel for GSE/RESPA, Grant E. Mitchell, Senior Attorney for RESPA, or Richard S. Bennett, Attorney, Office of General Counsel, Room 9262, telephone (202) 708–1550. (The telephone numbers are

not toll-free.) For hearing- and speech-impaired persons, these numbers may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1–800–877–8339. The address for the above-listed persons is: Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410.

SUPPLEMENTARY INFORMATION: In the final rule published on June 7, 1996 (61 FR 29238) entitled ''Amendments to Regulation X, the Real Estate Settlement Procedures Act: Withdrawal of Employer-Employee and Computer Loan Origination Systems (CLOs) Exemptions,'' the Department established an effective date of 120 days from publication: October 7, 1996. Subsequently, on August 12, 1996 (61 FR 41944), the Department revised a document associated with that rule—Appendix D, the Controlled Business Arrangement (CBA) Disclosure Statement Format—in order to clarify the directions for completing the format.

Section 2103 of the Economic Growth and Regulatory Paperwork Reduction Act of 1996, which was signed by the President on September 30, 1996, as Title II of the Omnibus Consolidated Appropriations Act, 1997 (Pub. L. 104–208; approved September 30, 1996) (the Act), delays the effective date of the amendment to Regulation X contained in the June 7, 1996 final rule concerning payments to employees by their employers. For instance, one provision of the June 7, 1996 rule would have eliminated 24 CFR 3500.14(g)(1)(vii) of Regulation X, which permits ''[a]n employer's payment to its own employees for any referral activities.'' Section 2103 of the Act delays the effectiveness of this provision of the June 7 rule. The Act also provides that the effective date of the following provisions is delayed: (1) The exemption for employer payments to managerial employees (§ 3500.14(g)(1)(viii) of the June 7 rule); (2) The exemption for employer payments to employees who do not perform settlement services in any transaction (§ 3500.14(g)(1)(ix) of the June 7 rule); and (3) The provision clarifying that ''[a] payment by an employer to its own *bona fide* employee for generating business for that employer'' is permissible (§ 3500.14(g)(1)(vii) of the June 7 rule). The Act also forbids the Department from providing public notice of the effective date of these provisions more than 180 days or less than 90 days before their effective date.

Although not required by the legislation, the Department decided to delay temporarily the effective date of the entire June 7 rule, as corrected and revised on August 12, and to continue the prior provisions relating to employer-employee payments (as in effect on May 1, 1996), as required by the Act. The Department published a notice in the Federal Register informing the public of this delay on October 4, 1996 (61 FR 51782). The October 4 notice announced that the Department would analyze the legislation and, within 30 days, publish a second notice providing the public information on a time schedule for making effective the various provisions of the June 7 rule, as revised August 12. Today's notice provides the Department's time schedule for those actions.

Time Schedule

The Department will shortly publish a revised final rule that will make effective those provisions of the June 7 final rule that the Department has determined are unaffected by the delay provisions in section 2103 of the Act. The Department intends to publish this rule within 15 days of date of publication of this notice and to establish an effective date of 60 days after the date of publication.

For the reasons explained in the preamble to the June 7 rule, the upcoming final rule will withdraw the Computer Loan Origination (CLO) exemption (24 CFR § 3500.14(g)(1)(viii)) and CLO disclosure format (Appendix F to part 3500). It will implement the controlled business format, as published on August 12, 1996 (61 FR 41944), with a technical revision discussed below.

The upcoming final rule will also make other technical revisions and clarifications to Regulation X, including some designed to conform the regulatory language to the language of the new legislation. For example, the Department intends, in the upcoming final rule, to replace references to ''controlled business arrangements'' with references to ''affiliated business arrangements'' or ''AfBAs,'' reflecting the change in terminology effected by section 2103(c) of the Act. The Department intends to make this change throughout the Regulation X (part 3500) and its appendices, including Appendix D, which will be renamed the ''Affiliated Business Arrangement Disclosure Statement Format.''

In the upcoming final rule, the Department intends to acknowledge section 2103(d) of the Act, which amends section 8(c)(4)(A) of RESPA to provide special affiliated business arrangement disclosure procedures for telemarketing and electronic media referrals, by adding a cross-reference to this amended statutory provision. The Department intends to undertake future rulemaking to provide guidance on this provision of the new Act. The Department also intends to revise the regulations in the future to reflect the amendments in section 2103(a) of the Act simplifying the disclosure to applicants relating to assignment, sale, or transfer of mortgage servicing.

Because of the legislation, the upcoming final rule will not address the employer-employee issues addressed in the June 7 final rule. Consistent with the Act, the Department is prohibited from announcing at this time the effective date for the employer-employee provisions of the June 7 rule. It is the Department's intent, however, to move forward expeditiously to make rules on this subject effective on or after the legally permissible date of July 31, 1997, as feasible in accordance with law. The Department's plans include issuing a proposed rule in the upcoming months to create an exemption to section 8's prohibition against referral fees for employer payments to *bona fide* employees for referrals of settlement service business to a settlement service provider in the same industry that has an affiliate relationship with the employer or in which the employer has a direct or beneficial ownership interest of more than 1 percent.

Further Guidance

The October 4 notice advised affected persons to comply with the guidance contained in the three Statements of Policy published simultaneously with the June 7, 1996 rule (61 FR 29255–29266), except to the extent that the guidance in them interprets rule provisions that are delayed from becoming effective. That advice remains in effect.

In addition, as indicated in the October 4 notice, to ease any compliance burden on the industry, the Department's position is that, until further notice, persons are free to use the revised disclosure statement format published on August 12, 1996, if they so choose, or they may continue to use the format which was in effect on May 1, 1996. As indicated above, however, the Department's plan is that the upcoming final rule will make effective the revised disclosure statement format published on August 12, 1996.

Dated: October 30, 1996.

Stephanie A. Smith,

General Deputy Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 96–28331 Filed 11–1–96; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AH51

Evidence of Dependents and Age

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning the evidence required to establish marriage, dissolution of marriage, birth of a child, and death of a family member. This amendment implements a provision of the ''Veterans' Benefits Improvements Act of 1994,'' which authorizes the Secretary to accept the written statement of a claimant as proof of the existence of these relationships. This amendment is intended to facilitate proof of the existence of these relationships.

EFFECTIVE DATE: November 4, 1996.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273–7230.

SUPPLEMENTARY INFORMATION: Section 301 of the ''Veterans' Benefits Improvements Act of 1994,'' Pub. L. 103–446, authorizes the Secretary to accept the written statement of a claimant as proof of the existence of the following relationships between the claimant and another person: marriage, dissolution of marriage, birth of a child, and the death of any family member. The statute further authorizes the Secretary to require documentation in support of the claimant's statement if: (1) The claimant does not reside within a State; (2) the claimant's statement on its face raises a question of its validity; (3) there is conflicting information of record; or (4) there is a reasonable indication, in the claimant's statement or otherwise, of fraud or misrepresentation. In the Federal Register of May 17, 1996 (61 FR 24910–11), VA published a proposal to amend 38 CFR 3.204 and 3.213 to allow the Secretary to exercise this discretionary authority. Interested persons were invited to submit written comments on or before July 16, 1996. No comments were received. The information presented in the proposed rule document still provides a basis for this final rule. Therefore, based on the rationale set forth in the proposed rule document, we are adopting the provisions of the proposed rule as a final rule without change.

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will not directly affect small entities. Only VA beneficiaries will be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

This regulatory action has been reviewed by the Office of Management and Budget under Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

The Catalog of Federal Domestic Assistance program numbers are 64.104, 64.105, 64.109, and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans, Vietnam.

Approved: October 22, 1996.
Jesse Brown,
Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. In § 3.204, the section heading is revised; paragraphs (a) and (b) are redesignated as paragraphs (b) and (c), respectively; and a new paragraph (a) is added to read as follows:

§ 3.204 Evidence of dependents and age.

(a)(1) Except as provided in paragraph (a)(2) of this section, VA will accept, for the purpose of determining entitlement to benefits under laws administered by VA, the written statement of a claimant as proof of marriage, dissolution of a marriage, birth of a child, or death of a dependent, provided that the statement contains: the date (month and year) and place of the event; the full name and relationship of the other person to the claimant; and, where the claimant's dependent child does not reside with the claimant, the name and address of the person who has custody of the child. In addition, a claimant must provide the social security number of any dependent on whose behalf he or she is seeking benefits (see § 3.216).

(2) VA shall require the types of evidence indicated in §§ 3.205 through 3.211 where: the claimant does not reside within a state; the claimant's statement on its face raises a question of its validity; the claimant's statement conflicts with other evidence of record; or, there is a reasonable indication, in the claimant's statement or otherwise, of fraud or misrepresentation of the relationship in question.

(Authority: 38 U.S.C. 5124)

* * * * *

§ 3.204 [Amended]

3. In § 3.204, newly redesignated paragraph (b) is amended by removing the first sentence and adding in its place ''The classes of evidence to be furnished for the purpose of establishing marriage, dissolution of marriage, age, relationship, or death, if required under the provisions of paragraph (a)(2), are indicated in §§ 3.205 through 3.211 in the order of preference.''.

§ 3.213 [Amended]

4. In § 3.213, paragraph (a) introductory text is amended by removing the first sentence and adding in its place ''For the purpose of establishing entitlement to a higher rate of pension, compensation, or dependency and indemnity compensation based on the existence of a dependent, VA will require evidence which satisfies the requirements of § 3.204.''.

5. Each Cross Reference following §§ 3.205, 3.206, 3.207, 3.208, 3.209, 3.210, 3.211, 3.212, and 3.214, is amended by removing ''Evidence other than evidence of service.'' wherever it appears and adding in its place ''Evidence of dependents and age.''.

6. The Cross Reference following § 3.213 is amended by removing ''Evidence other than evidence of services.'' and adding in its place ''Evidence of dependents and age.''.

[FR Doc. 96–28039 Filed 11–1–96; 8:45 am]
BILLING CODE 8320–01–P

38 CFR Part 3

RIN 2900–AI26

Willful Misconduct

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations regarding ''willful misconduct.'' The purpose is to remove unnecessary Latin phrases and to remove other unnecessary or

redundant material for purposes of clarity and readability.

EFFECTIVE DATE: This amendment is effective November 4, 1996.

FOR FURTHER INFORMATION CONTACT: Laurence Freiheit, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273–7252.

SUPPLEMENTARY INFORMATION: 38 U.S.C. 1110 and 1131 authorize the Secretary of Veterans Affairs to compensate veterans for disability resulting from injury or disease incurred or aggravated during active military service provided that the disability is not the result of the person's own willful misconduct. 38 U.S.C. 1521(a) authorizes the Secretary to pay disability pension to certain veterans who are permanently and totally disabled from nonservice-connected disability not the result of the veteran's willful misconduct. Although the statute does not define the term ''willful misconduct,'' the VA regulation at 38 CFR 3.1(n) defines it as ''an act involving conscious wrongdoing or known prohibited action (*malum in se* or *malum prohibitum*).''

We are deleting the Latin terms ''*malum in se* or *malum prohibitum*.'' Although they are standard legal terms, they serve no purpose here because the definition in § 3.1(n) is clear without them. *Malum in se* and *malum prohibitum* are legal terms of art which carry with them bodies of case law defining their meaning. Essentially, they differentiate between actions that are inherently evil or immoral and those that are not inherently immoral but which become so because their commission is expressly forbidden by positive law. These terms are apparently included in the regulation to make clear that both types of actions are included within the terms ''wrongdoing'' and ''prohibited action,'' together, would normally be understood to encompass both types of action, and, therefore, use of the Latin terms, the meaning of which is obscure to most persons, is not necessary.

A note following § 3.1(n)(3) directs users to § 3.1(y)(2)(iii) for a definition of the term ''willful misconduct'' in determining whether certain veterans meet the requirements to be considered former prisoners of war. The correct citation is § 3.1(y)(4); however, the definition at § 3.1(y)(4) merely duplicates the first sentence of § 3.1(n) (without the Latin terms) and all of § 3.1(n)(1). It is therefore, redundant, and we are deleting the last two sentences in § 3.1(y)(4) as well as the note following § 3.1(n)(3).

Since these amendments merely remove unnecessary material and are not substantive in nature, the Secretary finds under 5 U.S.C. 553(b) that prior notice and comment are unnecessary and that there is a basis for dispensing with a 30-day delay of the effective date.

Because no notice of proposed rulemaking was required in connection with the adoption of this final rule, no regulatory flexibility analysis is required under the Regulatory Flexibility Act, 5 U.S.C. 601–612. Even so, the Secretary hereby certifies that these regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility. These amendments are not substantive and do not affect any small entities.

The Catalog of Federal Domestic Assistance program numbers are 64.100, 64.101, 64.104, 64.105, 64.106, 64.109, and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans, Vietnam.

Approved: September 12, 1996.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A, continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

§ 3.1 [Amended]

2. In § 3.1, paragraph (n) introductory text is amended by removing ''(malum in se or malum prohibitum)''; and by removing the Note immediately following paragraph (n)(3).

3. In § 3.1, paragraph (y)(4) is amended by removing the last two sentences.

[FR Doc. 96–28190 Filed 11–1–96; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 57–8–6368a; FRL–5640–8]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on a revision to the California State Implementation Plan. The revision concerns a rule from the South Coast Air Quality Management District (SCAQMD). This approval action will incorporate this rule into the federally approved SIP. The intended effect of approving this rule is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The revised rule controls VOC emissions from solvent degreasing operations. Thus, EPA is finalizing the approval of this revision into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

DATES: This action is effective on January 3, 1997, unless adverse or critical comments are received by December 4, 1996. If the effective date is delayed, a timely notice will be published in the Federal Register.

ADDRESSES: Copies of the rule revisions and EPA's evaluation report for this rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW., Washington, DC 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 92123–1095

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182

FOR FURTHER INFORMATION CONTACT: Mae Wang, Rulemaking Section (A–5–3), Air

and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1200.

SUPPLEMENTARY INFORMATION:

Applicability

The rule being approved into the California SIP is: SCAQMD's Rule 1122, Solvent Degreasers. This rule was submitted by the California Air Resources Board (CARB) to EPA on May 13, 1993.

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the South Coast Air Basin. 43 FR 8964, 40 CFR 81.305. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the SCAQMD's portion of the California SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The South Coast Air Basin is classified as extreme;[2] therefore, this area was subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many revised RACT rules for incorporation into its SIP on May 13, 1993, including the rule being acted on in this document. This document addresses EPA's direct-final action for SCAQMD's Rule 1122, Solvent Degreasers. SCAQMD adopted Rule 1122 on April 5, 1991. This submitted rule was found to be complete on July 19, 1993 pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, Appendix V[3] and is being finalized for approval into the SIP.

Rule 1122 controls the emissions of VOCs from degreasing (cleaning) operations. VOCs contribute to the production of ground level ozone and smog. This rule was originally adopted as part of SCAQMD's effort to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and in response to EPA's SIP–Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and final action for this rule.

EPA Evaluation and Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to ''fix-up'' their RACT rules. See section 182(a)(2)(A). The CTG applicable to this rule is entitled, Control of Volatile Organic Emissions from Solvent Metal Cleaning; EPA–450/2–77–022 dated November 1977. Further interpretations of EPA policy are found in the Blue Book, referred to in footnote 1. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

SCAQMD's submitted Rule 1122, Solvent Degreasers includes the following significant changes from the current SIP:

- The definitions section has been expanded to include new terms,
- Requirements are separated for various degreaser types and general requirements are now specified,
- Standards for carbon adsorption systems have been added,
- The freeboard ratio for large degreasers has been raised from 0.75 to 1.0, and
- Compliance test methods and record keeping provisions have been added.

EPA has evaluated the submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, SCAQMD's Rule 1122, Solvent Degreasers, is being approved under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

EPA is publishing this document without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this Federal Register publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective January 3, 1997 unless, by December 4, 1996, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are

[1] Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice'' (Blue Book) (notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

[2] The South Coast Air Basin retained its designation of nonattainment and was classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 56 FR 56694 (November 6, 1991).

[3] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

received, the public is advised that this action will be effective January 3, 1997.

Regulatory Process

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises and government entities with jurisdiction over population of less than 50,000.

SIP approvals under sections 110 and 301(a) and subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S. Ct. 1976); 42 U.S.C. 7410 (a)(2).

Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector or to State, local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under Part D of the Clean Air Act. These rules may bind State, local, and tribal governments to perform certain actions and also require the private sector to perform certain duties. The rule being approved by this action will impose no new requirements because affected sources are already subject to these regulations under State law. Therefore, no additional costs to State, local, or tribal governments or to the private sector result from this action. EPA has also determined that this final action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866 review.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: October 17, 1996.

Felicia Marcus,

Regional Administrator.

Subpart F of part 52, chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c) (193) (i)(A)(*3*) to read as follows:

§ 52.220 Identification of Plan.

* * * * *

(c) * * *

(193) * * *

(i) * * *

(A) * * *

(*3*) Rule 1122, adopted on April 5, 1991.

* * * * *

[FR Doc. 96–28061 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[CA 009–0013a; FRL–5610–9]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Glenn County and Siskiyou County Air Pollution Control Districts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan (SIP). The revisions concern rules submitted by the State of California on behalf of the Air Pollution Control Districts of Glenn and Siskiyou Counties (the Counties) for the purpose of meeting requirements of the Clean Air Act, as amended in 1990 (CAA or the Act) with regard to general preconstruction permitting. This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to control air pollution in accordance with the requirements of the Act. The Counties' rules control emissions from new stationary sources. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals.

DATES: This direct final rule is effective on January 3, 1997, unless adverse or critical comments are received by December 4, 1996. If the effective date is delayed, a timely notice will be published in the Federal Register.

ADDRESSES: Copies of the rule revisions and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

New Source Section (A–5–1), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW., Washington, DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 92123–1095.

Glenn County Air Pollution Control District, PO Box 351, Willows, CA 95988.

Siskiyou County Air Pollution Control District, 525 S. Foothill Drive, Yreka, CA 96097.

FOR FURTHER INFORMATION CONTACT: Steve Ringer at (415) 744–1260, New Source Section, Air & Toxics Division (A–5–1), EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION:

Applicability

The rules that EPA is approving into the SIP include: Glenn County Air Pollution Control District Regulations: Section 51—New Source Review. Adopted on March 16, 1993. Siskiyou County Air Pollution Control District Rules and Regulations: Rule 1.2—Definitions (except section V1, Variance); Rule 1.4—Enforcement; Rule 2.1—Permits Required; Rule 2.2—Exemptions; Rule 2.10—Further Information; Rule 4.1—Visible Emissions; Rule 4.6—Circumvention; Rule 6.1—Standards for Permits to Construct; Appendix A—List/Criteria for Permit Applications. Adopted on January 24, 1989.

On March 26, 1990, the Siskiyou County rules were submitted to EPA as revision to the SIP. EPA found this submittal to be complete on June 20, 1990. On May 13, 1993, the Glenn County rules were submitted to EPA as a revision to the SIP. EPA found this submittal to be complete on July 19, 1993.

Background

The Counties are currently designated as in attainment of the national ambient air quality standards (NAAQS) for carbon monoxide, ozone, nitrogen dioxide, lead, sulfur dioxide, and particulate matter (PM_{10}).

EPA is taking this action to approve the rules identified above into the SIP for the purpose of meeting the general permitting requirements of 40 CFR 51.160 through 51.164, implementing section 110(a)(2)(C) of the Act. These provisions apply to sources whose emissions are below the major source thresholds regulated under Parts C and D of the Act. This action does not approve the Counties' rules for the purposes of meeting the nonattainment or prevention of significant deterioration (PSD) preconstruction permitting requirements of 40 CFR 51.165 and 51.166, nor does it approve the Counties' rules for the purposes of satisfying Title V of the Act.

The Counties' existing SIP approved preconstruction permitting rules were approved in several separate EPA actions occurring between May 31, 1972 and June 18, 1982. The changes contained in the submitted rules are improvements to the current SIP versions of these rules. These changes improve the rules because they either introduce needed language, or alter language so that the rules are in compliance with the Act and EPA regulations.

General preconstruction permitting requirements for sources with emissions below the major source thresholds regulated under Parts C and D of the Act are set out in 40 CFR 51.160 through 51.164, implementing section 110(a)(2)(C) of the Act.

EPA Evaluation and Action

To satisfy 40 CFR 51.160 through 51.164, the rules must (a) require sources to obtain legally enforceable permits before commencing construction or modification of a facility; and (b) contain procedures to prevent construction or modification of a facility that will interfere with attainment of the NAAQS. The rules must also ensure the availability of pertinent information to the public during the permitting process, and the opportunity for and consideration of public comments prior to permit issuance. EPA has reviewed the submitted rules and determined that they contain these elements. For a detailed description of how the submitted rules meet the applicable requirements, please refer to EPA's Technical Support Document (TSD) for this action.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments. However, should adverse or critical comments be filed, EPA is proposing approval of the submitted rules in a separate document in this Federal Register publication.

If EPA receives adverse or critical comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule with this action serving as the proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on January 3, 1997.

Administrative Review

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because this federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of State action. The Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct 1976); 42 U.S.C. 7410(a) (2).

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation.

The Office of Management and Budget has exempted this action from review under Executive Order 12866.

Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private section, of $100 million or more. EPA has determined that the approval promulgated in this notice does not include such a federal mandate, as this proposed federal action would approve pre-existing requirements under state or local law, and would impose no new federal requirements. Accordingly, no

additional costs to state, local, or tribal governments, or to the private section, will result from this action.

Under 5 U.S.C. 801(a) (1) (A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, and Sulfur dioxide.

Note: Incorporation by reference of the State Implementation Plan was approved by the Director of the Federal Register on July 1, 1982.

Dated: August 9, 1996.

Felicia Marcus,

Regional Administration.

Subpart F of Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Subpart F—California

Authority: 42 U.S.C. 7401–7671q.

1. Section 52.220 is amended by adding paragraphs (c)(179)(i)(E) and (c)(193)(i)(D) to read as follows:

§ 52.220 Identification of Plan.

* * * * *

(c) * * *

(179) * * *

(i) * * *

(E) Siskiyou County Air Pollution Control District.

(*1*) Rules 1.2 (except section V1), 1.4, 2.1, 2.2, 2.10, 4.1, 4.6, 6.1, and Appendix A, adopted on January 24, 1989.

* * * * *

(193) * * *

(i) * * *

(D) Glenn County Air Pollution Control District.

(*1*) Section 51, adopted on March 16, 1993.

* * * * *

[FR Doc. 96–28195 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 70

[AD–FRL–5643–5]

Withdrawal of Direct Final Rule for Interim Approval of Operating Permits Program; South Coast Air Quality Management District, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule for the interim approval of the South Coast Air Quality Management District title V operating permits program. EPA published the direct final rule on August 29, 1996, 61 FR 45330. As stated in that Federal Register document, if adverse or critical comments were received by September 30, 1996, the effective date would be delayed and notice would be published in the Federal Register. EPA subsequently received adverse comments on that direct final rule. EPA will address the comments received in a subsequent final action in the near future. EPA will not institute a second comment period on this document.

EFFECTIVE DATE: Withdrawal of the direct final rule becomes effective on November 4, 1996.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, Operating Permits Section (A–5–2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1252.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule located in the final rules section of the August 29, 1996 Federal Register, and in the short informational document located in the proposed rule section of the August 29, 1996 Federal Register.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: October 21, 1996.

Felicia Marcus,

Regional Administrator.

Therefore, the amendment to 40 CFR part 70, appendix A which added paragraph (dd) to the California entry is withdrawn.

[FR Doc. 96–28245 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 266

Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities

CFR Correction

In Title 40 of the Code of Federal Regulations, parts 260 to 299, revised as of July 1, 1996, § 266.100 is corrected by adding paragraphs (c)(3)(i)(B)–(D) as follows:

§ 266.100 Applicability.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) * * *

(B) The waste does not exhibit the Toxicity Characteristic of § 261.24 of this chapter for an organic constituent; and

(C) The waste is not a hazardous waste listed in subpart D of part 261 of this chapter because it is listed for an organic constituent as identified in appendix VII of part 261 of this chapter; and

(D) The owner or operator certifies in the one–time notice that hazardous waste is burned under the provisions of paragraph (c)(3) of this section and that sampling and analysis will be conducted or other information will be obtained as necessary to ensure continued compliance with these requirements. Sampling and analysis shall be conducted according to paragraph (c)(1)(ii) of this section and records to document compliance with paragraph (c)(3) of this section shall be kept for at least three years.

* * * * *

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 50

Policies of General Applicability

CFR Correction

In title 42 of the Code of Federal Regulations, parts 1 to 399, revised as of October 1, 1995, page 171, § § 50.604 through 50.606 are added as follows:

§ 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest

that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application for the funding to which this subpart applies, that:

(1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

(3) The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) The Institution will otherwise comply with this subpart.

§ 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 14

[CGD 94–004]

RIN 2115–AE72

Electronic Records of Shipping Articles and Certificates of Discharge

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: Consistent with the President's Regulatory Reinvention Initiative, the Coast Guard is revising the way that information on the engagement (shipment) and discharge of merchant mariners is maintained and submitted. The Coast Guard is also making editorial and other minor changes throughout its governing rules. The revision is due to statutory amendments directing, in effect, that ship-operating companies (shipping companies) maintain shipping articles and certificates of discharge, and that they be able to submit the information, electronically, to the Coast Guard. The rule should reduce approximately 70 percent of the ship-operating companies burden of preparing articles and certificates, and should reduce proportionately the number of personnel manually entering data and manually filing documents for the Coast Guard.

EFFECTIVE DATE: January 3, 1997.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G–LRA/3406) [CGD 94–004], U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593–0001, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477.

FOR FURTHER INFORMATION CONTACT: Mrs. Justine Bunnell, Marine Personnel Division (NMC–4A), U.S. Coast Guard National Maritime Center, (703) 235–1951.

SUPPLEMENTARY INFORMATION:

Regulatory History

On March 28, 1996, the Coast Guard published a notice of proposed rulemaking entitled Electronic Records of Shipping Articles and Certificates of Discharge in Federal Register (61 FR 13796). The Coast Guard received 12 letters commenting on the proposal. No public meeting was requested, and none was held.

Background and Purpose

In 1937, the Coast Guard became custodian of the program for protection of merchant mariners (''mariners''). To ensure that mariners are employed of their own will, that they are properly paid for their service, and that their time in service is properly documented, they and the masters or other persons in charge of their vessels, or these persons' representatives, sign contracts, known as shipping articles (''articles''). From this point forward, in the preamble, ''masters'' will stand for all of those persons other than mariners.

The content and form of articles for foreign and intercoastal voyages appear in 46 U.S.C. 10302, 10303, and 10304. The content of articles for coastwise voyages appears in 46 U.S.C. 10502, even as the form of these articles remains unspecified by statute, both the content and form of articles for voyages on the Great Lakes remain unspecified by statute. The articles consist of three parts: (1) features of the voyage and of several reciprocal duties, clear down to the caloric value of food served to each mariner daily; (2) particulars of engagement; and (3) particulars of discharge. Since 1937, usages or practices regarding articles have changed little. The same has been true regarding certificates of discharge.

When reporting for a foreign, intercoastal voyage, or for a coastwise voyage (including a voyage on the Great Lakes) aboard a vessel of 50 gross tons or more, the mariner presents to the master a valid merchant mariner's document (MMD), listing the mariner's qualifications. The master reviews the MMD, verifies the mariner's qualifications, and enters the information in the particulars of engagement (part 2 of the articles), then the master and the mariner sign the articles in the appropriate places. When finishing a foreign or intercoastal voyage, the master enters the mariner's wages and date for discharge in the particulars of discharge (part 3 of the articles), then the master and the mariner sign the articles in the other appropriate places. The master completes the certificate of discharge in the appropriate place, then the master and the mariner sign it in the appropriate place. The certificate indicates the mariner's name and identification number, the dates and places of shipment and discharge, the name and official number of the vessel, and the name of the shipping company. If the mariner holds a continuous discharge book, the master also completes and signs it in the appropriate place. The master ensures that the entries in the continuous discharge book (if held), on the certificate, and in the two particulars are proper, corresponding entries. The mariner keeps the continuous discharge book (if held). The mariner gets the original copy of the certificate of discharge.

When leaving the vessel before the end of the voyage, the mariner closes out the contract otherwise. The mariner and the master sign a ''mutual agreement'' as well as the particulars of discharge; the master notes in these particulars that the reason for the mariner's leaving is mutual agreement. The master completes and signs a certificate of discharge, then the mariner signs it. If the mariner holds a continuous discharge book, the master completes and signs it.

At the end of the voyage, after all mariners have signed the particulars of discharge and received their certificates of discharge, the shipping company sends the articles and signed copies of the certificates to the Coast Guard. The Coast Guard reviews the articles and certificates to ensure that they are complete and accurate. Next, it manually enters the data off the certificates into its own sea-service database and manually files the certificates in the mariners' records. Last, it manually files the articles (alphabetically, by name of vessel).

These usages or practices have prevailed for two generations. On December 20, 1993, Congress enacted the Coast Guard Authorization Act for 1994 [Pub. L. 103–206]. Title IV, 411, of that Act added 46 U.S.C. 10302(d) and 10502(e), each to read as follows:

> The owner, charterer, managing operator, master, or individual in charge shall maintain the shipping agreement [''articles''] and make [them] available to the [mariner].

The act added 46 U.S.C. 10320 to read as follows:

> The Secretary shall prescribe regulations requiring vessel owners to maintain records of [mariners] on matters of engagement, discharge, and service. A vessel owner shall make these records available to the [mariner] and the Coast Guard on request.

The Act also added 46 U.S.C. 10502(f), to read the same, except that it substituted ''shipping companies'' for ''vessel owners'':

> The Secretary shall prescribe regulations requiring shipping companies to maintain records of [mariners] on matters of engagement, discharge, and service. The shipping companies shall make these records available to the [mariner] and the Coast Guard on request.

The Act also raised the penalties in 46 U.S.C. 10321(a) and 10508(b), from $500 to $5,000 for violating any provision of these chapters or regulations prescribed under these chapters.

The Coast Guard had proposed the legislation because of budgetary constraints leading to cuts in its workforce and of the advent of computerization. Shipping companies will now be responsible for keeping articles and signed copies of certificates of discharge. They will still be free to submit them traditionally, but will now be free to submit just the data from them electronically. Either way, the Coast

Guard will now maintain its sea-service database electronically. The companies may develop their own software, use off-the-shelf software, or obtain software developed by the Coast Guard, to generate articles and certificates from existing records of personnel. Whichever of these three courses a particular company follows, the Coast Guard will provide standards that ensure compatibility for the electronic transfer of data from the company's system to the Coast Guard's sea-service database.

The primary purposes of this rule are to standardize the format of articles (for all voyages that require them), eliminate redundant forms such as masters' reports of mariners shipped or discharged, authorize persons acting as masters to initiate and sign articles and certificates of discharge, confer on shipping companies the legal and practical ability to transfer sea-service data electronically to the Coast Guard, and in general to lighten recordkeeping. The secondary purposes of this rule are to publish new statutory penalties, to remove gender-based language, and to clarify 46 CFR part 14.

Discussion of Comments and Changes

The Coast Guard received twelve responses to the Notice of Proposed Rulemaking. There were nine responses in support of the rulemaking with some corrections and minor changes to the written regulations. There were three responses that did not support the rulemaking.

The comment suggested that we add a statement to § 14.211, indicating that the next of kin information should not be included in the posted copy of the shipping articles. The Coast Guard agrees with this change and has incorporated the change in the regulations.

One comment suggested that in § 14.313, the report need not be sent more frequently than once per calendar month. The Coast Guard understands that some coastwise voyages, including those on the Great Lakes, are very short duration and would decrease the master's work if the information was transmitted on a monthly basis versus and voyage by voyage basis. The Coast Guard has changed the regulations to permit manual submission once per calendar month. Note: § 14.313 will be 14.311 in the final rule.

Three comments were received concerning §§ 14.303 and 14.305. Section 14.303 is revised to reflect the master's requirement to make the appropriate entries on the ships articles and consular's obligations, as specified in 46 U.S.C. 10318, to discharge a seaman upon request. Section 14.305 has been deleted.

One comment requested that we consider alternative methods of data transfer such as E-mail. Due to the sensitivity of the records and security issues, E-mail is not a viable alternative at this time.

The Coast Guard received five comments concerning the retention period that the shipping companies retain certificates of discharge and originals of shipping articles. Several comments requested the period be reduced to 3 years and one comment suggested no retention by shipping companies. Although the statutory change and this rulemaking require process changes by the companies, based on correspondence and conversations with shipping company personnel and masters of vessels, the Coast Guard feels that the burden on the companies will be minimal. However, the Coast Guard will reduce the retention period to 3 years. The record of service will be maintained by the Coast Guard electronically, for 6 years after the last transaction, and will be archived and available for retrieval for 60 years.

One comment suggested that § 14.313 which authorizes the use of electronic transmission is misleading and that electronic data transmission will eventually be required. The Coast Guard is not requiring shipping companies to submit data electronically.

One comment disagreed with the Coast Guard analysis regarding the cost savings. The comment suggested that any savings is not a result of new rules, but a product of technology. The comment writers assessment is correct since much of the savings is a product of technology; however, if we do not allow the use of technology by changing the existing rules, there will be no savings.

One comment expressed the concern that access to and retrieval of needed historical information will be sorely compromised to the department of the mariner who needs to retrieve information if a centralized database is not maintained by the Coast Guard. The Coast Guard will maintain the existing paper copies of shipping articles and certificates of discharge. A centralized database created in 1981, contains historical data from 1937 to the present, and will continue to be maintained. One comment suggested that the Coast Guard change the Mariner's Employment Information System (MEIS) to make the program useful rather than a burden to the shipping companies. The Coast Guard is continuing to work with the shipping companies, masters, and union representatives to insure that MEIS is a helpful tool, not a burden to the companies.

One comment recommended that the Coast Guard take this opportunity to allow use of individual articles. The Coast Guard must have a statutory change to allow individual articles, thus, we cannot address this suggestion in this rulemaking.

One comment suggested that the supplemental submission period be extended to at least 60 days. The Coast Guard will change § 14.213(b)(2), to extend the supplemental submission period to 60 days.

One comment recommended that the Coast Guard harmonize coastwise and foreign/intercoastal article formats using a format similar to coastwise articles. Section 14.207 provides for the use of form CG–705A for coastwise, foreign, intercoastal, and Great Lake voyages.

One comment suggested that all vessels under 1600 gross tons no longer be required to prepare certificates of discharge since masters/companies have difficulty obtaining the forms, that Congress make it illegal to withhold written sea service information, and that the Coast Guard discontinue collecting paperwork. Since all of these points require statutory changes, the Coast Guard will not address them in this rulemaking.

One comment urged the Coast Guard to ensure that they maintain adequate and reliable electronic sea-service database backup files in the event of a system breakdown, compromise, fire, or any other misfortune. The Coast Guard has an extensive Disaster Recovery Plan in place which addresses issues such as proper backups, off-site storage for backup tapes, and other security issues to insure that complete and adequate records are available.

The comment also recommended that the regulation include specific provisions that both shipping articles and certificates of discharge be available from the shipping company to the mariner upon request. The mariner may also obtain a printout of their sea service time from the Coast Guard.

One comment expressed concern that § 14.103 does not provide an electronic address. This electronic address was not included because the Coast Guard does not have this information currently available.

One comment requested the definition of an ''unrigged vessel.'' ''Unrigged vessel'' refers to a class of vessel no longer categorized, consequently the term is obsolete and removed. The reference to seagoing barges is moved to § 14.201.

One comment suggested that in § 14.207 the Coast Guard use ''approved'' off-the-shelf software for the shipping articles/certificates of discharge versus obtaining approval on a case by case basis. Due to the current security needs of the Coast Guard, companies must receive approval individually.

One comment indicated that bays and sounds would be exempt under § 14.201(b)(3) since they are in either adjoining states or one state. This is not true in all cases, i.e., Chesapeake Bay from a port in Virginia to a port in Delaware, not same or adjoining States. Also, §§ 14.201 (2) and (3) were further clarified to eliminate confusion as to their meaning.

One comment requested a prescribed format for a certificate of discharge detailed in § 14.309(a). The Coast Guard agrees that a prescribed format in the rule would be beneficial to the public; therefore, they have added the prescribed format to § 14.307(a) in the final rule.

One comment requested the elimination of gender-based language in § 14.311(b). The Coast Guard agrees and made the change in the rule (now § 14.309(b) in the final rule).

One comment objected to rewriting of regulations to ''eliminate gender-based language.'' The regulations were not rewritten to ''eliminate gender-based language,'' but were rewritten to reflect statutory changes.

One comment interpreted § 14.207 to allow articles in any form as long as the content complies with 46 U.S.C. 10502, which ignores requirements of U.S. Customs. The format in form CG–705A, which is approved, meets the needs of U.S. Customs and conforms to 46 U.S.C. 10502, as well as 46 U.S.C. 10302, 10303, 10304, and 10305. One comment indicated that the Coast Guard is unrealistic when they propose that shipping companies maintain original sets of articles and other documentation and then expect those items to be sent to the Coast Guard when the companies go out of business. The commenter writer wanted to know what penalties would then be levied upon whom. The company that holds the records will be held responsible for sending the records to the Coast Guard for storage. As stated in 46 U.S.C. 10321, they would be liable for a civil penalty of not more than $5,000.

One comment also stated that the Coast Guard incorrectly perceives that this regulation will reduce the workload on the ship's crew. Based on the Coast Guard's information, this rule will reduce the workload on most of the ships' crews.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and will not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget (OMB) under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) [44 FR 11040 (February 26, 1979)]. The Coast Guard expects the economic impact of this rule to be so minimal, that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Many shipping companies, for their own purposes and convenience, already maintain electronic records of employment, from which they can generate both articles and certificates of discharge. Until now they have had to generate both by writing or typing. Now they will be able to print both, when required, from the computer; transmit the data off the certificates directly to the Coast Guard, using the software developed by the Coast Guard if not software developed by themselves or bought off the shelf; and still provide original certificates to their mariners. Upgrades or enhancement to the software developed by the Coast Guard, and long-term support for it, may cost them $250 a year. But initial issue of it, and first-year support of it, will cost them nothing. This new way of doing business will save them time, effort, and money, about $1 million a year.

Small Entities

Under the Regulatory Flexibility Act [5 U.S.C. 601 *et seq.*], the Coast Guard must consider whether this final rule, will have a significant economic impact on a substantial number of small entities. ''Small entities'' may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

Smaller shipping companies may lack the equipment necessary to prepare articles and certificates of discharge and to transmit the data from the certificates to the Coast Guard, electronically. But the Coast Guard will continue to accept copies of the certificates, by mail, and manually enter data into the database. Shipping companies will not need to buy computers. This will let the Coast Guard maintain an accurate sea-service database receiving data from all companies required to submit them, by mail if not electronically.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule will does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded the environmental impact of this rule and concluded that, under paragraph 2.B.2 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. Subparagraphs 2.B.2.e. (34) (a) and (c) of that Instruction exclude, respectively, regulations that are editorial or procedural and those that concern maritime personnel. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

Collection of Information

Under the Paperwork Reduction Act [44 U.S.C. 3501 *et seq.*], the Office of Management and Budget (OMB) review each rule that contains a collection-of-information requirement to determine whether the practical value of the information would be worth the burden imposed by its collection. Collection-of-information requirements include reporting, recordkeeping, notification, and other, similar requirements.

This rule contains collection-of-information requirements in the following sections: 14.207, 14.209, 14.211, 14.213, 14.301, 14.303, 14.305, 14.307, 14.309, 14.311, 14.405, and 14.407. The following particulars apply:

DOT No: 2115.

OMB Control No.: 2115–0015 and 2115–0042.

Administration: U.S. Coast Guard.

Title: Electronic Records of Shipping Articles and Certificates of Discharge.

Need for Information: To protect merchant mariners by ensuring that records of their employment, wages, and next of kin are accurate and are available for their review.

Proposed Use of Information: To promote safety aboard domestic merchant vessels by ensuring that merchant mariners qualify by training and service for original or upgraded

credentials; to maintain sea-service data toward retirement benefits; and to furnish those data in the many cases litigated over collisions, injuries, or asbestosis.

Frequency of Response: Articles and copies of certificates of discharge have been due after each voyage. Articles and certificates would still have to be prepared for each voyage. Data from certificates would still have to reach the Coast Guard after each voyage. But now these data could move by wire rather than by mail; no forms would move, unless shipping companies chose not to avail themselves of the benefits of this rule, until after a lag of 3 years. The number and length of voyages depend on the companies.

Burden Estimate: The master of each vessel currently prepares, by hand, large, antiquated articles and certificates of discharge. The shipping companies send these records to the Coast Guard. The Coast Guard enters, by hand, sea-service data into its database, and files originals of articles (alphabetically, by names of vessels) and copies of certificates in individual mariners' records. It leaves the copies in the records. After 3 years, it transfers articles to the Federal Records Center in Suitland, Maryland, which stores them for 60 years. After 3 years of inactivity, it transfers the records themselves to that Center, which, again, stores them for 60 years.

In this final rule, the master of each vessel would still prepare articles and certificates of discharge. The shipping company would retain the option of his or her preparing both forms manually and sending copies of certificates to the Coast Guard for entry into its sea-service database. But it would gain that of his or her preparing both forms electronically on software developed by themselves or the Coast Guard, or bought from stock and of transmitting the data from certificates electronically to the Coast Guard. The Coast Guard would maintain the record of sea service in its database for 6 years after the mariner's last activity such as taking out an upgraded, renewed, modified, or duplicate license or MMD, or sailing and then transfer its record, in whatever electronic form, to the center.

The burden would decrease greatly for companies that already had, or that obtained, the capability of preparing articles and certificates electronically from their current records of employment. They would no longer collect data more than once and could collect them however they chose. It would decrease considerably even for companies lacking this capability. They would, while their masters continued preparing articles and certificates manually, need only to send copies of certificates to the Coast Guard voyage by voyage; even they would not need to send articles to the Coast Guard voyage by voyage. So both the cost of sending articles oftener than once a year and the cost of sending them at all during the first 3 years would be eliminated for all companies. All would maintain files of articles and of copies of certificates for 3 years; then they would send the articles to the Coast Guard, which would prepare the articles for storage at that Federal Records Center, and the shipping companies would destroy their copies of certificates, since the Coast Guard would hold the record in it's database. The added burden on these would take the forms of allotting more storage space in their offices to maintain the articles for 3 years and of, about one work week for one person per company per year after the first 3 years, both packing the articles to send to the Coast Guard for further storage and destroying their copies of discharges. The Coast Guard invites comments on the size of this added burden (or of any other burden, whether or not anticipated here).

Respondents: The chief regulatory impact would fall on the medium and large shipping companies because they operate most of the vessels required to execute articles and certificates of discharge. They would continue to prepare, issue, and keep files of articles and of copies of certificates. They would make these files accessible to the Coast Guard and mariners upon request and would send voyage by voyage, for the sea service database of the Coast Guard either copies of certificates, as they do now, though without articles, or data transmitted electronically from these files.

Form(s): The regulated community of shipping companies and mariners would be free to forgo the use of each of these records, in whole or in its current form: Forecastle Card, CG–704; Shipping Articles, CG-705A; Certificate of Discharge, CG–718A; Record of Entry, CG–718E; and Continuous Discharge Book, CG–719A; and (although OMB did not renew authority for its use after February 1995) Master's Report of Seamen Shipped or Discharged, CG–735T.

In this final rule, the regulated community would still have to deal with all of the data contained in these records, in some form: Shipping Articles, CG–705A; and Certificate of Discharge, CG–718A.

Average Burden Hours per Respondent: Each year, shipping companies prepare about 8,000 articles with accompanying certificates of Discharge; this costs them almost $1.43 million. Each year hereafter, they would still prepare about 8,000 articles with accompanying certificates, but this would cost them just about $0.43 million. The reason is the efficiency that this rule would bring. For each voyage, masters need about 2.5 hours to prepare the articles with accompanying certificates and send them. For each voyage hereafter, those able to file electronically would need about 0.5 hour to prepare the documents and 0.25 hour to file the data from them. The burden-hours would diminish by just about 70 percent.

Savings

For Respondents

The average salary for the staff to prepare the articles and certificates of discharge is $50 an hour. That staff could save 20,000 hours a year, though the exact figure would depend on two variables: the numbers and kinds of vessels and voyages; and the offsetting burden, in the fourth and later years, of purging 3-year-old copies of certificates and packing and sending 3-year-old articles. The Coast Guard invites comments on the sizes of these two variables.

For Coast Guard

The Coast Guard would save in three ways: (1) on its own personnel, (2) on its contractors' personnel, and (3) on storage space. Although some shipping companies may continue to submit paper copies of certificates of discharge requiring the Coast Guard to continue entering data from some records, the Coast Guard would save 950 hours or $20,000 a year on its own personnel. The Coast Guard has eliminated 10 ''positions'' and saved 19,000 hours and has lost $460,000 a year from it's budget to support contractors' personnel. Also, the Coast Guard would need 15 or 20 fewer cubic feet of storage-space a year over the next 15 years and so would save $7,500 at $500 a year over those years on storage space.

Persons are not required to respond to a collection of information unless it displays a current valid Office Management Budget (OMB) control number. The Coast Guard has submitted the information collection requirements in this rule to OMB for review pursuant to The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) OMB has approved information collection for shipping articles and the section numbers are 46 CFR 14.207, 14.209, 14.211, 14.213, 14.309, and the corresponding OMB approval number is OMB control

number 2115–0015, and expires October 31, 1997. OMB approval for Certificate of Discharge expires on September 30, 1996, and the Coast Guard has asked for OMB approval to review that request. See notice, number CGD 96–056 for details.

Individuals and organizations may submit comments by January 29, 1997, on the information collection requirements for this portion of the final rule. Comments should be directed to the Executive Secretary, Marine Safety Council as indicated under addresses and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, room 10235, 725 17th Street NW., Washington, DC 20503, Attention: Desk Officer for DOT. The Coast Guard will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the pending information Collection requirements.

List of Subjects in 46 CFR Part 14

Oceanographic research vessels, Reporting and recordkeeping requirements, Seamen (merchant mariners).

For the reasons set out in the preamble, the Coast Guard revises 46 CFR part 14, to read as follows:

PART 14—SHIPMENT AND DISCHARGE OF MERCHANT MARINERS

Subpart A—General

Subpart B—Shipment of Merchant Mariners

Subpart C—Discharge of Merchant Mariners

Subpart D—Oceanographic Research Vessels

Authority: 5 U.S.C. 552; 46 U.S.C. Chapters 103 and 104.

Subpart A—General

§ 14.101 Purpose of part.

This part prescribes rules for the shipment and discharge of merchant mariners aboard certain vessels of the United States.

§ 14.103 Addresses of Coast Guard.

(a) By mail: National Maritime Center (NMC–4A), U.S. Coast Guard, Suite 510, 4200 Wilson Boulevard, Arlington, VA 22203–1804.

(b) By facsimile: 703–235–1062.

§ 14.105 Disclosure and privacy.

The Coast Guard makes information available to the public in accordance with 49 CFR part 7, including appendix B.

Subpart B—Shipment of Merchant Mariners

§ 14.201 Voyages upon which shipping articles are required.

(a) Before proceeding either upon a foreign, intercoastal, or coastwise voyage (including a voyage on the Great Lakes) listed in paragraph (b) of this section or with the engagement or replacement of a merchant mariner for such a voyage, each master or individual in charge of a vessel or seagoing barge of the United States shall execute shipping articles however prepared, manually or electronically. The master or individual in charge and each mariner engaged or replaced shall sign the articles.

(b) Except as provided by § 14.203, articles are required upon each voyage by a vessel of the United States—

(1) Of 100 gross tons or more, on a foreign voyage, which is a voyage from a port in the United States to any foreign port other than a port in—

(i) Canada;

(ii) Mexico; or

(iii) The West Indies.

(2) Of 75 gross tons or more on a voyage between a port of the United States on the Atlantic Ocean and a port of the United States on the Pacific Coast; or

(3) Of 50 gross tons or more on a voyage between a port in one State and a port in another State other than an adjoining State.

§ 14.203 Voyages upon which shipping articles are not required.

Although they may be used for the voyage; shipping articles are not required for any voyage by—

(a) A yacht;

(b) A vessel engaged exclusively in fishing or whaling;

(c) A vessel aboard which the merchant mariners are by custom or agreement entitled to participate in the profits or results of a cruise or voyage;

(d) A vessel employed exclusively in trade on the navigable rivers of the United States; or

(e) A ferry, or a tug used in ferrying, if the vessel is employed exclusively in trade on the Great Lakes, other lakes, bays, sounds, bayous, canals, or harbors.

§ 14.205 Production of credentials by merchant mariner signing shipping articles.

On engagement for a voyage upon which shipping articles are required, each merchant mariner shall present to the master or individual in charge of the vessel every document, certificate, or license required by law for the service the mariner would perform.

§ 14.207 Content and form of shipping articles.

(a)(1) The content and form of shipping articles for each vessel of the United States of 100 gross tons or more upon a foreign or intercoastal voyage must conform to the present shipping articles, form CG–705A, which meets the requirements of 46 U.S.C. 10302, 10303, 10304, and 10305. The articles must identify the nature of the voyage and specify at least the name, the number of the license or merchant mariner's document, the capacity of service, the time due on board to begin work, and the name and address of the next of kin of, and the wages due to each merchant mariner, either who was discharged or whose services were otherwise terminated during the month.

(2) The content and form of articles for each such vessel upon a coastwise voyage (including a voyage on the Great Lakes) must also conform to the present shipping articles, form CG–705A, which meet the requirements of 46 U.S.C. 10502. The articles must specify at least the matter identified by paragraph (a)(1) of this section, except that they must not specify the wages due to the mariner. The wages section of the form shall be left blank for coastwise voyages.

(b) Any shipping company that manually prepares the articles may, upon request, obtain Shipping Articles, Form CG–705A, from any Officer in Charge, Marine Inspection (OCMI), of the Coast Guard.

(c) Any company that electronically prepares the articles may, upon request

submitted to either address in § 14.103, obtain a copy of software developed by the Coast Guard to produce articles in the proper format. Alternatively, a company may develop its own software or buy it off the shelf; but, in either of these cases, it must secure approval of the software from the National Maritime Center at either address in § 14.103.

§ 14.209 Preparation of shipping articles at beginning of voyage.

Each master or individual in charge of a vessel when shipping articles are required shall prepare an original and two copies of the articles. The original and one copy must be signed by the master or individual in charge and by each merchant mariner; but the second copy must not be signed by any of them.

§ 14.211 Posting of copy of shipping articles.

On commencement of a foreign, intercoastal, or coastwise voyage (including a voyage on the Great Lakes), each master or individual in charge of a vessel when shipping articles are required shall ensure that a legible copy of the articles, unsigned by the mariner, and without the next of kin information, is posted at a place accessible to the crew.

§ 14.213 Report of shipment of merchant mariner.

(a) When a vessel of the United States sails upon a foreign, intercoastal, or coastwise voyage (excluding a voyage on the Great Lakes), each master or individual in charge shall, at the commencement of the voyage, send one copy of shipping articles, signed by the master and by each merchant mariner, to the owner, charterer, or managing operator. The master shall keep the original throughout the voyage and enter in it all charges made to the crew during the voyage.

(b) (1) When a vessel of the United States sails exclusively on the Great Lakes, each master or individual in charge shall, at the commencement of the season, or once the vessel is put into service, whichever occurs earlier, send one copy of articles, signed by the master and by each mariner, to the owner, charterer, or managing operator.

(2) The master or individual in charge shall every 60 days send supplementary particulars of engagement covering each mariner engaged during this period, signed by the master and by each mariner, to the owner, charterer, or managing operator.

(3) The master of individual in charge shall, at the close of the season, or once the vessel is withdrawn from service, whichever occurs later, send articles, signed by the master and by each mariner, to the owner, charterer, or managing operator.

(c) When a vessel of the United States sales exclusively on bays or sounds, each master or individual in charge shall, at least every 60 days, send articles, signed by the master and by each mariner, to the owner, charter, or managing operator.

(d) Any person who fails to comply with the requirements of this section is subject to a civil penalty of $5,000.

Subpart C—Discharge of Merchant Mariners

§ 14.301 Paying off of merchant mariner during or after voyage upon which shipping articles are required.

Each master or individual in charge of a vessel when shipping articles are required shall complete and sign, and each merchant mariner paid off during or after such a voyage shall sign the articles and otherwise comply with the requirements of this subpart. When signed by the master or individual in charge and by the mariner, the articles constitute a release from the duties to which they bound their parties.

§ 14.303 Discharge of merchant mariner in foreign port.

Upon the discharge of any mariner in a foreign port, the master shall make the required entries on the ship's articles. Upon the request of the master or a mariner, the consular officer shall discharge the mariner in accordance with the requirements of 46 U.S.C. 10318.

§ 14.305 Entries in continuous discharge book.

If the merchant mariner holds a continuous discharge book, the master or individual in charge of the vessel shall make the proper entries in it.

§ 14.307 Entries on certificate of discharge.

(a) Each master or individual in charge of a vessel shall, for each merchant mariner being discharged from the vessel, prepare a certificate of discharge and two copies; whether by writing or typing them on the prescribed form with permanent ink or generating them from computer in the prescribed format; and shall sign them with permanent ink. The prescribed format for a certificate of discharge is the same as the present form CG–719A (Rev. 8–80). The left portion of the form has the mariner's printed name, signature, citizenship, and merchant mariner's document number; the certification statement, date and the master's signature. The right portion of the form contains the rate/rank the mariner is serving on the voyage, date and place of shipment, date and place of discharge, name of the vessel, name of the operating company, official number of the vessel, class of the vessel, and the nature of the voyage.

(b) Each mariner being discharged shall sign the certificate and both copies with permanent ink.

(c) When the mariner leaves the vessel, the master or individual in charge shall give the original certificate to the mariner.

(d) Except as directed by § 14.313, the shipping company shall keep both copies of the certificate.

(e) The company shall provide copies of certificates of discharge to the mariner and the Coast Guard upon request.

§ 14.309 Entries in shipping articles at end of voyage.

(a) At the end of each voyage upon which shipping articles are required, the master or individual in charge of the vessel shall—

(1) Complete the articles, conforming the pertinent entries in them to those on the certificate of discharge and its copies;

(2) Note in the articles the execution of each Mutual Release;

(3) Attach to the articles each Mutual Release and a copy of each certificate; and

(4) Pay to each merchant mariner all wages due.

(b) When paid off, each mariner shall sign the articles.

§ 14.311 Report of discharge of merchant mariner.

(a) At the end of each foreign, intercoastal, and coastwise voyage by a vessel of the United States, or of each voyage by such a vessel that sails exclusively on bays or sounds (or by such a vessel at the close of the season on the Great Lakes, or once the vessel is withdrawn from service there, whichever occurs later), the shipping company shall electronically transmit the data from the certificates of discharge via modem to an electronic address which the shipping company may request from the National Maritime Center.

(b) If the data is submitted manually, the shipping companies shall provide the data for foreign and intercoastal voyages at the end of each voyage. For coastwise voyages or of each voyage by such a vessel that sails exclusively on bays or sounds (or by such a vessel at the close of the season of the Great Lakes, or once the vessel is withdrawn from service there, whichever occurs later), the shipping companies shall

submit a copy of each certificate of discharge to the address in § 14.103(a) at least once per calendar month.

§ 14.313 Storage of shipping articles and of certificates of discharge.

(a) Each shipping company shall keep all original shipping articles and copies of all certificates of discharge for 3 years. After 3 years the shipping companies shall prepare the original shipping articles in alphabetical order by vessel name and send to the address in § 14.103(a) for storage at the Federal Records Center at Suitland, Maryland. The company may dispose of the copies of certificates of discharge. The Coast Guard will dispose of copies of certificates submitted manually, once the data are entered into its sea-service database and are validated.

(b) Each shipping company that goes out of business or merges with another company shall send all original articles to the address in § 14.103(a) within 30 days of the transaction.

(c) The shipping company must provide copies of shipping articles and certificates of discharge to the mariner and the Coast Guard upon request.

Subpart D—Oceanographic Research Vessels

§ 14.401 General.

Unless otherwise provided by Title 46 United States Code, by any act amending or supplementing that Title, or by this subpart, that Title as far as it governs the employment of merchant mariners remains, and any act amending or supplementing that title becomes, applicable to oceanographic research vessels.

§ 14.403 Exemptions.

(a) Certain requirements of Title 46, United States Code do not apply to the employment of merchant mariners on oceanographic research vessels. These requirements are those concerned with, among other things, the shipment and discharge of mariners, their pay and allotments, and the adequacy of their clothing. 46 U.S.C. 2113(2) allows exemptions of oceanographic research vessels from certain requirements of parts B, C, F, or G of subtitle II of 46 U.S.C., upon such terms as the Secretary of the Department of Transportation deems suitable. The exemptions available under this subpart are subject to the following terms:

(1) No use of any exemption relieves the owner, charterer, managing operator, master, or individual in charge of the vessel of other statutory responsibilities for the protection of every mariner under his or her command.

(2) If it is presented at a reasonable time and in a reasonable manner, the master or individual in charge shall receive, consider, and appropriately address the legitimate complaint of any mariner.

(b) For any oceanographic research vessel sailing with any mariner employed by any firm, association, corporation, or educational or governmental body or agency, the Commandant may grant exemptions from—

(1) 46 U.S.C. 10301, Application;

(2) 46 U.S.C. 10302, Shipping articles (for foreign and intercoastal voyages);

(3) 46 U.S.C. 10307, Posting of articles;

(4) 46 U.S.C. 10308, Foreign engagements;

(5) 46 U.S.C. 10311, Certificates of discharge;

(6) 46 U.S.C. 10313 and 10504, Wages;

(7) 46 U.S.C. 10314 and 10505, Advances;

(8) 46 U.S.C. 10315, Allotments;

(9) 46 U.S.C. 10316 and 10506, Trusts;

(10) 46 U.S.C. 10321 and 10508, General penalties;

(11) 46 U.S.C. 10502, Shipping articles (for coastwise voyages); and

(12) 46 U.S.C. 10509, Penalty for failure to begin coastwise voyages.

§ 14.405 Procedures.

(a) Upon written request for the owner, charterer, managing operator, master, or individual in charge of the vessel to the OCMI of the Coast Guard in whose zone the vessel is located, the Commandant may grant an exemption of any oceanographic research vessel designated by 46 U.S.C. 2113(2) from any requirement of any section listed by § 14.403(b).

(b) The request must state—

(1) Any requirement of any section listed in § 14.403(b) from which the applicant wishes an exemption; and

(2) What business practices regarding, among other things, the shipment and discharge of merchant mariners, their pay and allotments, and the adequacy of their clothing would justify the exemption.

(c) The OCMI will forward the request, along with his or her recommendation, to the Commandant, who will determine whether to grant any exemption of any vessel from any requirement. The OCMI will issue a letter indicating any exemption granted. The master or individual in charge of the vessel shall keep the letter aboard the vessel.

(d) If operating conditions change, the owner, charterer, managing operator, master, or individual in charge of the vessel shall so advise the OCMI. The OCMI will forward pertinent information on how the conditions have changed, along with his or her recommendation, to the Commandant, who will determine whether any exemption should remain granted.

§ 14.407 Reports.

(a) The owner, charterer, managing operator, master, or individual in charge of each oceanographic research vessel of 100 gross tons or more shall maintain a record of the employment, discharge, or termination of service of every merchant mariner in the crew. At least every 6 months, the person maintaining this record shall transmit it to the Coast Guard, either manually, in the form of a copy of a certificate of discharge, or electronically.

(b) The owner, charterer, managing operator, master, or individual in charge of the vessel shall keep original shipping articles and a copy of each certificate ready for review by the Coast Guard or the concerned mariner upon request. After January 3, 1997, the Coast Guard will no longer keep either original articles or copies of certificates; it will keep only electronic records of employment.

(c) The master or individual in charge of the vessel shall ensure that every entry made in the articles agrees with the corresponding entry made in a continuous discharge book, on a certificate, or in any other proof of sea service furnished to the mariner.

(d) Each oceanographic company shall keep all original articles and copies of all certificates for 3 years. After that each such company shall send all articles to the address in § 14.103(a).

(e) Each oceanographic company that goes out of business or merges with another company shall send all original articles to the address in § 14.103(a) within 30 days of the transaction.

Dated: October 28, 1996.

J.C. Card,

Rear Admiral, U.S. Coast Guard, Chief, Marine Safety and Environmental Protection.

[FR Doc. 96–28082 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–14–M

Proposed Rules

Federal Register
Vol. 61, No. 214
Monday, November 4, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–SW–05–AD]

Airworthiness Directives; Schweizer Aircraft Corporation Model 269A, A–1, B, and C, and TH–55A Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Schweizer Aircraft Corporation Model 269A, A–1, B, and C, and TH–55A helicopters, with a certain main rotor transmission ring gear (ring gear) installed. This proposal would require inspections of the ring gear teeth for pitting, wearing, cracking or corrosion, and replacement of the ring gear if such ring gear teeth surface deterioration is found; and would also require creating a main rotor transmission component log card, if none is available, and making a notation on the main rotor transmission component log card if a ring gear is changed. This proposal is prompted by reports of failures of the ring gear due to single tooth distress as a result of improper gear tooth spacing during the manufacturing of the ring gear. The actions specified by the proposed AD are intended to prevent failure of the ring gear, loss of drive to the main rotor gearbox, and a subsequent forced landing.

DATES: Comments must be received by January 3, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–SW–05–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Schweizer Aircraft Corporation, P.O. Box 147, Elmira, NY 14902, ATTN: Publications Dept. This information may be examined at the FAA, Office of the Assistant Chief Counsel, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond Reinhardt, Aerospace Engineer, New York Aircraft Certification Office, FAA, 181 South Franklin Ave., Room 202, Valley Stream, New York 11581, telephone (516) 256–7532, fax (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 96–SW05–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–SW–05–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

This document proposes the adoption of a new AD that is applicable to Schweizer Aircraft Corporation Model 269A, A1, B, and C, and TH–55A helicopters, with ring gear, part number (P/N) 269A5104–5, installed. This proposal is prompted by 35 reports of failures of the ring gear since July 1975. The failures were attributed to single tooth distress as a result of improper gear tooth spacing during the manufacturing of the gear. The tooth spacing variation forces the tooth that is improperly spaced to accept more of the load at longer duration or at a location that leads to higher point contact loads and surface distress. This surface distress eventually leads to subsurface cracking and finally fatigue failure. One of these failures resulted in loss of drive to the main rotor gearbox resulting in a forced autorotational landing of the helicopter. Three failures caused the ''XMSN TEMP./PRESS'' red warning indicator on the main instrument panel to illuminate due to low oil pressure caused by a secondary failure of the main transmission lube pump. The other failures resulted only in increased noise and/or vibration. This proposal would require inspections of the ring gear teeth for pitting, wearing, cracking or corrosion, and replacement of the ring gear if such ring gear teeth surface deterioration is found. The proposed inspections would be accomplished before further flight if clicking, tapping, or other unusual noises, or unusual vibration is detected while operating the helicopter, or if metal particles are found on the magnetic drain plug during routine maintenance; or, upon installation of replacement serviceable parts or transmissions; and within the next 50 hours TIS or at the next annual inspection, whichever occurs first. Thereafter, the notice proposes repetitive inspections at each 50 hours TIS inspection in accordance with the manufacturer's service bulletin. The actions specified by the proposed AD are intended to prevent failure of the ring gear, loss of drive to the main rotor gearbox, and a subsequent forced landing.

The FAA has reviewed Schweizer Aircraft Corporation Service Bulletin B–

244.2, dated February 19, 1996, which describes procedures for inspection of the ring gear for surface deterioration, pitting, wearing, cracking, or corrosion, and replacement of the main transmission if surface deterioration, pitting, wearing, cracking, or corrosion is found.

Since an unsafe condition has been identified that is likely to exist or develop on other Schweizer Aircraft Corporation Model 269A, A–1, B, and C, and TH–55A helicopters of the same type design, the proposed AD would require an inspection of the ring gear for surface deterioration, pitting, wearing, cracking, or corrosion, and replacement of the ring gear with ring gear, P/N 269A5104–7, if surface deterioration, pitting, wearing, cracking, or corrosion is found; and, creation of a main rotor transmission component log card if none is available, and a notation on the main rotor transmission component log card if a ring gear, P/N 269A5104–7, is installed. Schweizer Aircraft Corporation has blank component log cards available for main rotor transmissions that do not currently have a component log card. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 87 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per helicopter to accomplish the initial inspections, 0.5 hours to create a main rotor transmission component log card, and 28 work hours if removal and replacement of the ring gear is required, and that the average labor rate is $60 per work hour. Required parts would cost approximately $6,400 per ring gear and $1,219 per overhaul kit. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $822,063, assuming creation of a component log card and replacement of the ring gear in the entire fleet is necessary.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

Schweizer Aircraft Corporation: Docket No. 96–SW–05–AD.

Applicability: Model 269A, A–1, B, and C, and TH–55A helicopters, with main rotor transmission ring gear (ring gear), part number (P/N) 269A5104–5, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (f) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the ring gear, loss of drive to the main rotor gearbox, and a subsequent forced landing, accomplish the following:

(a) Inspect the ring gear teeth for surface deterioration, pitting, wearing, cracking or corrosion in accordance with Schweizer Service Bulletin B–244.2, dated February 19, 1996, as follows:

(1) Before further flight, if a clicking or tapping sound or other unusual noise or unusual vibration is detected while operating the helicopter, or if a metal particle is found on the magnetic drain plug during routine maintenance;

(2) Before installing a main rotor transmission which contains an affected ring gear on the helicopter;

(3) Within the next 50 hours time-in-service (TIS) after the effective date of this AD, or at the next annual inspection, whichever occurs first.

(b) Thereafter, inspect the ring gear teeth at intervals not to exceed 50 hours TIS in accordance with Schweizer Service Bulletin B–244.2, dated February 19, 1996.

(c) If surface deterioration, pitting, wearing, cracking or corrosion is discovered, before further flight, remove the transmission from service and replace the ring gear with a ring gear, P/N 269A5104–7.

(d) At the next main rotor transmission overhaul, remove and replace the ring gear, P/N 269A5104–5, identified on the face of the ring gear by the letters EGC, ACR, or the manufacturer code number 23751 (EGC) or 57152 (ACR) and replace it with a ring gear, P/N 269A5104–7.

(e) Installation of a ring gear, P/N 269A5104–7, is considered a terminating action for this AD and must be annotated on a Schweizer Aircraft Corporation component log card. A new component log card must be created if a component log card is not in the applicable maintenance records.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, New York Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York Aircraft Certification Office.

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished, provided no clicking or tapping sound or other unusual noise or unusual vibration was detected on any previous flight.

Issued in Fort Worth, Texas, on October 25, 1996.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 96–28168 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 95–CE–34–AD]

RIN 2120–AA64

Airworthiness Directives; Fairchild Aircraft SA226 and SA227 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to Fairchild Aircraft SA226 and SA227 series airplanes. The proposed action would require modifying the electrical power generation system. Three reports of both generators going off-line on the affected airplanes while in-flight prompted this action. The actions specified by the proposed AD are intended to prevent failure of both generators during critical phases of flight (such as night operation or while in icing conditions), which could result in loss of control of the airplane.

DATES: Comments must be received on or before February 3, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–34–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Field Support Engineering, Fairchild Aircraft, P.O. Box 790490, San Antonio, Texas 78279–0490; telephone (210) 824–9421; facsimile (210) 820–8609. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Ms. Ingrid D. Knox, Aerospace Engineer, FAA, Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150; telephone (817) 222–5190; facsimile (817) 222–5960.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–34–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–34–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has received three reports of both generators going off-line during flight operations on Fairchild Aircraft SA226 and SA227 series airplanes. In one instance, both generators went off-line when the airplane was cruising at 21,500 feet. The pilot immediately began resetting the generators without initial success. After the airplane had descended to an altitude of 13,000 feet, the pilot was able to bring the generators back on-line. In all three incidents, the generator control unit required replacement.

Applicable Service Information

Fairchild Aircraft has issued several service bulletins to address these electrical power generation system problems. The following presents and briefly describes the technical modification intent of each service bulletin (SB):

—SB 226–24–027, Issued: May 19, 1988, Revised: February 22, 1989: Specifies procedures for replacing the existing generator fault transformer wiring with dual conductor shielded wiring on Fairchild SA226 series airplanes.

—SB 227–24–008, Issued: March 18, 1988, Revised: February 22, 1989: Specifies the same procedures as SB 226–24–027, but provides these procedures for Fairchild Aircraft SA227 series airplanes.

—SB 226–24–023, Issued: October 25, 1985, Revised: January 23, 1989: Specifies procedures for rewiring the direct current (DC) generation system to reduce the possibility of 325-amp current limiter failure on Fairchild Aircraft SA226 series airplanes.

—SB 227–24–005, Issued: October 25, 1985, Revised: January 23, 1989: Specifies the same procedures as SB 226–24–023, but provides these procedures for Fairchild Aircraft SA227 series airplanes.

—SB 226–24–026, Issued: May 27, 1987: Specifies procedures for modifying the voltage regulator access panel and installing a connector in the wire bundle on Fairchild Aircraft SA226 series airplanes.

—SB 24–018, Issued: October 22, 1980, Revised: January 7, 1981: Specifies procedures for installing new voltage regulators, rerouting certain wires, and replacing the entire voltage regulator panel assembly on Fairchild Aircraft SA226 series airplanes.

—SB 226–24–031, dated July 27, 1989: Specifies procedures for modifying the DC generator control system so that it will operate off its respective generator output on Fairchild Aircraft SA226 series airplanes. This includes removing field current and reset resistors, removing the reset and generator relays and associated diodes, installing a 10-amp generator control circuit breaker to the left-hand and right-hand essential bus panels, and replacing the 10-amp generator control circuit breakers in the left-hand and right-hand wheelwells with 15-amp circuit breakers that are wired in series with the generator control circuit breakers.

—SB 227–24–012, Issued: May 4, 1989, Revised: July 27, 1989: Specifies the same procedures as SB 226–24–031, but provides these procedures for Fairchild Aircraft SA227 series airplanes.

The FAA's Determination

After examining the circumstances and reviewing all available information related to the incidents described above, including the referenced service information, the FAA has determined that AD action should be taken to prevent failure of both generators during critical phases of flight (such as night operation or while in icing conditions), which could result in loss of control of the airplane.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Fairchild Aircraft SA226 and SA227 series airplanes of the same type design, the proposed AD would require modifying the electrical power generation system. Accomplishment of the proposed modifications would be in accordance with the service bulletins previously referenced.

Cost Impact

The FAA estimates that 34 SA226 series airplanes and 206 SA227 series airplanes in the U.S. registry would be affected by the proposed modifications, that it would take approximately 80 workhours per SA226 series airplane and 50 workhours per SA227 series airplane to accomplish the proposed modifications, and that the average labor rate is approximately $60 an hour. Parts cost approximately $12,400 for SA226 series airplanes and $6,000 for SA227 series airplanes. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $584,800 for SA226 series airplane operators (or $17,200 per airplane) and $1,854,000 for SA227 series airplane operators (or $9,000 per airplane). This figure is based on the assumption that no owner/operator of the affected airplanes has accomplished the proposed modifications. Fairchild Aircraft has informed the FAA that no parts have been distributed to any affected airplane owner/operator.

The proposed AD allows 2,000 hours time-in-service (TIS) after the proposed AD would become effective before mandatory accomplishment of the design modifications. The average utilization of the fleet for those airplanes in commercial commuter service is approximately 25 to 50 hours TIS per week. Based on these figures, operators of commuter-class airplanes involved in commercial operation would have to accomplish the proposed modification within 24 to 48 calendar months after the proposed AD would become effective. For private owners, who typically operate between 100 to 200 hours TIS per year, this would allow 24 to 48 years before the proposed modification would be mandatory.

Regulatory Flexibility Determination and Analysis

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily or disproportionally burdened by government regulations. The RFA requires government agencies to determine whether rules would have a ''significant economic impact on a substantial number of small entities,'' and, in cases where they would, conduct a Regulatory Flexibility Analysis in which alternatives to the rule are considered. FAA Order 2100.14A, Regulatory Flexibility Criteria and Guidance, outlines FAA procedures and criteria for complying with the RFA. Small entities are defined as small businesses and small not-for-profit organizations that are independently owned and operated or airports operated by small governmental jurisdictions. A ''substantial number'' is defined as a number that is not less than 11 and that is more than one-third of the small entities subject to a proposed rule, or any number of small entities judged to be substantial by the rulemaking official. A ''significant economic impact'' is defined by an annualized net compliance cost, adjusted for inflation, which is greater than a threshold cost level for defined entity types. FAA Order 2100.14A sets the size threshold for small entities operating aircraft for hire at 9 aircraft owned and the annualized cost thresholds at $69,000 for scheduled operators and $5,000 for unscheduled operators.

The FAA has determined that, for four entities (two nonscheduled air carriers and two scheduled air carriers), the compliance costs of the proposed AD would impose a significant economic impact. Because at least 11 small entities are not affected, the proposed AD would not affect a ''substantial number of small entities'' as defined in Order 2100.14A.

A copy of the full Cost Analysis and Regulatory Flexibility Determination for the proposed action may be examined at the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–34–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Fairchild Aircraft: Docket No. 95–CE–34–AD.

Applicability: The following model and serial number airplanes, certificated in any category:

Model	Serial Nos.
SA226–T	T201 through T275 and T277 through T291.
SA226–T(B)	T(B)276 and T(B)292 through T(B)417.
SA226–AT	AT001 through AT074.
SA226–TC	TC201 through TC419.
SA227–TT	TT421 through TT541.
SA227–AT	AT423 through AT631.
SA227–AC	AC406, AC415, AC416, AC420 through AC705, and AC707 through AC733.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (g) of this AD. The request should include an assessment of the effect of the modification, alteration, or

repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 2,000 hours time-in-service after the effective date of this AD, unless already accomplished.

To prevent failure of both generators during critical phases of flight (such as night operation or while in icing conditions), which could result in loss of control of the airplane, accomplish the following:

(a) For the model and serial number airplanes presented below, replace the existing generator fault transformer wiring with new dual conductor shielded wire in accordance with Fairchild Service Bulletin (SB) 226–24–027, Issued: May 19, 1988, Revised: February 22, 1989, or Fairchild SB 227–24–008, Issued: October 25, 1985, Revised: January 23, 1989, as applicable.

(1) Model SA226–T airplanes, serial numbers T201 through T275 and T277 through T291; Model SA226–T(B) airplanes, serial numbers T(B)276 and T(B)292 through T(B)417; Model SA226–AT airplanes, serial numbers AT001 through AT074; and Model SA226–TC airplanes, serial numbers TC201 through TC419.

(2) Model SA227–TT airplanes, serial numbers TT421 through TT541; Model SA227–AT airplanes, serial numbers AT423 through AT631; and Model SA227–AC airplanes, serial numbers AC406, AC415, AC416, and AC420 through AC683.

(b) For the model and serial number airplanes presented below, rewire the electrical power generation system to reduce the possibility of 325-amp current limiter failure in accordance with Fairchild SB 226–24–023, Issued: October 25, 1985, Revised: January 23, 1989, or Fairchild SB 227–24–005, Issued: October 25, 1985, Revised: January 23, 1989, as applicable.

(1) Model SA226–T airplanes, serial numbers T249 through T275 and T277 through T291; Model SA226–T(B) airplanes, serial numbers T(B)276 and T(B)292 through T(B)417; Model SA226–AT airplanes, serial numbers AT025 through AT074; and Model SA226–TC airplanes, serial numbers TC209 through TC419.

(2) Model SA227–TT airplanes, serial numbers TT421 through TT541; Models SA227–AT airplanes, serial numbers AT423 through AT591; and SA227–AC airplanes, serial numbers AC420 through AC594.

(c) For Model SA226–T airplanes, serial numbers T249 through T275 and T277 through T291; Model SA226–T(B) airplanes, serial numbers T(B)276 and T(B)292 through T(B)417; Model SA226–AT airplanes, serial numbers AT025 through AT074; and Model SA226–TC airplanes, serial numbers TC209 through TC419, modify the voltage regulator access panel and install a connector in the wire bundle in accordance with Fairchild SB 226–24–026, Issued: May 27, 1987.

(d) For Model SA226–T airplanes, serial numbers T201 through T275 and T277 through T291; Model SA226–T(B) airplanes, serial numbers T(B)276 and T(B)292 through T(B)347; Model SA226–AT airplanes, serial numbers AT001 through AT074; and Model SA226–TC airplanes, serial numbers TC201 through TC348, install new voltage regulators, reroute certain wires, and replace the entire voltage regulator panel assembly in accordance with Fairchild SB 24–018, Issued: October 22, 1980, Revised: January 7, 1981.

(e) For the model and serial number airplanes presented below, modify the direct current (DC) generator control system so that it will operate off its respective generator output in accordance with Fairchild SB 226–24–031, dated July 27, 1989, or Fairchild SB 227–24–012, Issued: May 4, 1989; Revised: July 27, 1989, as applicable. This includes removing field current and reset resistors, removing the reset and generator relays and associated diodes, installing a 10-amp generator control circuit breaker to the left-hand and right-hand essential bus panels, and replacing the 10-amp generator control circuit breakers in the left-hand and right-hand wheelwells with 15-amp circuit breakers that are wired in series with the generator control circuit breakers.

(1) Model SA226–T airplanes, serial numbers T249 through T275 and T277 through T291; Model SA226–T(B) airplanes, serial numbers T(B)276 and T(B)292 through T(B)417; Model SA226–AT airplanes, serial numbers AT025 through AT074; and Model SA226–TC airplanes, serial numbers TC209 through TC419.

(2) Model SA227–TT airplanes, serial numbers TT421 through TT541; Model SA227–AT airplanes, serial numbers AT423 through AT695; and Model SA227–AC airplanes, serial numbers AC406, AC415, AC416, AC420 through AC556, AC558 through AC705, and AC707 through AC733.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(g) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Fort Worth Airplane Certification Office (ACO), FAA, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Fort Worth ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Fort Worth ACO.

(h) All persons affected by this directive may obtain copies of the document referred to herein upon request to Fairchild Aircraft, P.O. Box 790490, San Antonio, Texas 78279–0490; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on October 28, 1996.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–28165 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 71

[Airspace Docket No. 96–AWP–27]

Proposed Amendment of Class E Airspace; San Jose, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Class E airspace area at San Jose, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 14/32 at South County Airport of Santa Clara County has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at South County Airport of Santa Clara County, San Martin, CA.

DATES: Comments must be received on or before November 8, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, Operations Branch, AWP–530, Docket No. 96–AWP–27, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, Operations Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, Operations Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 96–AWP–27.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Operations Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Operations Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at San Jose, CA. The development of GPS SIAP at South County Airport of Santa Clara County has made this proposal necessary. The intended effect of this proposal is to provide adequate Class E airspace for aircraft executing the GPS RWY 14/27 SIAP at South County Airport of Santa Clara County, San Martin, CA. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963, Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace area extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 San Jose, CA [Revised]

San Jose International Airport, CA
(Lat. 37°21′42N, long. 121°55′43″W)
NAS Moffett Field TACAN
(Lat. 37°25′57N, long. 122°03′26″W)
San Jose NDB (Jorge)
(Lat. 37°20′56N, long. 121°54′54″W)
South County Airport of Santa Clara County, CA
(Lat. 37°04′55″N, long. 121°35′49″W)

That airspace extending upward from 700 feet above the surface within a 5-mile radius of the San Jose International Airport and within 4.3 miles each side of the NAS Moffett Field TACAN 157° radial extending from the NAS Moffett Field TACAN to 20 miles southeast of the TACAN and within 4 miles each side of the 139° bearing from the San Jose NDB, extending from the 5-mile radius of the San Jose International Airport to 24.3 miles southeast of the NDB and within a 6.9-mile radius of the South County Airport of Santa Clara County and that airspace bounded by a line beginning a lat. 37°30′00″N, long. 121°52′04″W; to lat. 37°22′00″N, long. 122°08′04″W; to lat. 37°22′00″N, long. 122°24′04″W; to lat. 37°30′00″N, long. 122°27′04″W; to the point of beginning. That airspace extending upward from 1,200 feet above the surface bounded on the north by lat. 37°30′00″N, on the east and northeast by long. 121°50′04″W; and the southwest edge of V–107, on the southeast and south by the northwest edge of V–111, and lat. 37°00′00″N, and on the west by the east edge of V–27 to lat. 37°30′00″.

* * * * *

Issued in Los Angeles, California, on October 17, 1996.

George D. Williams,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–28282 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 18 and 114

RIN 1515–AC03

Bilateral Carnet Agreement Between the American Institute in Taiwan and the Taipei Economic and Cultural Representative Office

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes amendments to those Customs Regulations which apply to carnets to reflect a recently signed bilateral agreement between the Taipei Economic and Cultural Representative in the United States (TECRO) and the American Institute in Taiwan (AIT). This agreement established a TECRO/AIT Carnet for the temporary admission of goods, commercial samples and professional equipment.

DATES: Comments must be received on or before January 3, 1997.

ADDRESSES: Comments (preferably in triplicate) may be submitted to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, Franklin Court, 1301 Constitution Avenue, NW., Washington, DC 20229, and may be inspected at Franklin Court, 1099 14th Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Sharon Goodson or Dennis Sequeira, International Organizations and Agreements Division, 202–927–0971.

SUPPLEMENTARY INFORMATION:

Background

A carnet is an international customs document, backed by an internationally valid guarantee, which may be used for the entry of articles under various customs procedures such as temporary importation and transportation in bond. The carnet is used in place of the usual national customs documentation and guarantees the payment of duties (including taxes and associated penalties) which may become due if the carnet requirements are not satisfied. The existence of a single document rather than numerous national documents facilitates international commerce.

The carnet guarantee is based on chains of national guaranteeing associations established in the countries accepting the carnets. The guaranteeing association is jointly and severally liable with the carnet holder for payment of the sums due in the event of noncompliance with the conditions or the procedures for which the carnet is used.

Benefits of the TECRO/AIT Carnet

In recent years, trade between the United States and Taiwan has increased. It is expected that this trend will continue, and that such trade can be facilitated through the use of carnets. However, Taiwan is currently ineligible to accede to the ATA Carnet Convention, under which carnets facilitate trade among more than fifty contracting parties. Thus, Taiwan has sought access to the carnet facility through the recently concluded TECRO/AIT Carnet Agreement. This agreement was negotiated pursuant to the authority contained in 22 U.S.C. 3305.

A Notice informing the public that Customs is accepting applications from parties desiring to undertake the obligation of an issuing and guaranteeing association for the TECRO/AIT carnet agreement that is the subject of this Notice of Proposed Rulemaking is also being published in this issue of the Federal Register.

Comments

Before adopting this proposal, consideration will be given to any written comments (preferably in triplicate) that are timely submitted to Customs. All such comments received from the public pursuant to this notice of proposed rulemaking will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m., at the Regulations Branch, 1099 14th Street, NW., Suite 4000, Washington, DC.

Regulatory Flexibility Act

Insofar as the proposed amendment is intended to facilitate international trade and remove some existing impediments to the conduct of business, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendment, if adopted, will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

The proposed amendment does not meet the criteria for a ''significant regulatory action'' under E.O. 12866.

Drafting Information

The principal author of this document was Peter T. Lynch, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects

19 CFR Part 10

Customs duties and inspection, Exports, Reporting and recordkeeping requirements.

19 CFR Part 18

Customs duties and inspection, Common carriers, Surety bonds, Exports.

19 CFR Part 114

Customs duties and inspection, Exports, Trade agreements.

Proposed Amendments to the Regulations

It is proposed to amend Parts 10, 18 and 114 of the Customs Regulations (19 CFR parts 10, 18 and 114) as set forth below:

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation for Part 10 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314.

* * * * *

2. It is proposed to amend § 10.31 by adding in paragraphs (a)(1) and (a)(2) the phrase ''or a TECRO/AIT carnet'' immediately after the words ''A.T.A. carnet''.

3. It is proposed to amend § 10.39(d)(2) by adding the words ''or Agreement'' immediately after the phrase ''in the Convention''.

PART 18—TRANSPORTATION IN BOND AND MERCHANDISE IN TRANSIT

1. The general authority citation for Part 18 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1551, 1552, 1553, 1624.

* * * * *

2. It is proposed to amend § 18.1 (a)(3) by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.'' each time it appears.

3. It is proposed to amend § 18.8 (a)(3) by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.'' each time it appears.

PART 114—CARNETS

1. The authority citation for Part 114 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1623, 1624.

2. It is proposed to amend § 114.1 (b) and (c) by adding the phrase ''or bilateral Agreement'' immediately after the words ''Customs Convention'' each time they appear, and by adding a new paragraph (g) to read as follows:

§ 114.1 Definitions.

* * * * *

(g) *TECRO/AIT Carnet.* ''TECRO/AIT carnet'' means the document issued pursuant to the Bilateral Agreement between the Taipei Economic and Cultural Representative Office (TECRO) and the American Institute in Taiwan (AIT) to cover the temporary admission of goods.

4. It is proposed to amend § 114.2 by revising the section heading and the introductory paragraph and by adding a new paragraph (d) to read as follows:

§ 114.2 Customs Conventions and Agreements.

The regulations in this part relate to carnets provided for in the following Customs Conventions and Agreements.

* * * * *

(d) Agreement Between The Taipei Economic and Cultural Representative Office in the United States and The American Institute in Taiwan on

TECRO/AIT Carnet for the Temporary Admission of Goods (hereinafter referred to as the Agreement).

5. It is proposed to amend § 114.3 (a) introductory text and (a)(2) by adding the words ''or Agreement'' immediately after the word ''Convention'' each time it appears.

6. It is proposed to amend § 114.11 by adding the words ''or Agreement'' immediately after the word ''Convention'' each time it appears.

7. It is proposed to amend § 114.22 by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 114.22 Coverage of carnets.

* * * * *

(d) *TECRO/AIT Carnet*—(1) *Use.* The TECRO/AIT carnet is acceptable for the following two categories of goods to be temporarily imported, unless importation is prohibited under the laws and regulations of the United States:

(i) Professional equipment; and

(ii) Commercial samples and advertising material imported for the purpose of being shown or demonstrated with a view to soliciting orders.

(2) *Issue and use.* (i) Issuing associations shall indicate on the cover of the TECRO/AIT carnet the customs territory in which it is valid and the name and address of the guaranteeing association.

(ii) The period fixed for re-exportation of goods imported under cover of a TECRO/AIT carnet shall not in any case exceed the period of validity of that carnet.

* * * * *

8. It is proposed to amend § 114.23 by adding a new paragraph (c) to read as follows:

§ 114.23 Maximum period.

* * * * *

(c) *TECRO/AIT carnet.* A TECRO/AIT carnet shall not be issued with a period of validity exceeding one year from the date of issue. This period of validity cannot be extended and must be shown on the front cover of the carnet.

9. It is proposed to amend § 114.24 by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.''.

10. It is proposed to amend § 114.25 by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.''.

11. It is proposed to amend § 114.26 (a) and (b) by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.'' each time it appears.

12. It is proposed to amend § 114.31(b) by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.''.

13. It is proposed to amend § 114.32 by adding the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.'' the first time it appears and by adding the phrase ''or TECRO/AIT Agreement'' immediately after the phrase ''A.T.A. Convention''.

14. It is proposed to amend § 114.33 by adding the words ''or Agreement'' immediately after the word ''Convention''.

15. It is proposed to amend § 114.34 by adding, in the heading and text of paragraph (b), the phrase ''or TECRO/AIT'' immediately after the abbreviation ''A.T.A.'' each time it appears.

Approved: October 2, 1996.

George J. Weise,

Commissioner of Customs.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–28170 Filed 11–1–96; 8:45 am]

BILLING CODE 4820–02–M

Internal Revenue Service

26 CFR Part 1

[SPR–247516–96]

Financial Asset Securitization Investment Trusts (FASITs); Solicitation for Comments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Solicitation for comments.

SUMMARY: The Treasury Department and the IRS are soliciting comments on issues to be considered in developing guidance under the newly enacted FASIT provisions of the Internal Revenue Code.

DATES: Comments are requested on or before December 31, 1996.

ADDRESSES: Send written comments to: Internal Revenue Service, Attn: CC:DOM:CORP:R (FASIT solicitation), room 5226, POB 7604, Ben Franklin Station, Washington, DC 20044. Alternatively, taxpayers may submit comments in writing, by hand delivery to CC:DOM:CORP:R (FASIT solicitation), Courier's Desk, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, D.C., or, electronically, via the IRS Internet site at: http://www.irs.ustreas.gov/prod/tax—regs/comments.html.

FOR FURTHER INFORMATION CONTACT: David L. Meyer at 202–622–3960 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 1621(a) of the Small Business Job Protection Act of 1996, Public Law 104–188, 110 Stat. 1755 (August 20, 1996), amends the Internal Revenue Code (Code) by adding new part V (sections 860H–860L) to subchapter M of chapter 1. These provisions authorize a new statutory vehicle, called a Financial Asset Securitization Investment Trust (FASIT), that will facilitate the securitization of debt obligations, including credit card receivables and automobile loans. In general, a FASIT will use such obligations to issue new, debt-like securities, referred to as regular interests. No Federal income tax is imposed on a FASIT, even if the underlying arrangement is otherwise regarded for tax purposes as a corporation, trust, partnership, or segregated pool of assets.

A FASIT must have a single ownership interest, which has to be held entirely by a non-exempt domestic C corporation other than a corporation that qualifies as a RIC, REIT, REMIC, or subchapter T cooperative. Because a FASIT is not subject to income tax, the holder of the ownership interest generally includes in its taxable income all of the FASIT's items of income, gain, deduction and loss. In addition, the holder recognizes gain (but not loss) when (1) the FASIT acquires property from the holder or an unrelated third party, or (2) the holder uses property to support a regular interest issued by the FASIT.

A FASIT may issue one or more classes of regular interests. Regular interests are treated as debt for all purposes of the Code. Ordinarily, a regular interest may be held by any person, unless the interest is a high-yield interest, in which case it may be held only by another FASIT or a corporation that is allowed to hold an ownership interest.

The FASIT provisions become effective on September 1, 1997. Special transitional rules apply to a securitization arrangement existing on August 31, 1997, that elects FASIT treatment (a pre-effective date FASIT).

In addition to the general authority under section 7805 to prescribe regulations, the Treasury and IRS have specific authority under section 860L(h) to issue regulations that carry out the purposes of the FASIT provisions, including rules to prevent the abuse of the purposes of the FASIT provisions through transactions that are not primarily related to securitization of debt instruments by a FASIT.

Comments

To develop needed guidance timely, the Treasury Department and the IRS invite interested persons to submit comments (in the manner described under the **ADDRESSES** caption) on issues arising under the FASIT provisions. Treasury and the IRS encourage respondents to give particular attention to the following: rules that would allow more than one member of an affiliated group to hold ownership interests in the same FASIT; transitional rules for pre-effective date FASITs; and any other rules that should be in place before September 1, 1997.

If a respondent is submitting written comments, a signed original and eight (8) copies are requested. All comments will be available for public inspection and copying in their entirety.

Judith C. Dunn,

Associate Chief Counsel (Domestic).

[FR Doc. 96–28103 Filed 11–1–96; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 943

[SPATS No. TX–030–FOR]

Texas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Texas regulatory program (hereinafter the ''Texas program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to and an addition of regulations pertaining to the replacement of water supply where it has been adversely impacted by contamination, diminution, or interruption resulting from surface mining activities. The amendment is intended to revise the Texas program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., c.s.t., December 4, 1996. If requested, a public hearing on the proposed amendment will be held on November 29, 1996. Requests to speak at the hearing must be received by 4:00 p.m., c.s.t. on November 19, 1996.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Jack R. Carson, Acting Director, Tulsa Field Office, at the address listed below.

Copies of the Texas program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Tulsa Field Office.

Jack R. Carson, Acting Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135–6547, Telephone: (918) 581–6430.

Railroad Commission of Texas, Surface Mining and Reclamation Division, 1701 North Congress Avenue, P.O. Box 12967, Austin, Texas 78711–2967, Telephone: (512) 463–6900.

FOR FURTHER INFORMATION CONTACT: Jack R. Carson, Acting Director, Tulsa Field Office, Telephone: (918) 581–6430.

SUPPLEMENTARY INFORMATION:

I. Background on the Texas Program

On February 16, 1980, the Secretary of the Interior conditionally approved the Texas program. General background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the February 27, 1980, Federal Register (45 FR 12998). Subsequent actions concerning the Texas program can be found at 30 CFR 943.10, 943.15, and 943.16.

II. Description of the Proposed Amendment

By letter dated October 21, 1996 (Administrative Record No. TX–629), Texas submitted a proposed amendment to its program pursuant to SMCRA. Texas submitted the proposed amendment in response to a July 8, 1996, letter (Administrative Record No. TX–618) that OSM sent to Texas in accordance with 30 CFR 732.17(c). The provisions of the Texas Coal Mining Regulations (TCMR) that Texas proposes to revise are: TCMR 701.008, Definitions: TCMR 779.130, Alternative water supply information; and TCMR 816.352, Hydrologic balance—water rights and replacement. Specifically, Texas proposes the following revisions to these regulations.

1. Texas proposes to add the following new definition at TCMR 701.005(77) for replacement of water supply.

Replacement of water supply means, with respect to protected water supplies contaminated, diminished, or interrupted by coal mining operations, provision of water supply on both a temporary and permanent basis equivalent to premining quantity and quality. Replacement includes provision of an equivalent water delivery system and payment of operation and maintenance costs in excess of customary and reasonable delivery costs for premining water supplies.

(a) Upon agreement by the permittee and the water-supply owner, at any time prior to commencement of mining operations, the obligation to pay such operation and maintenance costs may be satisfied by a one-time payment in an amount which covers the present worth of the increased annual operation and maintenance costs for a period agreed to by the permittee and the water supply owner.

(b) If the affected water supply was not needed for the land use in existence at the time of loss, contamination, or diminution, and if the supply is not needed to achieve the postmining land use, replacement requirements may be satisfied by demonstrating that a suitable alternative water source is available and could feasibly be developed. If the latter approach is selected, written concurrence must be obtained from the water supply owner.

2. Texas proposes to clarify its alternative water supply requirements at TCMR 779.130 by replacing the words ''mine plan'' with the word ''permit'' in the first sentence; adding the words ''which is used'' after the words ''adjacent areas'' in the first sentence; replacing the word ''description'' with the word ''application'' in the second sentence; adding the word ''water'' after the word ''existing'' in the second sentence; and by adding the phrase ''including the suitability of alternative water sources for existing premine uses and approved postmine land uses'' at the end of the second sentence. The revised provisions read as follows:

The application shall identify the extent to which the proposed surface mining activities may proximately result in contamination, diminution, or interruption of an underground or surface source of water within the proposed permit or adjacent areas which is used for domestic, agricultural, industrial, or other legitimate use. If contamination, diminution, or interruption may result, then the application shall identify the alternative sources of water supply that could be developed to replace the existing water sources including the suitability of alternative water sources for existing premine uses and approved postmine land uses.

3. Texas proposes to clarify its regulation for water rights and replacement at TCMR 816.352 by

replacing the word ''affected'' with the words ''adversely impacted'' and by adding the following new provision:

Baseline hydrologic information required in Sections 779.126, 779.130, and 780.146, of the Regulations shall be used to determine the extent of the impact of mining upon ground water and surface water.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Texas program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Tulsa Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.s.t. on November 19, 1996. The location and time of the hearing will be arranged with those persons requesting the hearing. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT.** If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

Public Meeting

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES.** A written summary of each meeting will be made a part of the Administrative Record.

IV. Procedural Determination

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 25, 1996.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 96–28255 Filed 11–1–96; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 57–8–6368b; FRL–5640–9]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) which concern the control of volatile organic compound (VOC) emissions from solvent degreasing. The intended effect of proposing approval of this rule is to regulate emissions of VOCs in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules Section of this Federal Register, the

EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by December 4, 1996.

ADDRESSES: Written comments on this action should be addressed to: Andrew Steckel, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule and EPA's evaluation report of the rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Divison, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.
South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182.

FOR FURTHER INFORMATION CONTACT: Mae Wang, Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1200.

SUPPLEMENTARY INFORMATION: This document concerns South Coast Air Quality Management District's Rule 1122, Solvent Degreasers, submitted to EPA on May 13, 1993 by the California Air Resources Board. For further information, please see the information provided in the Direct Final action which is located in the Rules Section of this Federal Register.

Authority: 42 U.S.C. 7401–7671q.

Dated: October 17, 1996.

Felicia Marcus,

Regional Administrator.

[FR Doc. 96–28062 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[CA 009–0013b; FRL 5611–1]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Glenn County and Siskiyou County Air Pollution Control Districts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP). The revisions concern rules submitted by the State of California on behalf of the Air Pollution Control Districts of Glenn and Siskiyou Counties (the Counties) for the purpose of meeting requirements of the Clean Air Act, as amended in 1990 (CAA or the Act) with regard to general preconstruction permitting.

The intended effect of proposing approval of these rules is to control air pollution in accordance with the requirements of the Act. In the Final Rules section of this Federal Register, the EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second public comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed rule must be received in writing by December 4, 1996.

ADDRESSES: Written comments on this action should be addressed to: Matt Haber, New Source Section (A–5–1), Air & Toxics Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the State's submittal and other information are available for inspection during normal business hours at EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. Copies of the State's submittal are also available at the California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 L Street, Sacramento, CA 95814.

FOR FURTHER INFORMATION CONTACT: Steve Ringer at (415) 744–1260, New Source Section, Air & Toxics Division (A–5–1), EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105.

SUPPLEMENTARY INFORMATION: EPA is proposing to approve the following rules into the SIP:

Glenn County Air Pollution Control District Regulations: Section 51—New Source Review. Adopted on March 16, 1993.

Siskiyou County Air Pollution Control District Rules and Regulations: Rule 1.2—Definitions (except section vi); Rule 1.4—Enforcement; Rule 2.1—Permits Required; Rule 2.2—Exemptions; Rule 2.10—Further Information; Rule 4.1—Visible Emissions; Rule 4.6—Circumvention; Rule 6.1—Standards for Permits to Construct; Appendix A—List/Criteria for Permit Applications. Adopted on January 24, 1989.

On March 26, 1990, the Siskiyou County rules were submitted to EPA as revisions to the SIP. EPA found this submittal to be complete on June 20, 1990. On May 13, the Glenn County rules were submitted to EPA as a revision to the SIP. EPA found this submittal to be complete on July 19, 1993.

For further information, please see the information provided in the direct final action which is located in the Rules section of this Federal Register.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 9, 1996.

Felicia Marcus,

Regional Administrator.

[FR Doc. 96–28194 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 437

[FRL–5645–5]

Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Centralized Waste Treatment Category: Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; reopening of comment period.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is reopening the comment period for Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards: Centralized Waste Treatment Category: Data Availability; Proposed Rule, which was published in the Federal Register on

September 16, 1996 (61 FR 48805). The public comment period for the Notice of Data Availability ended on October 16, 1996.

EPA has received several requests for an extension of time to comment on the Notice of Data Availability. These requests are from facilities that may be affected by the final rule. The additional time will provide the opportunity for more thorough review of new information and facility profiles and in turn, allow more informed public comment. The Agency has determined that an extension of time is in the public interest, and that an additional 20 days to comment on the Notice of Data Availability is reasonable.

DATES: Comments on this notice are solicited and will be accepted until November 25, 1996. Comments are to be submitted in triplicate, and also in electronic format (diskettes) if possible.

ADDRESS: Comments are to be submitted to Mr. Ed Terry at the following address: Engineering and Analysis Division (4303), U.S. EPA, 401 M Street, S.W., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Mr. Ed Terry, Engineering and Analysis Division (4303), U.S. EPA, 401 M Street, S.W., Washington, D.C. 20460, telephone number (202) 260–7128 or via EMAIL at: terry.ed@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On September 16, 1996, EPA published a notice in the Federal Register which describes the new information the Agency has obtained since the proposed rulemaking (60 FR 5464, January 27, 1995) for the Centralized Waste Treatment (CWT) Industry. The notice also explains the Agency's revised estimates of the size and regulatory impact of the proposed rulemaking on the proposed oils treatment and recovery subcategory and presents preliminary results of EPA detailed analysis for the subcategory.

This extension of time for comment does not represent any modification of the notice of data availability. The extension of time for receipt of comments simply provides interested parties an additional 20 days to provide comments to the Agency on the Notice of Data Availability. All other requirements stipulated in the initial notice for receipt of comments still apply.

All written comments submitted in accordance with the instructions in the Notice of Data Availability and received by November 25, 1996, including those received between the close of the comment period on October 16, 1996, and the publication of this notice, will be entered into the public record and considered by EPA before promulgation of the final rule.

Dated: October 28, 1996.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 96–28096 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3100

[WO–310–3110–02 1A]

Royalty Rate Reduction for Stripper Oil Properties

AGENCY: Bureau of Land Management, Interior.

ACTION: Review of regulations; reopening of comment period.

SUMMARY: On August 30, 1996, the Bureau of Land Management (BLM) published a document in the Federal Register announcing a review of the royalty rate reduction available to producers of Federal stripper well properties (61 FR 45926). The document requested comments from the public on the effectiveness of this program during a 60-day period that ended on October 29, 1996. BLM has received numerous requests from the public for additional time to research this issue and is re-opening the comment period for an additional 60 days.

DATES: Submit comments on or before January 3, 1997.

ADDRESSES: If you wish to comment, you may:

(a) Hand-deliver comments to the Bureau of Land Management, Administrative Record, Room 401, 1620 L St., NW., Washington, DC;

(b) Mail comments to the Bureau of Land Management, Administrative Record, Room 401LS, 1849 C Street, NW, Washington, DC 20240; or

(c) Transmit comments electronically via the Internet to WOComment@wo.blm.gov. Please include ''Attn: Stripper Wells'' in your message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly.

You will be able to review comments at BLM's Regulatory Affairs Group office, Room 401, 1620 L St., N.W., Washington, D.C., during regular business hours (7:45 a.m. to 4:15 p.m.) Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Wayne Melton, Roswell (NM) District Office, (505) 627–0254.

Dated: October 29, 1996.

Patrick W. Boyd,

Regulatory Affairs Group.

[FR Doc. 96–28186 Filed 11–1–96; 8:45 am]

BILLING CODE 4310–84–P

43 CFR Part 6400

RIN: 1004–AC87

Wild and Scenic Rivers

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: On September 10, 1996, the Bureau of Land Management (BLM) published a proposed rule in the Federal Register to establish uniform standards and procedures affecting Wild and Scenic Rivers or Study Rivers (61 FR 47726). The 30-day comment period for the proposed rule expired on October 10, 1996. BLM has received several requests from the public for additional time to comment and is reopening the comment period for an additional 30 days.

DATES: Submit comments on or before December 4, 1996.

ADDRESSES: If you wish to comment, you may

(a) Hand-deliver comments to the Bureau of Land Management, Administrative Record, Room 401, 1620 L St., NW., Washington, DC;

(b) Mail comments to the Bureau of Land Management, Administrative Record, Room 401LS, 1849 C Street, NW, Washington, DC 20240; or

(c) Transmit comments electronically via the Internet to WOComment@wo.blm.gov. Please include ''Attn: RIN 1004–AC87'' in your message. If you do not receive a confirmation from ''the system that we have received your Internet message, contact us directly at (202) 452–5030.

You will be able to review comments at BLM's Regulatory Affairs Group office, Room 401, 1620 L St., N.W., Washington, D.C., during regular business hours (7:45 a.m. to 4:15 p.m.) Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Gary Marsh, Cultural Heritage, Wilderness, Special Areas, & Paleontology Group, at (202) 452–7795.

Dated: October 29, 1996.

Annetta Cheek,

Regulatory Affairs Group, Manager.

[FR Doc. 96–28187 Filed 11–1–96; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 95–65; Notice 2]

RIN 2127–AF72

Federal Motor Vehicle Safety Standards; Air Brake Systems, Devices That Remove Moisture and Contaminants

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to amend Standard No. 121, *Air brake systems,* to require that each air brake-equipped truck, truck tractor, and bus be equipped with a means of automatically removing moisture and contaminants from the air system. The purpose of this proposal is to improve the safety of air-braked vehicles by improving the reliability and durability of antilock braking system (ABS) modulator valves and pneumatic control valves. This document also proposes to delete the requirement for a supply reservoir since its function (i.e., the elimination of moisture and contaminants) would be accomplished by the addition of such automatic means. Accordingly, the deletion would not adversely affect the safety of those vehicles.

DATES: Comments must be received on or before January 3, 1997.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted to: Docket Section, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are 9:30 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: *For non-legal issues:* Mr. Richard Carter, Office of Crash Avoidance, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington DC 20590, (202) 366–5274. FAX (202) 366–4329.

For legal issues: Mr. Marvin L. Shaw, NCC–20, Rulemaking Division, Office of Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–2992.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Regulations

Federal Motor Vehicle Safety Standard No. 121, *Air Brake Systems,* requires air-braked vehicles to be equipped with certain equipment, including one or more air service reservoir systems from which air is delivered to the brake chambers. (See S5.1.2) In addition, manufacturers are required to either (1) equip air-braked vehicles with an additional supply reservoir [1] between the service reservoir(s) and the compressor, or (2) equip each service reservoir with an automatic condensate drain valve.[2] Both options remove moisture. The supply reservoir collects moisture and solid particulate matter before it can enter the service reservoir or reservoirs. An automatic condensate drain valve automatically removes moisture and certain solid contaminants that become trapped in the bottom of a reservoir. Regardless of which option is chosen, all air reservoirs must be fitted with a condensate drain valve that can be manually operated. Accordingly, an automatic condensate drain valve must also be manually operable. (see S5.1.2.4 for trucks and buses and S5.2.1.3 for trailers).

The Federal Motor Carrier Safety Regulations (FMCSRs) require drivers of commercial vehicles to inspect specified features on their vehicles, including service brake system, prior to driving to ensure those features are ''* * * in good working order.'' (49 CFR 392.7) However, the FMCSRs do not require that air reservoirs be drained on any fixed periodic basis.

B. Petition for Rulemaking

On July 28, 1994, Domenic F. Coletta, M.D. submitted a petition for rulemaking requesting that Standard No. 121 be amended to require a condensate drain valve that automatically purges the moisture and contaminants from each reservoir tank on air-brake equipped vehicles. Dr. Coletta claimed that automatic drain valves would better ensure safety than manual valves since drivers frequently fail to remember to manually purge moisture and contaminants from reservoirs. The petitioner supplied a video showing New Jersey State police purging significant amounts of liquid and contaminants from the air reservoirs of heavy vehicles during roadside safety inspections.

C. Notice Requesting Comments About Devices That Remove Contaminants

On July 24, 1995, NHTSA issued a notice requesting information about devices that remove moisture and other contaminants from air brake systems (60 FR 37864). The agency explained that keeping air brake systems clean and dry prevents degraded brake performance and valve freezing, which can lead to brake failure. The agency was especially concerned about potential problems with antilock brake systems (ABS) malfunctioning, since their modulator valves have smaller orifices and therefore are more sensitive to contaminants. NHTSA explained that certain equipment such as automatic and manual drain valves and air dryer systems can keep air brake systems, particularly the air reservoirs, dry and free from contaminants. Drain valves purge the reservoirs of liquid condensate and contaminants suspended in that liquid. Manual drain valves must be opened by a truck driver or maintenance person to drain the reservoir. While ideally this should be done each morning before the vehicle is started, some drivers do not do so. Automatic drain valves periodically drain the reservoir without the need for human intervention.

There are a variety of devices that reduce the amount of moisture and other contaminants in an air brake system by cleaning and drying the air. Among the most common are desiccant style air dryers and ''after-cooler'' air dryers. In a typical desiccant style system, the incoming air is routed into the bottom end of an air dryer, where a large portion of the oil and water mist fall to its bottom. This partially cleaned air then goes through an oil separator. Next the air, which is still moist with both oil and water vapor, is passed through a ''drying bed'' of desiccant material that absorbs the remaining moisture. These dryers are equipped with an automatic drain valve that periodically purges moisture and contaminants from the air system. In contrast, in a typical ''after-cooler''

[1] The colloquial term for a supply reservoir is ''wet'' tank.

[2] The colloquial term for an automatic condensate drain valve is ''spitter valve.''

system, which uses an air cleaner only, not all the moisture is removed, since the air is not passed through a drying bed of desiccant material.

NHTSA stated that according to AlliedSignal, over 80 percent of new air braked heavy trucks are being built with air dryers and that more than 90 percent of the dryers are the desiccant type. Moreover, that company predicted that in five years almost all air braked vehicles will be equipped with an air cleaning and drying system.

NHTSA posed several questions about whether it should nevertheless initiate rulemaking to require devices to remove moisture and other contaminants from air brake systems. These included questions whether contaminants in air brake systems cause a significant safety problem, whether devices such as automatic drain valves and air dryers are effective in removing moisture and contaminants from air brake systems, and whether requiring such devices would be cost effective.

D. Comments on the Notice

NHTSA received 34 comments from vehicle and equipment manufacturers, a safety advocacy group (Advocates for Highway and Auto Safety) (Advocates), the Truck Manufacturers Association (TMA), the Heavy Duty Brake Maintenance Council (HDBMC), the Truck Trailer Manufacturers Association (TTMA), the National Truck Equipment Association (NTEA), the National School Transportation Association (NSTA), the American Trucking Associations (ATA), individual truck operators and fleets, Senator Frank R. Lautenberg, the petitioner, and numerous private citizens.

The manufacturers and associations generally stated that a Federal requirement was not necessary, claiming that the present use of air dryers, and the trend towards their increased use, was sufficient to maintain a safe level of performance. ATA, AlliedSignal, NTEA, NSTA, Navistar, TTMA, and TMA stated that they had no records of any accidents or crashes caused by contaminated air. TMA stated that while contaminants in air brake systems can cause reliability problems in specific components, they believe contamination does not result in a significant safety problem. TMA, Penske Truck Leasing, and ATA stated that a desiccant style air dryer with an integral automatic drain valve more effectively removes moisture and other contaminants from an air brake system than an automatic drain valve by itself. TMA requested that instead of a supply reservoir, the agency should allow either an automatic drain valve on each service reservoir or a desiccant style air dryer. ATA also stated that desiccant air dryers were more effective in keeping air in the brake system clean than automatic drain valves. That organization stated that ''automatic drain valves have not been found to be an effective device for removing contaminants.''

The petitioner (Dr. Coletta), manufacturers of automatic drain valves, Advocates, and a number of private citizens commented that significant safety problems result from moisture and contaminants in a vehicle's air system. The petitioner stated that it is very important to keep the air reservoir system dry and free of contaminants to prevent the contamination and deterioration of the brake system, which can result in serious safety problems. To support this claim, Dr. Coletta referenced a National Transportation Safety Board (NTSB) study of 18 heavy vehicle crashes [3] in which NTSB investigated the extent to which brake system performance caused or increased the severity of heavy vehicle crashes. Inadequate brake system maintenance and poor brake adjustment were either the primary or a contributory causal factor in most of the crashes investigated. While not specifically mentioned as a primary or direct contributory factor to these crashes, the NTSB report noted that in 4 of the 18 cases (22 percent), significant amounts of moisture and sludge were found in the air reservoirs, thereby contributing to the overall poor functioning of the vehicles' brake system.

Dr. Coletta and others stated that the agency should require that each service reservoir be equipped with an automatic drain valve instead of a manual drain valve, because truck drivers typically do not manually drain the reservoirs. They further claimed that air dryers are not an effective way to solve the problem of contaminants and moisture in air systems, since air dryers do not remove all moisture from the system and are difficult to maintain. These commenters also stated that truck drivers will not perform the routine maintenance necessary for desiccant systems.

II. Agency Proposal

A. General Considerations

Based on the available information, NHTSA has decided to propose amending Standard No. 121 to require that each air brake-equipped truck, truck tractor, and bus be equipped with an automatic means of removing moisture and contaminants from the air brake system. The term ''contaminants'' includes, but is not limited to, carbon and other particulates, dirt, oil, soot, and sludge. The agency believes that removing moisture and contaminants would increase the reliability and durability of both ABS and pneumatic control valves of air brake systems, thereby increasing the safety of these vehicles. This is so because contaminants cause valves to stick, thereby preventing sufficient air pressure from being delivered to the brake. The proper functioning of ABS valves is especially important since heavy vehicles will be required to be equipped with ABS, beginning in March 1997. In addition, the proposed requirements would ensure that air supply lines are clear and that maximum air reservoir capacity is available to drivers when braking.

NHTSA is proposing to require air braked vehicles to be equipped with a means of automatically removing moisture and contaminants from the air brake system for the following reasons. First, according to NHTSA's extensive fleet study [4] of ABS-equipped heavy vehicles, ABS-equipped truck tractors that were also equipped with desiccant-style air dryers performed better than truck tractors without these air dryers. In particular, vehicles with desiccant-style air dryers did not experience leaks in their relay valves. Second, the previously mentioned NTSB study of heavy vehicle crashes found that in 4 of 18 cases (22 percent), significant amounts of moisture and contaminants were found in the vehicles' air reservoirs. The agency emphasizes that while the study is not a statistically representative sampling of all heavy vehicle crashes, it suggests that air system contamination may be a problem. Third, AlliedSignal recently conducted a voluntary recall [5] to address freezing relay valves because the valves failed due to exposure to solvents and chemicals such as antifreeze and glycol. Apparently, some drivers and mechanics attempted to unfreeze the valves by pouring antifreeze into the trailer's air supply and control lines.

To achieve this rule's objective, i.e., keeping air brake systems dry and free of contaminants, NHTSA considered a number of regulatory approaches and decided to propose a broad-based

[3] Heavy Vehicle Air Brake Performance (NTSB/SS–92/01; 1992)

[4] Klusmeyer, L.F., Gray, A.W., Bishop, J.S., and Van Schoiack, M. *An In-Service Evaluation of the Performance, Reliability, Maintainability, and Durability of Antilock Braking Systems (ABSs) for Semitrailers,* USDOT Report No. HS 808 059, October 1993.

[5] Ref. Voluntary Recall No.94–E–027.

equipment requirement rather than specifying a specific device, detailed design specifications, or general performance requirements. This is the same approach the agency used in establishing S5.1.8 which requires that ''wear of the service brakes on newly manufactured heavy vehicles to be compensated for by means of a system of automatic adjustment.'' (57 FR 47793, October 20, 1992). Moreover, the agency believes today's proposal is consistent with the agency's desire to avoid issuing regulations that are unnecessarily design specific. NHTSA is wary of specifying a particular device, an action that might preclude the development of new technologies, particularly in light of a recent paper[6] by the Society of Automotive Engineers (SAE) that discussed a number of devices and methods that can remove moisture and other contaminants from compressed air systems. These methods include filtration, desiccant absorption, coalescing, centrifugal force, or a combination of these processes. The SAE paper stated that the most effective device would employ a combination of these processes, particularly filtration, coalescing, and desiccant. These devices would be permitted by this proposal.

Another device that would be permitted under this proposal is the automatic condensate drain valve, the solution suggested in Dr. Coletta's petition. These devices eliminate moisture (i.e., liquid condensate) and solid contaminants suspended in that liquid that collect at the bottom of the supply reservoir.

NHTSA has decided at this time not to develop a test procedure and performance requirements to evaluate the dryness and cleanness of an air brake system for several reasons. First, the practicality of developing such a test procedure is unclear at this time. To ensure that all (or substantially all) contaminants had been removed, it might be necessary for the test procedure to assess the performance of the entire air system, including all piping and valves. Such a test could be expensive, since the piping and valves are very extensive. Moreover, it might be necessary to develop different test set-ups to evaluate the wide range of air systems. Second, to the agency's knowledge, criteria for evaluating the amount of contamination removal do not currently exist. Developing such a test procedure and criteria would have been too time-consuming.

[6] Fitzsimmons, D. *Synergy in Air Dryers, Multiple-State Processes and Application* Requirements, SAE Paper No. 952675, November, 1995.

For these reasons, NHTSA has decided to propose an equipment requirement at this time. Nevertheless, the agency would prefer ultimately to establish performance requirements for this equipment. Federal law generally requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies when such technical standards are available; *see* section 12(d) of Pub. L. 104–113. The subject of moisture and solid contaminant removal from air brake systems appears to present an opportunity for NHTSA to adopt consensus performance requirements developed by an organization such as the Society of Automotive Engineers (SAE). SAE would be performing a service to the public by developing such consensus performance requirements, as well as permitting a significant savings in resources for the government. NHTSA is aware of and has been monitoring the efforts of the SAE to develop a Recommended Practice for assessing the amount of airborne moisture and solid particulate matter contaminant levels present at the output side of the service reservoirs. If the SAE can reach consensus on some performance requirements, NHTSA anticipates relying on those consensus requirements in its further consideration of this issue.

NHTSA requests comments on its decision to propose requiring that air-braked vehicles be equipped with a means of automatically removing moisture and other contaminants rather than proposing a test procedure and performance requirements. The agency also invites comments about the proposed terminology used to describe the equipment that the amendment would require, especially whether various devices would comply with the proposal.

NHTSA has decided to propose deleting the requirement for a supply reservoir since the service reservoirs in an air system would be equipped with an automatic means of removing moisture and contaminants from the air system. The agency believes that removing supply reservoirs would not compromise air brake system performance, provided that a means of automatically removing moisture and contaminants is added. Nevertheless, the agency invites commenters to submit data and test results comparing the durability and reliability of air brake systems on vehicles that are equipped as follows: those vehicles equipped with a supply reservoir but are not equipped with a means for automatically removing moisture and contaminants versus those vehicles that are not equipped with a supply reservoir but are equipped with a means for automatically removing moisture and contaminants. Also, the agency requests comments about the likelihood that a purchaser would decide not to equip its vehicles with supply reservoirs, if the proposed amendment were adopted.

NHTSA has decided to retain the requirement of S5.1.2.4 that each reservoir be fitted with a manual draining capacity. The agency believes this capability is needed as a supplemental means of verifying that the primary means of automatically removing moisture and contaminants is functioning properly. Periodic manual purging checks to ascertain that liquids are not collecting in service reservoirs should accomplish this function. Automatic condensate drain valves (or an air dryer with an automatic drain valve) that can be manually actuated, would comply with this requirement.

B. Cost Considerations

In its notice requesting comments, NHTSA estimated that devices that would comply with requirements to keep the air system clean and dry could range from $75–$400 per vehicle. The commenters generally concurred with these estimates. The agency estimates that the annual production of air braked vehicles is approximately 209,000 (148,000 truck tractors and approximately 61,000 single unit trucks and buses), based on its earlier analysis in the Final Regulatory Evaluation for the ABS final rule (60 FR 13216, March 10, 1995). NHTSA estimates that 90 percent of all currently manufactured truck tractors are already equipped with a means of automatically removing moisture and contaminants and that 75 percent of all single unit trucks and buses are so equipped. This proposal would affect the remaining 30,000 vehicles (14,800 truck tractors + 15,200 single unit vehicles). They would need to be equipped with these devices at a total annual cost of between $2.25 million to $12 million.

NHTSA notes that some of these costs might be offset by savings if manufacturers choose to eliminate the supply reservoirs from the estimated 209,000 air brake equipped truck tractors, trucks and buses that are manufactured each year. The amount of these offsetting savings could vary appreciably, depending on a number of factors. First, removing one of the three air reservoirs could necessitate increasing the size of the remaining two service reservoirs to meet the reservoir sizing requirements of S.5.2.1.1. Nevertheless, two larger reservoirs

would cost less than three reservoirs and their associated piping and fittings. The agency estimates that there would be a savings of between $10–$75 per vehicle. Second, the extent to which manufacturers and heavy vehicle users decide to no longer equip their vehicles with a supply reservoir is uncertain.

Accordingly, for the purposes of this analysis, the agency has conservatively assumed that between 0–50 percent of newly manufactured air-braked power units would no longer be equipped with supply reservoirs. Based on this assumption, the agency estimates that no longer equipping vehicles with supply reservoirs would offset the proposal's costs by between $0–$7.8 million per year, with a conservative estimate being $1 million. The agency invites comments on these cost estimates. After reviewing this information, NHTSA will factor in these cost savings in assessing the rulemaking's overall cost.

Based on applying this $1 million cost savings to the costs associated with requiring air-braked vehicles to be equipped with a means of automatically removing moisture and contaminants, NHTSA estimates that a total cost of $1.25 million to $11 million would be incurred to comply with the proposed requirements. In addition, by ensuring dry and clean air, today's rulemaking would contribute to more fully achieving the anticipated benefits expected from equipping heavy vehicles with ABS.

NHTSA decided not to propose requiring a means of automatically removing moisture and contaminants separately on both towing and towed units in a combination-unit vehicle. The agency reasoned that since the air used on trailers is supplied by the towing unit, having the means to automatically remove moisture and contaminants on the towing unit would be sufficient to ensure dry and clean air on towed units as well. The agency further reasoned that sufficient safety enhancement, relative to the costs incurred, would be achieved by specifying such a requirement only for the towing unit. The agency estimates that it would cost an additional $13.9 million to $74 million per year to equip the 186,100 heavy truck trailers that are manufactured each year. The agency solicits additional data and comments on its decision not to propose requiring that trailers be equipped with a means of automatically removing moisture and contaminants.

Rulemaking Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This notice has not been reviewed under Executive Order 12866. NHTSA has considered the impacts of this rulemaking action and determined that it is not ''significant'' within the meaning of the Department of Transportation's regulatory policies and procedures. The agency's Final Economic Assessment of the final rules amending Standard No. 105 and Standard No. 121 to require medium and heavy vehicles to be equipped with ABS, concluded that the benefits associated with those requirements exceeded the costs that would result. The additional costs associated with adding a means of automatically removing moisture and contaminants to those vehicles that would otherwise not be equipped with them, would increase the costs of the ABS rule by 0.2 percent to 1.7 percent. This small increase does not alter the agency's original determination. Based on the discussion above and this consideration, NHTSA believes that the impacts are so minimal as not to warrant preparation of an additional full regulatory evaluation.

B. Regulatory Flexibility Act

NHTSA has also considered the effects of this proposal under the Regulatory Flexibility Act. I hereby certify that it would not have a significant economic impact on a substantial number of small entities. Accordingly, the agency has not prepared a preliminary regulatory flexibility analysis.

NHTSA concluded that the March 1995 final rule amending Standard No. 121 did not have a significant impact on a substantial number of small entities. The agency concluded then that a small number of intermediate and final stage manufacturers that are small businesses might be affected by the rule, but that the impact would not be substantial. That conclusion is equally valid for this proposal, since today's proposal addresses the same types of manufacturers as addressed in the March 1995 action, and since the costs of this rulemaking are much less.

C. National Environmental Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act of 1969. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment. No changes in existing production or disposal processes would result.

D. Executive Order 12612 (Federalism)

NHTSA has analyzed this action under the principles and criteria in Executive Order 12612. The agency believes that this rulemaking action would not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. No State laws would be affected.

E. Civil Justice Reform

This rulemaking would not have any retroactive effect. Under 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the State requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of rulemakings establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Public Comments

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket

at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and tires.

PART 571—[AMENDED]

In consideration of the foregoing, the agency proposes to amend Standard No. 121, *Air Brake Systems,* in Title 49 of the Code of Federal Regulations at Part 571 as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

1. The authority citation for part 571 would continue to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.50

§ 571.121 Standard No. 121; Air Brake Systems

2. § 571.121 would be amended by revising S5.1.2 and by adding a new section S5.1.9, which would read as follows:

§ 571.121 Standard No. 121; Air Brake Systems

* * * * *

S5.1.2 *Reservoirs.* One or more service reservoir systems, from which air is delivered to the brake chambers.

* * * * *

S5.1.9 *Contamination Removal.* Each truck, truck tractor and bus shall be equipped with a means of automatically removing moisture and contaminants from the air system.

Issued on: October 29, 1996.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 96–28228 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board

49 CFR Part 1310

[STB Ex Parte No. 555]

Household Goods Tariffs

AGENCY: Surface Transportation Board.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Board proposes to establish regulations governing the tariffs that motor carriers and freight forwarders are required to maintain, under 49 U.S.C. 13702, for the transportation of household goods. The Board also proposes to establish notice requirements that household goods carriers must comply with in order to be entitled to enforce the provisions of their tariffs against individuals whose shipments are subject to such tariffs.

DATES: Comments are due on December 4, 1996.

ADDRESSES: Send comments (an original and 10 copies) referring to STB Ex Parte No. 555 to: Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, NW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927–5660. [TDD for the hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (1995) (ICCTA), abolished the Interstate Commerce Commission (ICC) and transferred to the Surface Transportation Board (Board) various regulatory responsibilities, including certain responsibilities regarding the rates charged by motor carriers and freight forwarders for transportation of household goods. As pertinent here, the ICCTA retained the requirement that these carriers maintain tariffs containing their common carriage rates (and related rules and practices) for household goods transportation (except when providing such transportation for charitable purposes without charge). However, the ICCTA eliminated the requirement that household goods tariffs be filed with a regulatory body. Rather, the carriers are required to make such tariffs available to the Board for inspection, and available for inspection by shippers upon reasonable request. The Board may invalidate a tariff that violates section 13702 of the statute or a regulation of the Board carrying out that section.

Because household goods tariffs are no longer required to be filed, they are no longer governed by the tariff regulations at 49 CFR Part 1312 (see 49 CFR 1312.1(c)(i)). Accordingly, the Board is proposing a new Part 1310 and regulations to govern the household goods tariffs that motor carriers and freight forwarders are required to maintain. Our proposed regulations are designed to ensure that the required information is included in and easily determinable from the tariffs, and that they are made available as required by the ICCTA. We do not propose to prescribe the particular formats that must be employed; rather, we propose to give carriers the flexibility to devise publications that will best fulfill the needs of the carriers and their customers.

Additionally, at the request of the Household Goods Carriers' Bureau Committee (HGCBC), the proposed regulations address the notice requirements that carriers must comply with in order to enforce tariff terms incorporated by reference into their bills of lading or other documents embodying the contract of carriage.[1] HGCBC notes that the ICCTA specifically allows household goods carriers to incorporate tariff provisions into their bills of lading or other documents embodying the contract of carriage, subject to a notice requirement. HGCBC expresses concern that, without uniform rules specifying what is required, the issue of what constitutes adequate notice of incorporated tariff provisions would be litigated in various state and Federal courts, with potentially differing results.

We believe that there is merit to establishing uniform notice requirements for the incorporation of tariff terms and conditions into contracts of carriage for the transportation of household goods, and we are proposing regulations for that purpose. Because most of the movements subject to the proposed regulations will involve individual consumers who typically deal with commercial carriers on a relatively infrequent basis, the proposed rules are designed to highlight important terms and conditions that are likely to be incorporated, and to require that shippers be provided with a brief summary of the principal features of such terms. In this way, the information should be disclosed in a way that will be meaningful to individual consumers.

Request for Comments

We invite comments on all aspects of the proposed regulations. We encourage any commenter that has the necessary

[1] HGCBC's petition requesting that we promulgate regulations for this purpose was filed on September 20, 1996, and was initially docketed as Ex Parte No. 554, but we will consider it in this proceeding instead.

technical wherewithal to submit its comments as computer data on a 3.5-inch floppy diskette formatted for WordPerfect 5.1, or formatted so that it can be readily converted into WordPerfect 5.1. Any such diskette submission (one diskette will be sufficient) should be in addition to the written submission (an original and 10 copies).

Small Entities

The Board preliminarily concludes that these rules, if adopted, would not have a significant economic effect on a substantial number of small entities. Nonetheless, the Board seeks comment on whether there would be effects on small entities that should be considered. If comments provide information that there would be significant effects on small entities, the Board will prepare a regulatory flexibility analysis at the final rule stage.

Environment

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects in 49 CFR Part 1310

Household goods carriers, Tariffs.

Decided: October 23, 1996.

By the Board, Chairman Morgan, Vice Chairman Simmons and Commissioner Owen.

Vernon A. Williams,

Secretary.

For the reasons set forth in the preamble, the Board proposes to add a new part 1310 to title 49, Chapter X, of the Code of Federal Regulations to read as follows:

PART 1310—TARIFF REQUIREMENTS FOR HOUSEHOLD GOODS CARRIERS

Sec.

Authority: 49 U.S.C. 721(a), 13702(a)(2), 13702(c) and 13702(d).

§ 1310.1 Scope; Definitions.

(a) The provisions of this part address the tariff requirements imposed by 49 U.S.C. 13702 on motor carriers and freight forwarders for the transportation of household goods, and the notice requirements that such carriers must comply with in order to be entitled to enforce the provisions of their tariffs against individuals whose shipments are subject to such tariffs.

(b) The provisions of this part apply to all movements of household goods defined in paragraph (c)(1) of this section, and to those movements of household goods defined in paragraph (c)(2) of this section that are not provided under contracts entered into pursuant to 49 U.S.C. 14101(b) or former 49 U.S.C. 10702.

(c) For the purposes of this part, the term *household goods* means personal effects and property used or to be used in a dwelling, when a part of the equipment or supply of such dwelling, and similar property if the transportation of such effects or property is:

(1) Arranged and paid for by the householder, including transportation of property from a factory or store when the property is purchased by the householder with intent to use in his or her dwelling; or

(2) Arranged and paid for by another party.

(d) For the purposes of this part *service terms* means all classifications, rules and practices that affect the rates, charges, or level of service for movements of household goods.

§ 1310.2 Requirement to maintain tariffs.

(a) Except when providing transportation for charitable purposes without charge, carriers subject to the Board's jurisdiction under Chapter 135 of Title 49 of the United States Code may provide transportation or service for movements of household goods only if the rates, and related rules and practices, for such transportation or service are contained in a published tariff that is in effect under this section. The carrier may not charge or receive a different compensation for the transportation or service than the rate specified in the tariff, whether by returning a part of that rate to a person, giving a person a privilege, allowing the use of a facility that affects the value of that transportation or service, or another device. A rate contained in a tariff shall be stated in money of the United States.

(b) Tariffs maintained pursuant to this part must be available for inspection by the Board and must be made available for inspection by shippers upon reasonable request.

(c) A carrier that maintains a tariff pursuant to this part may not enforce the provisions of the tariff unless the carrier has given notice that the tariff is available for inspection in its bill of lading or by other actual notice to individuals whose shipments are subject to the tariff, as provided in § 1310.4 of this part.

(d) The Board may invalidate a tariff prepared by or on behalf of a carrier under this part if that tariff violates 49 U.S.C. 13702 or the regulations contained in this part.

§ 1310.3 Contents of tariffs.

(a) Tariffs prepared under this part must include an accurate description of the services offered to the public; must provide the specific applicable rates, charges and service terms; and must be arranged in a way that allows for the determination of the exact rate, charges and service terms applicable to any given shipment. Increases, reductions and other changes must be symbolized or highlighted in some way to facilitate ready identification of the changes and their effective dates.

(b) All information necessary to determine applicable rates, charges and service terms for a given shipment need not be contained in a single tariff, but if multiple tariffs are used to convey that information, the tariff containing the rates must make specific reference to all other tariffs required to determine applicable rates, charges and service terms. The carrier(s) party to the rate(s) must participate in all of the tariffs so linked and all such tariffs must be made available to shippers upon reasonable request.

§ 1310.4 Incorporation of tariff provisions by reference.

(a) Carriers that maintain tariffs pursuant to this part may incorporate the terms of such tariffs by reference (i.e., without stating their full text) into the bill of lading or other document embodying the contract of carriage for the transportation of household goods, provided that:

(1) The bill of lading or other document must contain a conspicuous notice that the contract of carriage incorporates the terms of the carrier's tariffs; the carrier must give notice that its tariffs are available for inspection in its bill of lading or by other actual notice to individuals whose shipments are subject to such tariffs; and the carrier must make the full text of incorporated terms readily available for inspection by the shipper, free of charge, upon request. If such terms cannot be made available immediately, they must be made available promptly by mail or other delivery service.

(2) If the incorporated terms include any of the terms set forth in paragraphs (a)(2)(i) through (a)(2)(iii) of this section, the notice on the bill of lading or other document must indicate that such terms are included; the shipper must be provided with a brief summary of the principal features of such terms on or with the document; and the notice or summary must indicate that the shipper

will be able to obtain a more complete explanation of such terms upon request.

(i) Limits on the carrier's liability for loss, damage, or delay of goods, including fragile or valuable goods.

(ii) Claim restrictions, including time periods within which shippers or consignees must file a claim or bring an action against the carrier for its acts or omissions or those of its agents.

(iii) Rights of the carrier to impose monetary penalties on shippers or consignees, increase the price of the transportation, or change any terms of the contract.

(b) A carrier may not claim the benefit as against a shipper or consignee of, and a shipper or consignee shall not be bound by, any tariff term that is incorporated by reference under this section unless the carrier has complied with the requirements of paragraph (a) of this section.

(c) The disclosure requirements established by this section preempt any State requirements on the same subject, for tariff terms that are incorporated by reference into the bill of lading or other document embodying the contract of carriage for the transportation of household goods.

[FR Doc. 96–28090 Filed 11–1–96; 8:45 am]

BILLING CODE 4915–00–P

Notices

Federal Register
Vol. 61, No. 214
Monday, November 4, 1996

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Consumer Service

Agency Information Collection Activities: Proposed Collection; Comment Request

Food Security Supplement to the Current Population Survey, April, 1997

AGENCY: Food and Consumer Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on proposed information collection of supplemental food security questions for the April, 1997 Current Population Survey.

DATES: Written comments must be submitted on or before January 6, 1997.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of information collection on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Michael E. Fishman, Acting Director, Office of Analysis and Evaluation, Food and Consumer Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION: Requests for additional information or copies of the information collection instruments and instructions should be directed to Michael E. Fishman, (703) 305–2117.

SUPPLEMENTARY INFORMATION:

Title: Food Security Supplement to the Current Population Survey.

OMB Number: Not yet assigned.

Form Number: None.

Expiration Date: N/A.

Type of Request: New Collection of Information.

Abstract: The U.S. Bureau of the Census will supplement the April, 1997 Current Population Survey with questions regarding household food shopping, food sufficiency, coping mechanisms and food scarcity, and concern about food sufficiency. A similar supplement was also appended to the CPS in April, 1995 and September, 1996. These data will be used to develop a scale of food security reflecting a range from food secure households through households experiencing severe food insecurity. Ultimately, this scale will be used to identify the prevalence of poverty-linked food insecurity and hunger experienced in the United States. The purpose of this project is to provide a consistent measure of the extent and severity of food insecurity that will aid in policy decision making. The supplemental survey instrument has been developed in conjunction with food security experts nationwide as well as survey method experts within the Census Bureau. This supplemental information will be collected by both personal visit and telephone interviews in conjunction with the regular monthly CPS interviewing. All interviews, whether by personal visit or by telephone, are conducted using computers.

Affected Public: Individuals or households.

Estimated Number of Respondents: 50,000.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden: 8,330 hours.

Dated: October 31, 1996.

William E. Ludwig,

Administrator, Food and Consumer Service.

[FR Doc. 96–28409 Filed 11–1–96; 8:45 am]

BILLING CODE 3410–30–U

Forest Service

Newspapers to be Used for Publication of Legal Notice of Appealable Decisions Under 36 CFR 217 and Corrections Under 36 CFR 215 for the Southern Region; Alabama, Kentucky, Georgia, Tennessee, Florida, Louisiana, Mississippi, Virginia, West Virginia, Arkansas, Oklahoma, North Carolina, South Carolina, Texas, Puerto Rico

AGENCY: Forest Service, USDA.

ACTION: Notice and correction.

SUMMARY: Deciding Officers in the Southern Region will publish notice of decisions subject to administrative appeal under 36 CFR 217 in the legal notice section of the newspapers listed in the Supplementary Information section of this notice. As provided in 36 CFR 217.5(d), the public shall be advised through Federal Register notice, of the principal newspaper to be utilized for publishing legal notices of decisions. Newspaper publication of notices of decisions is in addition to direct notice of decisions to those known to be interested in or affected by a specific decision. The Responsible Official under 36 CFR part 215 gave annual notice in the Federal Register published on May 10, 1996, of principal newspapers to be utilized for publishing notices of proposed actions and of decisions subject to appeal under 36 CFR part 215. The list of newspapers to be used for 215 notice and decision is corrected.

DATES: Use of these newspapers for purposes of publishing legal notices of decisions subject to appeal under 36 CFR parts 217 and the use of the corrected newspaper listed under 36 CFR 215 shall begin on or after November 4, 1996.

FOR FURTHER INFORMATION CONTACT: Jean Paul Kruglewicz, Regional Appeals Coordinator, Southern Region, Planning, 1720 Peachtree Road, NW, Atlanta, Georgia 30367–9102, Phone: 404–347–4867.

SUPPLEMENTARY INFORMATION: Deciding Officers in the Southern Region will

give legal notice of decisions subject to appeal under 36 CFR Part 217 in the following newspapers which are listed by Forest Service Administrative unit. Where more than one newspaper is listed for any unit, the first newspaper listed is the principal newspaper that will be utilized for publishing the legal notices of decisions. Additional newspapers listed for a particular unit are those newspapers the Deciding Officer expects to use for purposes of providing additional notice. The timeframe for appeal shall be based on the date of publication of the legal notice of the decision in the principal newspaper. The following newspapers will be used to provide notice.

Southern Region

Regional Forester Decisions

Affecting National Forest System lands in more than one state of the 13 states of the Southern Region and the Commonwealth of Puerto Rico.

Atlanta Journal, published daily in Atlanta, GA.

Southern Region

Regional Forester Decisions

Affecting National Forest System lands in only one state of the 13 states of the Southern Region and the Commonwealth of Puerto Rico or one Ranger District will appear in the principal newspaper elected by the National Forest(s) of that state or Ranger District.

National Forests in Alabama, Alabama

Forest Supervisor Decisions

Montgomery Advertiser, published daily in Montgomery, AL.

District Ranger Decisions

Bankhead Ranger District: *Northwest Alabamian*, published weekly (Monday & Thursday) in Haleyville, AL.

Conecuh Ranger District: *The Andalusia Star*, published daily (Tuesday through Saturday) in Andalusia, AL.

Oakmulgee Ranger District: *The Tuscaloosa News*, published daily in Tuscaloosa, AL.

Shoal Creek Ranger District: *The Anniston Star*, published daily in Anniston, AL.

Talladega Ranger District: *The Daily Home*, published daily in Talladega, AL.

Tuskegee Ranger District: *Tuskegee News*, published weekly (Thursday) in Tuskegee, AL.

Caribbean National Forest, Puerto Rico

Forest Supervisor Decisions

El Nuevo Dia, published daily in Spanish in San Juan, PR.

San Juan Star, published daily in English in San Juan, PR.

Chattahoochee-Oconee National Forest, Georgia

Forest Supervisor Decisions

The Times, published daily in Gainesville, GA.

District Ranger Decisions

Armuchee Ranger District: *Walker County Messenger*, published bi-weekly (Wednesday & Friday) in Lafayette, GA.

Toccoa Ranger District: *The News Observer*, published weekly (Wednesday) in Blue Ridge, GA.

Brasstown Ranger District: *North Georgia News*, published weekly (Wednesday) in Blairsville, GA.

Tallulah Ranger District: *Clayton Tribune*, published weekly (Thursday) in Clayton, GA.

Chattooga Ranger District: *Northeast Georgian*, published weekly (Tuesday) in Cornelia, GA.

Toccoa Record, published weekly (Thursday) in Toccoa, GA.

White County News, published weekly (Thursday) in Cleveland, GA.

Cohutta Ranger District: *Chatsworth Times*, published weekly (Wednesday) in Chatsworth, GA.

Oconee Ranger District: *Monticello News*, published weekly (Thursday) in Monticello, GA.

Cherokee National Forest, Tennessee

Forest Supervisor Decisions

Knoxville News Sentinel, published daily in Knoxville, TN (covering McMinn, Monroe, and Polk Counties).

Johnson City Press, published daily in Johnson City, TN (covering Carter, Cocke, Greene, Johnson, Sullivan, Unicoi and Washington Counties).

District Ranger Decisions

Ocoee Ranger District: *Polk County News*, published weekly (Wednesday) in Benton, TN.

Hiwassee Ranger District: *Daily Post-Athenian*, published daily (Monday–Friday) in Athens, TN.

Tellico Ranger District: *Monroe County Advocate*, published weekly (Thursday) in Sweetwater, TN.

Nolichucky Ranger District: *Greeneville Sun*, published daily (Monday–Saturday) in Greeneville, TN.

Unaka Ranger District: *Johnson City Press*, published daily in Johnson City, TN.

Watauga Ranger District: *Elizabethton Star*, published daily (Sunday–Friday) in Elizabethton, TN.

Daniel Boone National Forest, Kentucky

Forest Supervisor Decisions

Lexington Herald-Leader, published daily in Lexington, KY.

District Ranger Decisions

Morehead Ranger District: *Morehead News*, published bi-weekly (Tuesday and Friday) in Morehead, KY.

Stanton Ranger District: *The Clay City Times*, published weekly (Thursday) in Stanton, KY.

Berea Ranger District: *Jackson County Sun*, published weekly (Thursday) in McKee, KY.

London Ranger District: *The Sentinel-Echo*, published tri-weekly (Monday, Wednesday, and Friday) in London, KY.

Somerset Ranger District: *Commonwealth-Journal*, published daily (Sunday through Friday) in Somerset, KY.

Stearns Ranger District: *McCreary County Record*, published weekly (Tuesday) in Whitley City, KY.

Redbird Ranger District: *Manchester Enterprise*, published weekly (Thursday) in Manchester, KY.

National Forests in Florida, Florida

Forest Supervisor Decisions

The Tallahassee Democrat, published daily in Tallahassee, FL.

District Ranger Decisions

Apalachicola Ranger District: *The Liberty Journal*, published weekly (Wednesday) in Bristol, FL.

Lake George Ranger District: *The Ocala Star Banner*, published daily in Ocala, FL.

Osceola Ranger District: *The Lake City Reporter*, published daily (Monday-Saturday) in Lake City, FL.

Seminole Ranger District: *The Daily Commercial*, published daily in Leesburg, FL.

Wakulla Ranger District: *The Tallahassee Democrat*, published daily in Tallahassee, FL.

Francis Marion & Sumter National Forest, South Carolina

Forest Supervisor Decisions

The State, published daily in Columbia, SC.

District Ranger Decisions

Enoree Ranger District: *Newberry Observer*, published tri-weekly (Monday, Wednesday, and Friday) Newberry, SC.

Andrew Pickens Ranger District: *Seneca Journal and Tribune*, published bi-weekly (Wednesday and Friday) in Seneca, SC.

Long Cane Ranger District: *The Augusta Chronicle,* published daily in Augusta, GA.

Wambaw Ranger District: *News and Courier,* published daily in Charleston, SC.

Witherbee Ranger District: *News and Courier,* published daily in Charleston, SC.

George Washington and Jefferson National Forests, Virginia

Forest Supervisor Decisions

Roanoke Times, published daily in Roanoke, VA.

District Ranger Decisions

Lee Ranger District: *Shenandoah Valley Herald,* published weekly (Wednesday) in Woodstock, VA.

Warm Springs Ranger District: *The Recorder,* published weekly (Thursday) in Monterey, VA.

Pedlar Ranger District: *News-Gazette,* published weekly (Wednesday) in Lexington, VA.

James River Ranger District: *Virginian Review,* published daily (except Sunday) in Covington, VA.

Deerfield Ranger District: *Daily News Leader,* published daily in Staunton, VA.

Dry River Ranger District: *Daily News Record,* published daily (except Sunday) in Harrisonburg, VA.

Blacksburg Ranger District: *Roanoke Times,* published daily in Roanoke, VA.

Monroe Watchman, published weekly (Thursday) in Union, WV (only for those decisions in West VA—notice will be published in the *Roanoke Times* and *Monroe Watchman.*)

Glenwood Ranger District: *Roanoke Times,* published daily in Roanoke, VA.

New Castle Ranger District: *Roanoke Times,* published daily in Roanoke, VA.

Monroe Watchman, published weekly (Thursday) in Union, WV (only for those decisions in West VA—notice will be published in the *Roanoke Times* and *Monore Watchman.*)

Mount Rogers National Recreation Area: *Bristol Herald Courier,* published daily in Bristol, VA.

Clinch Ranger District: *Kingsport-Times News,* published daily in Kingsport, TN.

Wythe Ranger District: *Southwest Virginia Enterprise,* published bi-weekly (Wednesday and Saturday) in Wytheville, VA.

Kisatchie National Forest, Louisiana

Forest Supervisor Decisions

Alexandria Daily Town Talk, published daily in Alexandria, LA.

District Ranger Decisions

Caney Ranger District: *Minden Press Herald,* published daily in Minden, LA.

Homer Guardian Journal, published weekly (Wednesday) in Homer, LA.

Catahoula Ranger District: *Alexandria Daily Town Talk,* published daily in Alexandria, LA.

Colfax Chronicle, published weekly (Wednesday) in Colfax, LA.

Evangeline Ranger District: *Alexandria Daily Town Talk,* published daily in Alexandria, LA.

Kisatchie Ranger District: *Natchitoches Times,* published daily (Tuesday–Friday and on Sunday) in Natchitoches, LA Vernon Ranger District: *Leesville Leader,* published daily in Leesville, LA.

Winn Ranger District: *Winn Parish Enterprise,* published weekly (Wednesday) in Winnfield, LA.

National Forests in Mississippi, Mississippi

Forest Supervisor Decisions

Clarion-Ledger, published daily in Jackson, MS.

District Ranger Decisions

Bienville Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Chickasawhay Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Delta Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

De Soto Ranger District: *Clarion Ledger,* published daily in Jackson, MS.

Holly Springs Ranger District: *Clarion Ledger,* published daily in Jackson, MS.

Homochitto Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Tombigbee Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Ashe-Erambert Project: *Clarion-Ledger,* published daily in Jackson, MS.

National Forests in North Carolina, North Carolina

Forest Supervisor Decisions

The Asheville Citizen-Times, published daily in Asheville, NC.

District Ranger Decisions

Appalachian Ranger District: *The Asheville Citizen-Times,* published daily in Asheville, NC.

Cheoah Ranger District: *Graham Star,* published weekly (Thursday) in Robbinsville, NC.

Croatan Ranger District: *The Sun Journal,* published weekly (Sunday through Friday) in New Bern, NC.

Grandfather Ranger District: *McDowell News,* published daily in Marion, NC.

Highlands Ranger District: *The Highlander,* published weekly (May–Oct Tues & Fri; Oct–April Tues only) in Highlands, NC.

The Crossroads Chronicle, published weekly (May–Oct Tues & Fri; Oct–April Tues only) in Cashiers, NC.

The Sylva Herald, published weekly on Thursday in Sylva, NC.

Pisgah Ranger District: *The Asheville Citizen-Times,* published daily in Asheville, NC.

Tusquitee Ranger District: *Cherokee Scout,* published weekly (Wednesday) in Murphy, NC.

Uwharrie Ranger District: *Montgomery Herald,* published weekly (Wednesday) in Troy, NC.

Wayah Ranger District: *The Franklin Press,* published bi-weekly (Wednesday and Friday) in Franklin, NC.

Ouachita National Forest, Arkansas, Oklahoma

Forest Supervisor Decisions

Arkansas Democrat-Gazette, published daily in Little Rock, AR.

District Ranger Decisions

Caddo Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Cold Springs Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Fourche Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Jessieville Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Mena Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Oden Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Poteau Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Winona Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Womble Ranger District: *Arkansas Democrat-Gazette,* published daily in Little Rock, AR.

Choctaw Ranger District: *Tulsa World,* published daily in Tulsa, OK.

Kiamichi Ranger District: *Tulsa World,* published daily in Tulsa, OK.

Tiak Ranger District: *Tulsa World,* published daily in Tulsa, OK.

Ozark-St. Francis National Forest: Arkansas

Forest Supervisor Decisions

The Courier, published daily (Sunday through Friday) in Russellville, AR.

District Ranger Decisions

Sylamore Ranger District: *Stone County Leader,* published weekly (Tuesday) in Mountain View, AR.

Buffalo Ranger District: *Newton County Times,* published weekly (Thursday) in Jasper, AR.

Bayou Ranger District: *The Courier,* published daily (Sunday through Friday) in Russellville, AR.

Pleasant Hill Ranger District: *Johnson County Graphic,* published weekly (Wednesday) in Clarksville, AR.

Boston Mountain Ranger District: *Southwest Times Record,* published daily in Fort Smith, AR.

Magazine Ranger District: *SouthwestTimes Record,* published daily in daily in Fort Smith, AR.

St. Francis Ranger District: *The Daily World,* published daily (Sunday through Friday) in Helena, AR.

National Forests and Grasslands in Texas, Texas

Forest Supervisor Decisions

The Lufkin Daily News, published daily in Lufkin, TX.

District Ranger Decisions

Angelina National Forest: *The Lufkin Daily News,* published daily in Lufkin, TX.

Davy Crockett National Forest: *The Lufkin Daily News,* published daily in Lufkin, TX.

Sabine National Forest: *The Lufkin Daily News,* published daily in Lufkin, TX.

Sam Houston National Forest: *The Courier,* published daily in Conroe, TX.

Caddo & LBJ National Grasslands: *Denton Record-Chronicle,* published daily in Denton, TX.

The Responsible Official under 36 CFR part 215 gave annual notice in the Federal Register published on May 10, 1996, of principal newspapers to be utilized for publishing notices of proposed actions and of decisions subject to appeal under 36 CFR 215. The list of newspapers to be used for 215 notice and decision is corrected as follows:

Caribbean National Forest, Puerto Rico

District Ranger Decisions

Newspaper Removed

El Horizonte, published weekly (Wednesday) in Fajardo, PR.

Francis Marion & Sumter National Forest, South Carolina

District Ranger Decisions

Long Cane Ranger District: (Correction to existing newspaper) *The Augusta Chronicle,* published daily in Augusta, GA.

National Forests in Mississippi

District Ranger Decisions

Deletion of Ranger District

Biloxi Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Black Creek Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Bude Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Strong River Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

Addition of Ranger District

De Soto Ranger District: *Clarion-Ledger,* published daily in Jackson, MS.

National Forests in North Carolina

District Ranger Decisions

Deletion of Ranger District

French Broad Ranger District: *The Asheville Citizen-Times,* published daily in Asheville, NC.

Toecane Ranger District: *The Asheville Citizen-Times,* published daily in Asheville, NC.

Addition of Ranger District

Appalachian Ranger District: *The Asheville Citizen-Times,* published daily in Asheville, NC.

Dated: October 28, 1996.

R. Gary Pierson,

Acting Deputy Regional Forester, Natural Resources.

[FR Doc. 96–28205 Filed 11–1–96; 8:45 am]

BILLING CODE 3410–11–M

Klamath Provincial Advisory Committee (PAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of Meeting.

SUMMARY: The Klamath Provincial Advisory Committee will meet on November 14 and November 15, 1996 at the Weaverville Victorian Inn Conference Room, 1709 Main Street, Weaverville, California. The meeting will begin at 9:30 a.m. on November 14 and adjourn at 5:00 p.m. The meeting will reconvene at 8:00 a.m. on November 15 and continue until 4:00 p.m. Agenda items to be covered include: (1) socio-economic monitoring overview; (2) Province-wide approach to implementation of a fuels strategy (values at risk); (3) salvage subcommittee report; (4) Province Interagency Executive Committee Report; and (5) public comment periods. All PAC meetings are open to the public. Interested citizens are encouraged to attend.

FOR FURTHER INFORMATION CONTACT: Connie Hendryx, USDA, Klamath National Forest, at 1312 Fairlane Road, Yreka, California 96097; telephone 916–842–6131, (FTS) 700–467–1309.

Dated: October 23, 1996.

Nancy J. Gibson,

Administrative Officer.

[FR Doc. 96–28149 Filed 11–1–96; 8:45 am]

BILLING CODE 3410–11–M

Rural Utilities Service

Iliamna-Newhalen-Nondalton Electric Cooperative, Inc.; Finding of No Significant Impact

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of finding of no significant impact.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS), pursuant to the National Environmental Policy Act of 1969, as amended, the Council on Environmental Quality Regulations (40 CFR parts 1500–1508), and RUS Environmental Policies and Procedures (7 CFR part 1794), has made a finding of no significant impact (FONSI) with respect to a project proposed by Iliamna-Newhalen-Nondalton Electric Cooperative, Inc. (INNEC), of Iliamna, Alaska. The proposed project is a 700 kilowatt hydroelectric generating plant which will be built on the Tazimina River near Iliamna, Newhalen, and Nondalton, Section 24, Range 32 West, Township 3 South, Seward Meridian, in Southcentral Alaska. On January 31, 1995, INNEC filed an application to the Federal Energy Regulatory Commission (FERC) to exempt the Tazimina River Project from the licensing requirements pursuant to Section 2407 of the Energy Policy Act of 1992. The FONSI is based on an environmental assessment (EA) prepared by the FERC. RUS made an independent evaluation of the impacts resulting from the proposed construction and concurs with the scope and content of the EA. In accordance with RUS Environmental Policies and Procedures, 7 CFR Part 1794, Subpart I, Adoption of Environmental Documents, RUS has adopted the FERC EA as its EA for the project.

FOR FURTHER INFORMATION CONTACT: Lawrence R. Wolfe, Senior Environmental Protection Specialist, RUS, Engineering and Environmental Staff, 1400 Independence Avenue, SW, Stop 1571, Washington, DC 20250–1571, telephone (202) 720–1784.

The project, located near the towns of Iliamna, Newhalen, and Nondalton, Alaska, would provide nearly all

present and near-term future energy demands of these three communities.

Copies of the EA and FONSI are available for review at, or can be obtained from, RUS at the address provided herein or from Mr. Brent Petrie, Manager, INNEC, P.O. Box 210, Iliamna, Alaska 99606, telephone (907) 571–1259.

SUPPLEMENTARY INFORMATION: RUS has reviewed the FERC EA and has determined that it represents an accurate assessment of the scope and level of environmental impacts of the proposed project. The FERC EA, which includes input from certain Federal and state agencies, has been adopted by RUS to serve as its EA.

RUS has determined that the FERC EA adequately considered the potential impacts of the proposed project and concluded that approval of RUS financing for the project would not result in a major Federal action significantly affecting the quality of the human environment. RUS determined that the proposed project will either have no effect on wetlands, floodplains, important farmlands, threatened or endangered species, formally classified areas and cultural resources or no significant effect on water quality. RUS has identified no other potential significant impact resulting from construction and operation of the proposed hydroelectric generating plant.

Alternatives examined for the proposed project included the INNEC's proposed project, no action and denial of license by FERC to build the project. RUS determined that the proposed project is an environmentally acceptable alternative that meets INNEC's need with a minimum of adverse environmental impact. RUS has concluded that approval of RUS financing for the project would not constitute a major Federal action significantly affecting the quality of the human environment. Therefore, the preparation of an environmental impact statement is not necessary.

In accordance with their regulations, FERC published a notice and requested comments on the application submitted by INNEC. All comments received were adequately addressed in the FERC EA. The notice published by FERC meets the RUS notice requirements contained in 7 CFR Part 1794.62. On September 14, 1995, FERC issued an order granting exemption from licensing to INNEC to build the proposed project.

Dated: October 28, 1996.

Adam M. Golodner,

Deputy Administrator, Program Operations.

[FR Doc. 96–28193 Filed 11–1–96; 8:45 am]

BILLING CODE 3410–15–M

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Opportunity to Request Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 353.22 or 355.22 of the Department of Commerce (the Department) Regulations (19 CFR 353.22/355.22 (1993)), that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

Opportunity to Request a Review: Not later than November 30, 1996, interested parties may request an administrative review of the following orders, findings, or suspended investigations, with anniversary dates in November for the following periods:

Antidumping proceedings	Period
Brazil: Circular Welded Non-Alloy Pipe A–351–809	11/1/95–10/31/96
Mexico: Circular Welded Non-Alloy Pipe A–201–805	11/1/95–10/31/96
South Korea: Circular Welded Non-Alloy Pipe A–580–809	11/1/95–10/31/96
Taiwan: Circular Welded Non-Alloy Pipe A–583–814	11/1/95–10/31/96
Venezuela: Circular Welded Non-Alloy Pipe A–307–805	11/1/95–10/31/96
Argentina: Barbed Wire A–357–405	11/1/95–10/31/96
Argentina: Carbon Steel Wire Rods A–357–007	11/1/95–10/31/96
Japan: Light Scattering Instruments A–588–813	11/1/95–10/31/96
Japan: Bicycle Speedometers A–588–038	11/1/95–10/31/96
Japan: Titanium Sponge A–588–020	11/1/95–10/31/96
Peoples Republic of China: Garlic A–570–831	11/1/95–10/31/96
Peoples Republic of China: Tungsten Ore Concentrates A–570–831	11/1/95–10/31/96
Peoples Republic of China: Paper Clips	11/1/95–10/31/96
Singapore: Rectangular Pipe & Tube A–559–502	11/1/95–10/31/96

Countervailing duty proceedings	Period
Argentina: Oil Country Tubular Goods: C–357–403	1/1/95–12/31/95

Suspension agreements	Period
Japan: Small Motors: A–588–090	11/1/95–10/31/96
Ukraine: Siliconmanganese A–823–805	11/1/95–10/31/96

In accordance with sections 353.22(a) and 355.22(a) of the regulations, an interested party as defined by section 353.2(k) may request in writing that the Secretary conduct an administrative review. The Department has changed its requirements for requesting reviews for countervailing duty orders and suspension agreements. Pursuant to 19 CFR 355.22(a) of the regulations, an interested party must specify the individual producers or exporters covered by the order or suspension agreements for which they are requesting a review, (Interim Regulations, 60 FR 25130, 25137 (May 11, 1995)). Therefore, for antidumping and countervailing duty reviews, and suspension agreements, the interested party must specify for which individual producers or exporters covered by an antidumping finding, antidumping or countervailing duty order or suspension agreement it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin, and

each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Sheila Forbes, in room 3065 of the main Commerce Building. Further, in accordance with section 353.31(g) or 355.31(g) of the regulations, a copy of each request must be served to every party on the Department's service list.

The Department will publish in the Federal Register a notice of ''Initiation of Administration Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation,'' for requests received by November 30, 1996. If the Department does not receive, by November 30, 1996, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: October 28, 1996.

Jeffrey P. Bialos,

Principal Deputy Assistant Secretary for Import Administration.

[FR Doc. 96–28247 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–DS–M

Intent To Revoke Antidumping Duty Orders and Findings and To Terminate Suspended Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of intent to revoke antidumping duty orders and findings and to terminate suspended investigations.

SUMMARY: The Department of Commerce (the Department) is notifying the public of its intent to revoke the antidumping duty orders and findings and to terminate the suspended investigations listed below. Domestic interested parties who object to these revocations and terminations must submit their comments in writing no later than the last day of November 1996.

EFFECTIVE DATE: November 4, 1996.

FOR FURTHER INFORMATION CONTACT: Michael Panfeld or the analyst listed under Antidumping Proceeding at: Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230.

SUPPLEMENTARY INFORMATION:

Background

The Department may revoke an antidumping duty order or finding or terminate a suspended investigation if the Secretary of Commerce concludes that it is no longer of interest to interested parties. Accordingly, as required by § 353.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke the following antidumping duty orders and findings and to terminate the suspended investigations for which the Department has not received a request to conduct an administrative review for the most recent four consecutive annual anniversary months:

Antidumping Proceeding

Argentina

Barbed Wire & Barbless Fencing Wire
A–357–405
50 FR 46808
November 13, 1985
Contact: Tom Killiam at (202) 482–2704

Argentina

Carbon Steel Wire Rods
A–357–007
49 FR 46180
November 23, 1984
Contact: Tom Killiam at (202) 482–2704

Singapore

Light-Walled Rectangular Pipe & Tube
A–559–502
51 FR 41142
November 13, 1986
Contact: Tom Killiam at (202) 482–2704

The People's Republic of China

Tungsten Ore Concentrates
A–570–811
56 FR 58681
November 21, 1991
Contact: Andrea Chu at (202) 482–4733

Japan

Certain Small Electric Motors of 5 to 150 Horsepower
A–588–090
45 FR 73723
November 6, 1980
Contact: Jacqueline Winbush at (202) 482–1394

If no interested party requests an administrative review in accordance with the Department's notice of opportunity to request administrative review, and no domestic interested party objects to the Department's intent to revoke or terminate pursuant to this notice, we shall conclude that the antidumping duty orders, findings, and suspended investigations are no longer of interest to interested parties and shall proceed with the revocation or termination.

Opportunity To Object

Domestic interested parties, as defined in § 353.2(k) (3), (4), (5), and (6) of the Department's regulations, may object to the Department's intent to revoke these antidumping duty orders and findings or to terminate the suspended investigations by the last day of November 1996. Any submission to the Department must contain the name and case number of the proceeding and a statement that explains how the objecting party qualifies as a domestic interested party under § 353.2(k) (3), (4), (5), and (6) of the Department's regulations.

Seven copies of such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, Washington, D.C. 20230. You must also include the pertinent certification(s) in accordance with § 353.31(g) and § 353.31(i) of the Department's regulations. In addition, the Department requests that a copy of the objection be sent to Michael F. Panfeld in Room 4203.

This notice is in accordance with 19 CFR 353.25(d)(4)(i).

Dated: October 25, 1996.

Barbara R. Stafford,

Deputy Assistant Secretary for AD/CVD Enforcement.

[FR Doc. 96–28318 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–475–017]

Pads for Woodwind Instrument Keys from Italy, Revocation of the Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of revocation of antidumping duty order.

SUMMARY: The Department of Commerce (the Department) is notifying the public of its revocation of the antidumping duty order on pads for woodwind instrument keys from Italy because it is no longer of any interest to domestic interested parties.

EFFECTIVE DATE: November 4, 1996.

FOR FURTHER INFORMATION CONTACT: Lyn Johnson or Michael Panfeld, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, N.W., Washington, D.C. 20230, telephone (202) 482–5287.

SUPPLEMENTARY INFORMATION:

Background

The Department may revoke an antidumping duty order if the Secretary concludes that the duty order is no longer of any interest to domestic interested parties. We conclude that there is no interest in an antidumping duty order when no interested party has requested an administrative review for five consecutive review periods and when no domestic interested party objects to revocation (19 CFR § 353.25(d)(4)(iii)).

On September 3, 1996, the Department published in the Federal Register (61 FR 46437) its notice of intent to revoke the antidumping duty order on pads for woodwind instrument keys from Italy (September 21, 1984). Additionally, as required by 19 CFR § 353.25(d)(4)(ii), the Department served written notice of its intent to revoke this antidumping duty order on each domestic interested party on the service list. Domestic interested parties who might object to the revocation were provided the opportunity to submit their comments not later than the last day of the anniversary month.

In this case, we received no requests for review for five consecutive review periods. Furthermore, no domestic interested party, as defined under § 353.2 (k)(3), (k)(4), (k)(5), or (k)(6) of the Department's regulations, has expressed opposition to revocation. Based on these facts, we have concluded that the antidumping duty order on pads for woodwind instrument keys from Italy is no longer of any interest to interested parties. Accordingly, we are revoking this antidumping duty order in accordance with 19 CFR § 353.25(d)(4)(iii).

Scope of the Order

Imports covered by the revocation are shipments of pads for woodwind instrument keys from Italy. This merchandise is currently classifiable under Harmonized Tariff Schedules (HTS) item number 9209.99.40. The HTS number is provided for convenience and customs purposes. The written description remains dispositive.

This revocation applies to all unliquidated entries of pads for woodwind instrument keys from Italy entered, or withdrawn from warehouse, for consumption on or after September 1, 1996. Entries made during the period September 1, 1995, through August 31, 1996, will be subject to automatic assessment in accordance with 19 CFR § 353.22(e). The Department will instruct the Customs Service to proceed with liquidation of all unliquidated entries of this merchandise entered, or withdrawn from warehouse, for consumption on or after September 1, 1996, without regard to antidumping duties, and to refund any estimated antidumping duties collected with respect to those entries. This notice is in accordance with 19 CFR § 353.25(d).

Dated: October 23, 1996.

Barbara R. Stafford,

Deputy Assistant Secretary for AD/CVD Enforcement.

[FR Doc. 96–28248 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–DS–P

[A–821–802]

Amendments to the Agreement Suspending the Antidumping Investigation on Uranium From the Russian Federation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of amendments to the agreement suspending the antidumping investigation on uranium from the Russian Federation.

SUMMARY: The Department of Commerce (the Department) and the Ministry of Atomic Energy of the Russian Federation (MINATOM) have signed two amendments to the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation, as amended (the Suspension Agreement). One amendment provides for the sale in the United States of feed associated with imports of low-enriched uranium (LEU) derived from high-enriched uranium (HEU) which makes the Suspension Agreement consistent with the USEC Privatization Act. The second amendment restores previously unused quota for separative work units, and covers Russian uranium which has been enriched in a third country within the terms of the Suspension Agreement, for a period of two years from the effective date of the amendments.

EFFECTIVE DATE: October 3, 1996.

FOR FURTHER INFORMATION CONTACT: James Doyle, Sally C. Gannon, or Karla Whalen, Office of Antidumping Countervailing Duty Enforcement, Group 3, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0172, (202) 482–1391, or (202) 482–0408, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 16, 1992, the Department and the GRF signed the Suspension Agreement on uranium and, on October 30, 1992, the Agreement was published in the Federal Register (57 FR 49220, 49235). On March 11, 1994, the Department and the GRF signed an amendment to the Suspension Agreement on uranium and, on April 1, 1994, this amendment was published in the Federal Register (59 FR 15373). This amendment provided for entry of Russian uranium into the United States based on a concept of matched sales between the United States and Russian producers. Although this amendment has operated to the benefit of all parties concerned, substantial qualities of uranium products not subject to the Suspension Agreement which were produced from Russian ore began to undermine the Suspension Agreement. Thus, pursuant to Section X.B. of the Suspension Agreement, the Department and the GRF entered into consultations. A proposed amendment providing for coverage of Russian ore which has been enriched in a third country was initialled on August 16, 1996. In addition, on August 16, 1996, the Department and the GRF initialled an amendment in order to allow HEU feed [1] to be used in matched sales.[2] The Department subsequently released the proposed amendments to interested parties for comment. After careful consideration by the Department of the comments submitted and further consultations between the two parties, the Department and the GRF signed the final amendments on October 3, 1996.

[1] HEU feed refers to the natural uranium feed associated with the LEU (derived from HEU), which is imported pursuant to the Agreement Between the Government of the United States of America and the Government of the Russian Federation Concerning the Disposition of Highly Enriched Uranium Extracted from Nuclear Weapons (The HEU Agreement), signed February 18, 1993.

[2] A third amendment dealing with the re-export provision was initialled on August 16, 1996 as well, but this amendment has not yet been finalized.

The text of these amendments follow in the Annex to this notice.

Dated: October 24, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

Annex

(Amendment Regarding HEU Feed)

Amendment to the Agreement Suspending the Antidumping Investigation on Uranium From the Russian Federation

Consistent with the requirement of Section 734(l) of the U.S. Tariff Act of 1930, as amended, to prevent the suppression or undercutting of price levels of domestic products in the United States, Section IV of the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation, as amended on March 11, 1994, (the Agreement) is amended as set forth below. All other provisions of the Agreement, particularly Section VII, remain in force and apply to this Amendment.

1. Section IV.M.2 is replaced with:

2. Exports pursuant to such sales will not be counted against the export limits established in accordance with this Section IV. Permitting importation and disposition of the HEU, or LEU derived from the HEU, is consistent with the purposes of this Agreement, subject to the following requirements: (1) The HEU or LEU must be disposed of by DOE or the United States Executive Agent(s) consistent with the Agreement between the Government of the United States of America and the Government of the Russian Federation Concerning the Disposition of Highly Enriched Uranium Extracted from Nuclear Weapons; (2) Uranium products deemed to be of Russian origin pursuant to section 3112(b) of P.L. 104–134, the USEC Privatization Act, must be sold only in accordance with section 3112(b) and the relevant provisions of this Agreement, as amended; (3) Contracts for the purchase of the HEU or LEU must be provided to the Department; and (4) Annual summaries of disposition of the HEU and LEU, and uranium products deemed to be of Russian origin pursuant to section 3112(b) of P.L. 104–134, the USEC Privatization Act, must be provided to the Department.

2. Paragraph two of Section IV of the Agreement is amended as follows:

Sentence two, beginning ''For purposes of this Section, Russian-origin means,'' is replaced by:

For purposes of this Section, Russian-origin means natural uranium (*i.e.* U_3O_8 or UF_6) or SWU which is produced in Russia and exported from Russia for the first time after March 11, 1994, or uranium hexafluoride (and U_3O_8 derived therefrom) deemed to be of Russian origin pursuant to section 3112(b) of P.L. 104–134, the USEC Privatization Act.

The Parties agree that this Amendment constitutes an integral part of the Agreement.

The English language version of this Amendment shall be controlling.

Signed on this 27th day of September, 1996.

For the Ministry of Atomic Energy of the Russian Federation:

N. N. Yegorov,

Deputy Minister, Ministry of Atomic Energy of the Russian Federation.

Signed on this 3rd day of October, 1996.

For the United States Department of Commerce:

(Joseph A. Spetrini, for)

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

(Amendment Regarding Russian Uranium Enriched in a Third Country Prior to Entry Into the United States and the Separative Work Unit Quota)

Amendment to the Agreement Suspending the Antidumping Investigation on Uranium From the Russian Federation

Consistent with the requirement of Section 734(1) of the U.S. Tariff Act of 1930, as amended (the Act) to prevent the suppression or undercutting of price levels of domestic products in the United States, Sections III, IV, VII, X, and Attachment 1 of the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation, as amended on March 11, 1994 (the Agreement), are amended as set forth below. All other provisions of the Agreement, particularly Section VII, remain in force and apply to this Amendment.

1. Section III, ''Product Coverage,'' is amended as follows:

The second paragraph of Section III, beginning ''Uranium ore * * *,'' is replaced by:

Further, uranium ore from Russia that is milled into U_3O_8 and/or converted into UF_6 and/or enriched in U^{235} in another country prior to direct and/or indirect importation into the United States is considered uranium from Russia and is subject to the terms of this Agreement. When imported as enriched uranium (excluding highly enriched uranium (HEU) and LEU derived from HEU, imported pursuant to Section IV.M of this Agreement and subject to the provisions of the USEC Privatization Act, P.L. 104–134), the full amount of the natural uranium equivalent required to produce the enriched product will be counted against the existing quota under this Agreement. For the purposes of calculating this amount of natural uranium, the terms of the last bullet of definition II (a) shall apply unless otherwise reported.

The second sentence in the third paragraph of Section III, beginning ''Uranium enriched in U^{235} in another country * * *,'' is deleted.

2. Paragraph D of Section VII, ''Anticircumvention,'' is amended as follows:

D. In addition to the above requirements, the Department shall direct the U.S. Customs Service to require all importers of uranium into the United States, regardless of stated country of origin, to submit at the time of entry written statements certifying the following:

(A) The country(ies) in which the ore was mined and, if applicable, converted, enriched, and/or fabricated (unless for use as a fuel assembly in the United States as fabricated), for all imports; and

(B) That the uranium being imported was not obtained under any arrangement, swap, or other exchange designed to circumvent the export limits for uranium of Russian origin established by this agreement.

Where there is reason to believe that such a certification has been made falsely, the Department will refer the matter to Customs or the Department of Justice for further action.

The Department and MINATOM reaffirm that an export certificate endorsed by the Ministry of Foreign Economic Relations (MFER) is required as a condition of entry into the United States. Under no circumstances will uranium from the Russian Federation be allowed entry into the United States without an authorized export certificate allowing importation into the United States.

3. Paragraph one of Section IV.A of the Agreement, as amended on March 11, 1994, is amended as follows:

- Sentence five, beginning ''Because the annual matching SWU quota expires,'' is deleted, and replaced with ''The SWU available for matching under this section which was not matched by March 31, 1996, 1,608,840 SWU, may be sold through matched sales at any time on or before [the date two years after the effective date of this Amendment]. After that date, no further matched SWU sales will be allowed.''
- Sentence six, beginning ''However,'' is deleted, and replaced with the following: ''However, the matching

SWU sold during 1994 and 1995, as well as on or before [the date two years after the effective date of this Amendment], may be delivered at any time during the life of the relevant matched sales contract.''

5. Attachment 1 is amended as follows:

Add footnote 2 to the ''2,000,000'' volumes in the ''SWU'' column for the years 1994 and 1995. Footnote 2 shall read:

Beginning on the effective date of this Amendment, the remaining SWU quota from 1994 and 1995, 1,608,840 SWU, may be used for matched sales consistent with Section IV.A of this Agreement.

6. Section X., Consultations, is amended by adding the following:

C. No later than [the date one year after the effective date of this Amendment], the Department and MINATOM shall enter into consultations toward the consideration of a possible successor plan for containing their cooperative efforts on the issues addressed by this amendment.

These modifications to Sections III, IV, VII, X, and Attachment 1 will remain in effect until [the date two years after the effective date of this Amendment].

The Parties agree that this Amendment constitutes an integral part of the Agreement.

The English language version of this Amendment shall be controlling.

Signed on this 27th day of September, 1996.

For the Ministry of Atomic Energy of the Russian Federation:

N.N. Yegorov,

Deputy Minister, Ministry of Atomic Energy of the Russian Federation.

Signed on this 3rd day of October, 1996.

For the United States Department of Commerce:

(Joseph A. Spetrini, for)

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96–28246 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–DS–M

National Oceanic and Atmospheric Administration

[I.D. 102896F]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting of the Socioeconomic Assessment Panel (SEP).

DATES: The meeting will be held beginning at 1:00 p.m. on December 2, 1996, and will conclude at 5:00 p.m. on December 4, 1996.

ADDRESSES: This meeting will be held at the Radisson Bay Harbor Inn, 7700 Courtney Campbell Causeway, Tampa, FL; telephone: 813–281–8900.

Council address: Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL 33609.

FOR FURTHER INFORMATION CONTACT: Antonio B. Lamberte, Economist; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION: The purpose of the meeting will be to review available social and economic data on the Gulf of Mexico red snapper, vermilion, and amberjack fisheries and to determine the social and economic implications of the levels of acceptable biological catch recommended by the Council's Reef Fish Stock Assessment Panel. The SEP may recommend to the Council total allowable catch levels for the 1996–97 fishing year. The SEP will also review a draft of Amendment 15 to the Reef Fish Fishery Management Plan. This amendment proposes a license limitation program for the commercial red snapper fishery.

A copy of the agenda can be obtained by contacting the Council (see **ADDRESSES**).

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by November 22, 1996.

Dated: October 28, 1996.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 96–28251 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 100796B]

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of scientific research permit 1018.

SUMMARY: Notice is hereby given that on September 27, 1996, NMFS issued scientific research permit 1018 to Thomas S. Squiers, Jr., of the Maine Department of Marine Resources (P618), to take listed shortnose sturgeon for the purpose of scientific research subject to certain conditions set forth therein.

ADDRESSES: The application, permit, and related documents are available for review by appointment in the following offices:

Office of Protected Resources, F/PR3, NMFS, 1315 East-West Hwy., Room 13307, Silver Spring, MD 20910–3226 (301–713–1401); and

Director, Northeast Region, NMFS, NOAA, One Blackburn Drive, Gloucester, MA 01930–2298 (508–281–9250).

SUPPLEMENTARY INFORMATION: Notice was published on August 16, 1996 (61 FR 42592) that an application had been filed by Thomas S. Squiers, Jr., Maine Department of Marine Resources (P618), to take listed shortnose sturgeon as authorized by the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217–222).

The applicant requested a five-year permit to capture, examine, tag, and take tissue samples of 500 adult listed shortnose sturgeon annually in Maine waters. 50 of these adult shortnose sturgeon may be fitted with a sonic transmitter and a Carlin tag. The applicant has requested authorization to capture and release 25 juvenile shortnose sturgeon, and to lethally take 200 eggs and 50 larvae. The applicant also has requested two incidental mortalities per year. The purpose of the research is to determine migratory movements and to help identify spawning, feeding, and overwintering areas.

Issuance of this permit, as required by the ESA, was based on a finding that such permit: (1) Was applied for in good faith, (2) will not operate to the disadvantage of the listed species that is the subject of this permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: October 29, 1996.

Robert C. Ziobro,

Acting Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–28198 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092596A]

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of issuance of modifications 1 and 2 to amendment 1 of permit 942.

SUMMARY: Notice is hereby given that NMFS issued modifications 1 and 2 to amendment 1 of Permit 942 to Jane Provancha of the Kennedy Space Center (P576), to take listed sea turtles subject to certain conditions set forth therein.

ADDRESSES: The applications, permits, and related documents are available for review by appointment in the following offices:

Office of Protected Resources, F/PR3, NMFS, 1315 East-West Hwy., Room 13307, Silver Spring, MD 20910–3226 (301–713–1401); and

Director, Southeast Region, NMFS, 9721 Executive Center Drive, St. Petersburg, FL 33702–2432 (813–893–3141).

Written comments, or requests for a public hearing on this application should be submitted to the Chief, Endangered Species Division, Office of Protected Resources.

SUPPLEMENTARY INFORMATION: On August 19, 1996, and September 23, 1996, NMFS issued modifications 1 and 2 to amendment 1 of Permit 942 to Jane Provancha of the Kennedy Space Center (P576) to take listed sea turtles as authorized by the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217–227). Permit 942 authorizes the capture of loggerhead and green sea turtles in Mosquito Lagoon, FL, to determine trends of population structure and distribution. Turtles are netted, examined, measured, photographed, triple tagged, lavaged, and have 10cc of blood taken. Modification 1 was issued to change the study area to include all waters of the Kennedy Space Center. Modification 2 was issued to change the net length limit from 91.4m to 250m. Issuance of these modifications to Permit 942, as required by the ESA, was based on a finding that such modifications: (1) Were applied for in good faith, (2) will not operate to the disadvantage of the listed species that are the subject of the modifications, and (3) are consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: October 29, 1996.

Robert C. Ziobro,

Acting Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–28200 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 102896A]

Marine Mammals; Permit No. 873 (P773#63)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Scientific research permit amendment.

SUMMARY: Notice is hereby given that a request for amendment of scientific research permit no. 873 submitted by the Southwest Fisheries Science Center, NMFS, P.O. Box 271, La Jolla, CA 92038–0271, has been granted.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Suite 13130, Silver Spring, MD 20910 (301/713–2289); and

Director, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802, (310/980–4016).

SUPPLEMENTARY INFORMATION: On September 20, 1996, notice was published in the Federal Register (61 FR 40439) that an amendment of permit no. 873, issued July 28, 1993 (58 FR 34038), had been requested by the above-named organization. The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the provisions of § 216.39 of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973 (ESA), as amended (16 U.S.C. 1531 *et seq.*), and the provisions of § 222.25 of the Regulations Governing the Taking, Importing, and Exporting of Endangered Fish and Wildlife (50 CFR part 222).

Permit no. 873 authorized the permit holder to biopsy several species of cetaceans off the Pacific, Southern, and Indian Oceans, and to import biopsy tissues collected outside of U.S. waters. The permit has been amended to: (1) Expand the location of the research activities on particular species to include the U.S. and international waters of the Gulf of Mexico; (2) increase the number of biopsy tissue sample takes from 20 to 50 for northern right whale dolphins (*Lissodelphis borealis*), pilot whales (*Globicephala spp.*), killer whales (*Orcinus orca*), harbor porpoise (*Phocoena phocoena*), Dall's porpoise (*Phocoenoides dalli*), and blue whales (*Balaenoptera musculus*) in the Pacific Ocean; and (3) increase the number of biopsy tissue sample takes for sperm whales (*Physeter macrocephalus*) from 20 to 200.

Issuance of this amendment, as required by the ESA, was based on a finding that such amendment: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which are the subject of this permit; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: October 25, 1996.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96–28199 Filed 11–1–96; 8:45 am]

BILLING CODE 3510–22–F

COMMISSION ON CIVIL RIGHTS

Notice of Cancellation of Public Meeting of the Arizona Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Arizona Advisory Committee to the Commission which was to have convened at 9:00 a.m. and adjourned at 3:00 p.m. on November 4, 1996, at the Hyatt Regency Phoenix, 122 North Second Street, Phoenix, Arizona, has been canceled.

The original notice for the meeting was announced in the Federal Register on October 28, 1996, FR Doc. 96–27595, 61 FR 55616.

Persons desiring additional information should contact Philip Montez, Director of the Western Regional Office, 213–894–3437 (TDD 213–894–3435).

Dated at Washington, DC, October 29, 1996.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 96–28230 Filed 10–30–96; 2:38 pm]

BILLING CODE 6335–01–P

Agenda and Notice of Public Meeting of the New York State Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the New York State Advisory Committee to the Commission will convene at 8:30 a.m. and adjourn at 5:00 p.m. on Thursday, November 21, 1996, at the Sheraton University Hotel and Conference Center, 801 University Avenue, Syracuse, NY 13210. The purpose of the meeting is to gather information on equal housing opportunities in Section 8 housing in Syracuse.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson M. D. Taracido, 212–645–8999, or Ki-Taek Chun, Director of the Eastern Regional Office, 202–376–7533 (TDD 202–376–8116). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, October 21, 1996.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 96–28152 Filed 11–1–96; 8:45 am]

BILLING CODE 6335–01–P

Hearing on Racial and Ethnic Tensions in American Communities: Poverty, Inequality, and Discrimination—Los Angeles

AGENCY: Commission on Civil Rights.

ACTION: Amended notice of hearing.

SUMMARY: Notice is hereby given pursuant to the provisions of the Civil Rights Commission Amendments Act of 1994, section 3, Pub. L. 103–419, 108 Stat. 4338, as amended, and 45 CFR section 702.3, that the public hearing on Racial and Ethnic Tensions in American Communities: Poverty, Inequality, and Discrimination-Los Angeles before a Subcommittee of the U.S. Commission on Civil Rights has been continued and relocated. The hearing will reconvene on Wednesday, November 13, 1996 beginning at 3:00 p.m., in the Stauffer Courtroom, Room 3483, UCLA School of Law, 405 Hilgard Avenue, Los Angeles, California 90024.

The purpose of the hearing remains the same as previously published in 61 FR 41125 (August 7, 1996).

Hearing impaired persons who will attend the hearing and require the services of a sign language interpreter, should contact Betty Edmiston, Administrative Services and Clearinghouse Division, at (202) 376–8105 (TDD (202) 376–8116), at least five (5) working days before the scheduled date of the hearing.

FOR FURTHER INFORMATION CONTACT: Barbara Brooks, Press and Communications (202) 376–8312.

Dated: October 31, 1996.

Miguel A. Sapp,

Attorney-Advisor.

[FR Doc. 96–28400 Filed 10–31–96; 12:59 pm]

BILLING CODE 6335–01–M

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 97–C0003]

In the matter of Four Seasons General Merchandise, Inc., a corporation; Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Provisional acceptance of a Settlement Agreement under the Consumer Product Safety Act.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Consumer Product Safety Act in the Federal Register in accordance with the terms of 16 CFR 1118.20 (e)–(h). Published below is a provisionally-accepted Settlement Agreement with Four Seasons General Merchandise, Inc., a corporation.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by November 19, 1996.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 97–C0003, Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Earl A. Gershenow, Trial Attorney, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0626.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: October 30, 1996.

Sadye E. Dunn,

Secretary.

[FR Doc. 96–28288 Filed 11–1–96; 8:45 am]

BILLING CODE 6355–01–M

[CPSC Docket No. 97–C0003]

Four Seasons General Merchandise, Inc. a corporation; Settlement Agreement and Order

1. Four Seasons General Merchandise, Inc. (hereinafter, ''Four Seasons''), a corporation, enters into this Settlement Agreement (hereinafter, ''Agreement'') with the staff of the Consumer Product Safety Commission, and agrees to the entry of the Order described herein. The purpose of the Agreement and Order is to settle the staffs allegations that Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, certain banned hazardous toys, baby rattles, pacifiers, water timers, and magic diamond and certain misbranded hazardous art materials and butane lighters, in violation of sections 4(a) and (c) of the Federal Hazardous Substances. Act (FHSA), 15 U.S.C. §§ 1263(a) and (c).

I. The Parties

2. The ''staff'' is the staff of the Consumer Product Safety Commission, an independent regulatory commission of the United States established pursuant to section 4 of the Consumer Product Safety Act (CPSA), 15 U.S.C. § 2053.

3. Four Seasons is a corporation organized and existing under the laws of the State of California, since 1995, with its principal corporate offices located at 2801 E. Vernon Avenue, Vernon, CA 90058. Four Seasons is engaged in the import, distribution, and re-export of a wide variety of consumer products. Approximately 5% of Four Seasons' business involves toys or other articles intended for children.

II. Allegations of the Staff

A. Toys With Small Parts

4. On five occasions between October 16, 1991, and January 11, 1995, Four Seasons introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, eight kinds of toys (96,530 units) intended for use by

children under three years of age. These toys are identified and described as follows:

Sample No.	Product	Collect date* Entry date	Expt./Mfg.	Quantity
P–867–7637	Toy Train	10/16/91	CSK World	24,336
P–867–7638	Toy Elephant	.....	.....	.....
P–867–7745	Telephone Money Box	01/22/92	Canada, Inc	20,304
P–867–7746	Boy/Girl Doll Set	01/22/92	CSK World Wide Ltd	18,864
R–867–8215	Hexagon Telephone	04/17/93	Lee Shing Fat Industries	2,400
R–867–8216	Hexagon Clock	04/17/93	Lee Shing Fat Industries	2,400
R–867–8217	Hexagon Speaker	04/17/93	Lee Shing Fat Industries	2,400
S–867–8220	Toy Train	04/16/94	Lee Shing Fat Industries	25,751
S–867–8221	Toy Elephant	.....	.....	.....
T–830–4906	Pull Along Wooden Snail	*01/11/95	Unknown	75

5. The toys identified in paragraph 4 above are subject to, but failed to comply with, the Commission's Small Parts Regulation, 16 CFR Part 1501, in that when tested under the ''use and abuse'' test methods specified in 16 CFR §§ 1500.51 and 1500.52, (a) one or more parts of each tested toy separated and (b) one or more of the separated parts from each of the toys fit completely within the small parts test cylinder, as set forth in 16 CFR § 1501.4.

6. Because the separated parts fit completely within the test cylinder as described in paragraph 5 above, each of the toys identified in paragraph 4 above presents a ''mechanical hazard'' within the meaning of section 2(s) of the FHSA, 15 U.S.C. § 1261(s) (choking, aspiration, and/or ingestion of small parts).

7. Each of the toys identified in paragraph 4 above is a ''hazardous substance'' pursuant to section 2(f)(1)(D) of the FHSA, 15 U.S.C. § 1261(f)(1)(D).

8. Each of the toys identified in paragraph 4 above is a ''banned hazardous substance'' pursuant to section 2(q)(1)(A) of the FHSA, 15 U.S.C. § 1261(q)(1)(A) and 16 CFR § 1500.18(a)(9) because it is intended for use by children under three years of age and bears or contains a hazardous substance; and because it presents a mechanical hazard as described in paragraph 6 above.

9. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid banned hazardous toys, identified in paragraph 5 above, in violation of sections 4 (a) and (c) of the FHSA, 15 U.S.C. §§ 1263 (a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

B. Baby Rattle

10. On one occasion in 1992, Four Seasons introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, one kind of baby rattle (14,400 units) intended for use by children. This baby rattle is identified and described as follows:

Sample No.	Product	Collect date* Entry date	Expt./Mfg.	Quantity
P–867–8580	Baby Rattle	08/16/92	Lee Shing Fat Industries	14,400

11. The baby rattle identified in paragraph 10 above is subject to, but failed to comply with, the Commission's Rattle Regulations, 16 CFR Part 1510, in that when tested under the procedures specified in 16 CFR § 1510.4, the handle of the baby rattle penetrated the full depth of the cavity of the test fixture.

12. Because the handle of the baby rattle identified in paragraph 10 above penetrated the full depth of the cavity of the test fixture as specified in 16 CFR § 1510.4 and described in paragraph 11 above, the baby rattle identified in paragraph 10 above presents a ''mechanical hazard'' within the meaning of section 2(s) of the FHSA, 15 U.S.C. § 1261(s) (choking).

13. The rattle identified in paragraph 10 above is a ''hazardous substance'' pursuant to section 2(f)(1)(D) of the FHSA, 15 U.S.C. § 1261(f)(1)(D).

14. The rattle identified in paragraph 10 above is a ''banned hazardous substance'' pursuant to section 2(q)(1)(A) of the FHSA, 15 U.S.C. § 1261(q)(1)(A) and 16 CFR § 1500.18(a)(15) because it is intended for use by children and bears and contains a hazardous substance; and because it presents a mechanical hazard as defined in paragraph 12 above.

15. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid banned hazardous baby rattle identified in paragraph 10 above, in violation of sections 4 (a) and (c) of the FHSA, 15 U.S.C. §§ 1263 (a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

C. Art Material

16. On one occasion in 1993, Four Seasons introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, one type of art material (41,520 units). This art material product is identified and described as follows:

Sample No.	Product	Collect date* Entry date	Expt./Mfg.	Quantity
R–867–8321	Multi-Colored Crayons	*06/07/93	CSK World Wide Ltd.	41,520

17. The art material product identified in paragraph 16 above is subject to, but failed to comply with the requirements for the Labeling of Art Materials Act in that (a) Four Seasons did not submit this art material product for review by a toxicologist as required by section 23(a) of the FHSA, 15 U.S.C. § 1277(a) and 16 CFR § 1500.14(b)(8)(C)(1); and (b) this art material product did not bear the statement of conformance with ASTM D–4236, as required by section 23(a) of the FHSA, 15 U.S.C. § 1277(a) and 16 CFR § 1500.14(b)(8)(C)(7).

18. The art material product identified in paragraph 16 above is a ''misbranded hazardous substance'' pursuant to section 3(b) of the FHSA, 15 U.S.C. § 1262(b) and 16 CFR §§ 1500.14(b)(8)(C) (1) and (7).

19. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid misbranded hazardous art material product identified in paragraph 16 above, in violation of sections 4 (a) and (c) of the FHSA, 15 U.S.C. §§ 1263 (a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

D. Pacifier

20. On one occasion in 1993, Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffer delivery thereof for pay or otherwise, one kind of pacifier (24 units) intended for use by children. The pacifier is identified and described below:

Sample No.	Product	Collect date* Entry date	Expt./Mfg.	Quantity
R–863–7316	Diplomat Pacifier	*07/30/93	Unknown	24

21. The pacifier identified in paragraph 20 above failed to comply with the Requirements For Pacifiers, 16 CFR Part 1511 (structural integrity of nipples, guard or shield requirements, and labeling requirements).

22. Because the pacifier identified in paragraph 20 failed to comply with the Requirements For Pacifiers, 16 CFR Part 1511, the pacifier presents a ''mechanical hazard'' within the meaning of section 2(s) of the FHSA, 15 U.S.C. § 1261(s) (choking).

23. The pacifier identified in paragraph 20 above is a ''hazardous substance'' pursuant to section 2(f)(1)(D) of the FHSA, 15 U.S.C. § 1261(f)(1)(D).

24. The pacifier identified in paragraph 20 above is a ''banned hazardous substance'' pursuant to section 2(q)(1)(A) of the FHSA, 15 U.S.C. § 1261(q)(1)(A) and 16 CFR 1500.18(a)(8) because it is intended for use by children and bears or contains a hazardous substance; and because it presents a mechanical hazard as described in paragraph 22 above.

25. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid banned hazardous pacifier, in violation of sections 4 (a) and (c) of the FHSA, 15 U.S.C. §§ 1263 (a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

E. Water Timers

26. On one occasion in 1995, Four Seasons introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, two kinds of water timers with adjacent tubes (384 units) intended for use by children. The tubes contain fluid of various colors. Within each tube there is an upper chamber from which fluid drops into a lower chamber that spins an internal wheel as the fluid drops. The water timers are identified and described as follows:

Sample No.	Product	Collect date* Entry date	Expt./Mfg.	Quantity
T–800–3386	Two Column Water Timer	*02/13/95	Unknown	240
T–800–3387	Three-Tube Water Timer	*02/13/95	Unknown	144

27. Because each tube of water timers identified in paragraph 26 above contains 10 percent or more by weight of ethylene glycol, each water timer is a ''hazardous substance'' pursuant to section 2(f)(1)(A)(i) of the FHSA, 15 U.S.C. § 1261(f)(1)(A)(i) and 16 CFR § 1500.14(a)(2).

28. Each of the water timers identified in paragraph 26 above is a ''banned hazardous substance'' pursuant to section 2(q)(1)(A) of the FHSA, 15 U.S.C. § 1261(q)(1)(A), because it is intended for use by children and bears or contains 10 percent or more by weight of ethylene glycol, a hazardous substance.

29. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid banned hazardous water timers, identified in paragraph 26 above, in violation of sections 4(a) and (c) of the FHSA, 15 U.S.C. §§ 1263(a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

F. Magic Diamond

30. On one occasion in 1995, Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the Magic Diamond (864 units) intended for use by children. The Magic Diamond is identified and described as follows:

Sample No.	Product	Collect date* Entry date	Expt/Mfg.	Quantity
T–867–8196	Magic Diamond	*03/09/95	Kab Trade	864

31. Because the Magic Diamond identified in paragraph 30 above is filled with 10 percent or more by weight of petroleum distillates, the Magic Diamond is a ''hazardous substance'' pursuant to section 2(f)(1)(A) (i) and (v) of the FHSA, 15 U.S.C. § 1261(f)(1)(A) (i) and (v) and 16 C.F.R. § 1500.14(a)(3).

32. The Magic Diamond identified in paragraph 30 above is a ''banned hazardous substance'' pursuant to section 2(q)(1)(A) of the FHSA, 15 U.S.C. § 1261(q)(1)(A) because it is intended for use by children and bears or contains 10 percent or more by weight of petroleum distillates, a hazardous substance.

33. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid banned hazardous Magic Diamond, identified in paragraph 30 above, in violation of sections 4(a) and (c) of the FHSA, 15 U.S.C. §§ 1263 (a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

G. Butane Lighter

34. On one occasion in 1995, Four Seasons introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, one kind of butane lighter (480 units). The butane lighter is identified and described as follows:

Sample No.	Product	Collect date* Entry date	Expt/Mfg.	Quantity
T–867–6231	Butane Utility Lighter	*04/06/95	Rubin's	480

35. The butane lighter identified in paragraph 34 above contains a flammable gas that generates pressure and is, therefore, a ''hazardous substance'' pursuant to sections 2(f)(1)(A)(v) and (vi) of the FHSA, 15 U.S.C. §§ 1261(f)(1)(A) (v) and (vi).

36. The butane lighter identified in paragraph 34 above is a ''misbranded hazardous substance'' pursuant to section 2(p)(1) of the FHSA, 15 U.S.C. § 1261(p)(1), because it is a hazardous substance intended, or packaged in a form suitable, for use in the household, and fails to bear on the front panel of the lighters and their packaging, as required by section 2(p)(1) of the FHSA, 15 U.S.C. § 1261(p)(1) and 16 CFR § 1500.130(b) the signal word, ''DANGER;'' the statement of hazards: ''EXTREMELY FLAMMABLE. CONTENTS UNDER PRESSURE;'' and the additional statements of the product and packaging: ''Do not use near sparks or flame,'' and ''Do not store at a temperature above 120 degrees F.''

37. Four Seasons knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the aforesaid misbranded hazardous butane lighter, identified in paragraph 34 above, in violation of sections 4 (a) and (c) of the FHSA, 15 U.S.C. § 1263 (a) and (c), for which a civil penalty may be imposed pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. § 1264(c)(1).

III. Response of Four Seasons

38. Four Seasons denies the allegations of the staff set forth in paragraphs 4 through 37 above that it has knowingly introduced or caused the introduction in interstate commerce; and received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise, the banned hazardous toys, baby rattle, pacifier, water timers, and magic diamond and the misbranded hazardous art material and butane lighter, in violation of the FHSA. Four Seasons states that (i) it has acted reasonably and in good faith to comply with the aforementioned regulations promulgated under the FHSA, (ii) the violations of those regulations were inadvertent, (iii) many of the violations involved differences of opinion as to appropriate age grading, (iv) it cooperated fully with the Commission's compliance actions, and (v) most of the products were detained at the port of entry and never sold or distributed after receipt in interstate commerce.

IV. Agreement of the Parties

39. The Consumer Product Safety Commission has jurisdiction over Four Seasons and the subject matter of this Settlement Agreement and Order under the Consumer Product Safety Act, 15 U.S.C. 2051 *et seq.*, and the Federal Hazardous Substances Act, 15 U.S.C. 1261 *et seq.*

40. Upon final acceptance by the Commission of this Settlement Agreement and Order, the Commission shall issue the attached Order incorporated herein by reference.

41. The Commission does not make any determination that Four Seasons knowingly violated the FHSA. The Commission and Four Seasons agree that this Agreement is entered into for the purposes of settlement only.

42. Upon final acceptance of this Settlement Agreement by the Commission and Issuance of the Final Order, Four Seasons knowingly, voluntarily, and completely waives any rights it may have in this matter (1) To an administrative or judicial hearing, (2) to judicial review or other challenge or contest of the validity of the Commission's actions; (3) to a determination by the Commission as to whether Four Seasons failed to comply with the FHSA as aforesaid, (4) to a statement of findings of fact and conclusions of law; and (5) to any claims under the Equal Access to Justice Act.

43. For purposes of section 6(b) of the FHSA, 15 U.S.C. § 2055(b), this matter shall be treated as if a complaint had issued; and the Commission may publicize the terms of the Settlement Agreement and Order.

44. Upon provisional acceptance of this Settlement Agreement and Order by the Commission, this Settlement Agreement and Order shall be placed on the public record and shall be published in the Federal Register in accordance with the procedures set forth in 16 CFR § 1118.20 (e)–(h). If the Commission does not receive any written request not to accept the Settlement Agreement and Order within 15 days, the Settlement Agreement and Order will be deemed to be finally accepted on the 16th day after the date it is published in the Federal Register.

45. The parties further agree that the Commission shall issue the attached Order; and that a violation of the Order shall subject Four Seasons to appropriate legal action.

46. Agreements, understandings, representations, or interpretations made outside this Settlement Agreement and Order may not be used to vary or contradict its terms.

47. The provisions of the Settlement Agreement and Order shall apply to Four Seasons and each of its successors and assigns.

Dated: September 19, 1996.

John Pourmoradi,

President, Four Seasons General Merchandise, Inc., 2801 E. Vernon Avenue, Vernon, CA 90058.

Commission Staff

David Schmeltzer,

Assistant Executive Director, Office of Compliance and Enforcement.

Eric L. Stone,

Acting Director, Division of Administrative Litigation, Office of Compliance and Enforcement.

Dated: September 25, 1996.

Earl A. Gershenow,

Trial Attorney, Division of Administrative Litigation, Office of Compliance and Enforcement.

Dated: September 25, 1996.

Dennis C. Kacoyanis,

Trial Attorney, Division of Administrative Litigation, Office of Compliance and Enforcement.

Consumer Product Safety Commission

Order

In the Matter of FOUR SEASONS GENERAL MERCHANDISE, INC. a corporation. [CPSC Docket No. 97–C0003].

Upon consideration of the Settlement Agreement entered into between respondent Four Seasons General Merchandise, Inc., a corporation, and the staff of the Consumer Product Safety Commission; and the Commission having jurisdiction over the subject matter and Four Seasons General Merchandise, Inc.; and it appearing that the Settlement Agreement and Order is in the public interest, it is

Ordered, That the Settlement Agreement and Order be and hereby is accepted, as indicated below; and is

Further Ordered, That upon final acceptance of the Settlement Agreement and Order, Four Seasons General Merchandise, Inc. shall pay to the Commission a civil penalty in the amount of ONE HUNDRED AND TEN THOUSAND AND 00/100 DOLLARS ($110,000.00) in four payments consisting of TWENTY-SEVEN THOUSAND FIVE HUNDRED AND 00/100 DOLLARS ($27,500.00) each. The first payment of TWENTY-SEVEN THOUSAND FIVE HUNDRED AND 00/100 DOLLARS ($27,500.00) shall be due within twenty (20) days after the service of the Final Order accepting the Settlement Agreement and Order (hereinafter the anniversary date). The second payment of TWENTY-SEVEN THOUSAND FIVE HUNDRED AND 00/100 DOLLARS ($27,500.00) shall be paid within one year of the anniversary date. The third payment of TWENTY-SEVEN THOUSAND FIVE HUNDRED AND 00/100 DOLLARS ($27,500.00) shall be paid within two years of the anniversary date. The fourth payment of TWENTY-SEVEN THOUSAND FIVE HUNDRED AND 00/100 DOLLARS ($27,500.00) shall be paid within three years of the anniversary date. Payment of the full amount of the civil penalty shall settle fully the staff's allegations set forth in paragraphs 4 through 37 of the Settlement Agreement and Order that Four Seasons General Merchandise, Inc. violated the FHSA. Upon failure of Four Seasons General Merchandise, Inc. to make payment or upon the making of a late payment by Four Seasons General Merchandise, Inc. (a) the entire amount of the civil penalty shall be due and payable, and (b) interest on the outstanding balance shall accrue and be paid at the federal legal rate under the provisions of 28 U.S.C. §§ 1961 (a) and (b).

Provisionally accepted and Provisional Order issued on the 30th day of October, 1996.

By Order of the Commission.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 96–28289 Filed 11–1–96; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Department of the Army

Army Science Board; Notice of Open Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 6 & 7 November 1996.

Time of Meeting: 0900–1600, (both days).

Place: Aberdeen Proving Ground, MD.

Agenda: The Army Science Board (ASB) Issue Group Study on ''Groundwater Treatment Systems (GWTS)'' will review the Army's remedial alternative selection decision process for GWTS, and visit a groundwater technology site. These meetings will be open to the public. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. For further information, please call Michelle Diaz at (703) 695–0781.

Michelle P. Diaz,

Program Support Specialist, Army Science Board.

[FR Doc. 96–28345 Filed 11–1–96; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Energy Information Administration

American Statistical Association Committee on Energy Statistics; Notice of Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: American Statistical Association's Committee on Energy Statistics, a utilized Federal Advisory Committee.

Date and Time: Thursday, November 7, 9:00 a.m.–4:15 p.m.; Friday, November 8, 9:00 a.m.–12:00 p.m.

Place: Holiday Inn-Capitol, 550 C Street, S.W., Washington, DC.

Contact: Ms. Renee Miller, EIA Committee Liaison, U.S. Department of Energy, Energy Information Administration, EI–72, Washington, DC 20585, Telephone: (202) 426–1117.

Purpose of Committee: To advise the Department of Energy, Energy Information Administration (EIA), on EIA technical statistical issues and to enable the EIA to benefit from the Committee's expertise concerning other energy statistical matters.

Tentative Agenda

Thursday, November 7, 1996

A. Opening Remarks
B. Major Topics
1. Restructuring the Electric Power Industry
2. Time Series for the Value of In-ground US Oil and Gas Reserves
3. Impact of Federal Tax Increase on State Gasoline Tax Revenues
(Public Comment)

Friday, November 8, 1996

4. Statistical Maps
5. Business Re-engineering Implementation: An Update and Performance Measures/Statistics
6. An Update for the Natural Gas Data Collection on Industrial Prices
(Public Comment)
C. Topics for Future Meetings

Public Participation: The meeting is open to the public. The Chairperson of the committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Written statements may be filed with the committee either before or after the meeting. If there are any questions, please contact Ms. Renee Miller, EIA Committee Liaison, at the address or telephone number listed above or Mrs. Antoinette Martin at (202) 426–1110. This notice is being published less than 15 days before the date of the meeting due to programmatic issues that had to be resolved prior to publication.

Transcripts: Available for public review and copying at the Public Reading Room, (Room 1E–290), 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–6025, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday.

Issued at Washington, DC on October 30, 1996.

Rachel M. Samuel,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96–28403 Filed 11–1–96; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. CP97–64–000]

ANR Pipeline Company; Notice of Application

October 29, 1996.

Take notice that on October 24, 1996, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP97–64–000 an application pursuant to Section 7(b) of the Natural Gas Act, for authority to abandon by transfer to ANR Field Services Company (ANR Field Services), its affiliate, certain gathering facilities located in the states of Kansas, Oklahoma, and Texas, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

ANR states that in Docket No. CP96–186–000, it had proposed to spindown certain facilities, mainly in its Southwest gathering area, to ANR Field Services. ANR also proposed to refunctionalize certain facilities as transmission and to retain such facilities as part of its system. ANR notes that in an order issued August 2, 1996,[1] the Commission approved the proposed spindown and approved in part, and denied, in part, the proposed refunctionalization. Since the Commission denied part of the refunctionalization request, certain facilities remain classified as gathering. Inasmuch as ANR seeks to terminate its gathering activities in the Southwest area, ANR proposes to abandon by transfer to ANR Field Services, all those facilities for which refunctionalization was denied in the August 2, 1996, order. Collectively, it is stated that the facilities proposed to be transferred include 161 miles of pipeline ranging in size from 2-inch to 12-inch together with meters and recording equipment at 113 locations. ANR states that the net book value of the facilities proposed to be abandoned as of December 31, 1995, was $2.4 million.

ANR states that it will file, as required, any notice of termination of the services pursuant to Section 4 of the Natural Gas Act upon receipt of the authorization requested herein. Upon transfer of facilities, ANR states it will provide service to ANR's then-existing customers who desire such service pursuant to either negotiated agreements or the default agreement which was approved, with certain modifications, in the August 2, 1996, order.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 5, 1996, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that approval for the proposed abandonment is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for ANR to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28174 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[1] 76 FERC ¶ 61,153 (1996).

[Docket No. RP97–43–000]

Koch Gateway Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

October 29, 1996.

Take notice that on October 24, 1996, Koch Gateway Pipeline Company (Koch) tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets, to become effective December 1, 1996.

Fifth Revised Volume No. 1
Fifteenth Revised Sheet No. 20
Fourteenth Revised Sheet No. 21
Fifteenth Revised Sheet No. 22
Ninth Revised Sheet No. 23
Fifteenth Revised Sheet No. 24

Koch states that the revised tariff sheets are being filed to revise its currently effective rates. Koch states that the proposed changes would increase revenues from jurisdictional service by $1,986,734 based on the 12-month period ending June 30, 1996, as adjusted. The rates are being adjusted to reflect the elimination of excess accumulated deferred income taxes and the corresponding amortization for Koch's rate base and cost of service.

Koch also states that copies of the filing are being served upon all its customers, State Commissions, and other interested parties.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's rules and regulations. All such motions or protests must be filed as provided by Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a part must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28179 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–185–017]

Northern Natural Gas Company; Notice of Compliance Filing

October 29, 1996.

Take notice that on October 25, 1996, Northern Natural Gas Company (Northern), tendered for filing to become part of Northern's FERC Gas Tariff, the tariff sheets listed on Exhibit A, to the filing.

On March 15, 1996, Northern filed a proposed Stipulation and Agreement of Settlement (Settlement) which would resolve all outstanding issues regarding Northern's rate case filing in Docket No.

RP95–185–000 et al. On July 31, 1996, the Commission issued an Order Approving Settlement Subject to Conditions (July 31 Order). On September 26, 1996, the Commission issued an Order Denying Rehearing, Accepting Tariff Sheets Subject to Conditions, and Granting Request for Clarification (September 26 Order). With the issuance of the September 26 Order, the Commission's approval of the Settlement became final and, therefore, the Settlement became effective.

Northern is filing to comply with the Settlement as approved by the Commission's July 31 and September 26 Orders. Such compliance includes two steps: (1) To reinstate the base tariff rates, services, and provisions in effect as on December 31, 1995; and (2) to refile the tariff sheets filed and accepted subsequent to January 1, 1996 to reflect the Settlement base tariff rates and provisions as approved in the Commission's July 31 and September 26 Orders. These two steps are reflected in the tariff sheets listed on Exhibit A to the filing.

Northern states that copies of the filing were served upon the company's customers and interested State Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken in this proceeding, but will not serve to make Protestant a party to the proceeding. Copies of this filing are on file with the Commission and are available for inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28177 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP97–44–000]

Pacific Gas Transmission Company; Notice of Motion for Limited Waiver of Tariff Provisions

October 29, 1996.

Take notice that on October 25, 1996, Pacific Gas Transmission Company (PGT) filed motion for limited waiver of provisions of its FERC Gas Tariff which provide for crediting of revenues received by shippers releasing capacity on PGT's system through a credit on the releasing shipper's monthly invoice.

PGT asserts that the purpose of this filing is to seek a limited waiver of Section 28.9 of its FERC Gas Tariff, First Revised Volume No. 1–A, which requires PGT to credit revenues received for released capacity to the releasing shipper through a credit on the releasing shipper's monthly invoice. PGT seeks this waiver in accordance with the Commission's October 21, 1996 Order in Docket No. CP96–544–000, in which Pacific Interstate Transmission Company (PITCO) was granted authority to receive revenue credits for released capacity on PGT in the form of a check directly to PITCO. The Commission directed PGT to request a waiver of its relevant tariff provisions to allow such a crediting procedure.

PGT states that a copy of this filing has been served upon its jurisdictional customers and upon interested state regulatory agencies.

Any person desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28180 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–271–007]

Transwestern Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

October 29, 1996.

Take notice that on October 25, 1996, Transwestern Pipeline Company (Transwestern) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets, with an effective date of November 1, 1996:

7th Revised Sheet No. 1
119th Revised Sheet No. 5
24th Revised Sheet No. 5A
16th Revised Sheet No. 5A.01
16th Revised Sheet No. 5A.02
16th Revised Sheet No. 5A.03
11th Revised Sheet No. 5A.04
20th Revised Sheet No. 5B
3rd Revised Sheet No. 5B.01
4th Revised Sheet No. 5B.02
Original Sheet No. 5B.03
3rd Revised Sheet No. 5C–5E(viii)
4th Revised Sheet No. 5M
1st Revised Sheet No. 5N
7th Revised Sheet No. 20
13th Revised Sheet No. 48
3rd Revised Sheet No. 83–91A
1st Revised Sheet No. 91B
1st Revised Sheet No. 91C
1st Revised Sheet No. 91D

Transwestern states that the purpose of this filing is to comply with a Federal Energy Regulatory Commission Letter Order issued on October 16, 1996. The Letter Order approved a Settlement filed by Transwestern in Docket Nos. RP95–271 and RP94–227 on May 21, 1996. The Settlement provides for an effective date of November 1, 1996.

Transwestern states that copies of the filing were served on its gas utility customers, interested state commissions, and all parties to this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28178 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER97–198–000]

Vermont Electric Power Company, Inc.; Notice of Filing

October 29, 1996.

Take notice that Vermont Electric Power Company, Inc. (VELCO) on October 16, 1996, tendered for filing a notice of cancellation, pursuant to 18 CFR 35.15, 31.53, of its Open Access Transmission Tariff (tariff) filed October 11, 1996 in Docket No. OA98–7–000.

VELCO requests waiver of the 60-day notice requirement to permit the cancellation to be effective on October 11, 1996, the date the tariff was filed.

VELCO states that it has served copies of this filing on each of the Vermont

distribution utilities served by VELCO, the Vermont Department of Public Service, the Vermont Public Service Board, all intervenors in Docket No. OA–23–000, and all eligible customers under the tariff that requested in writing a copy of the filing.

Any person desiring to be heard or to protest VELCO's notice of cancellation should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.W., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules and Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before November 8, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28172 Filed 11–4–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EL95–51–000, et al.]

Midwest Power Systems, Inc., et al. Electric Rate and Corporate Regulation Filings

October 29, 1996.

Take notice that the following filings have been made with the Commission:

1. Midwest Power Systems, Inc.

[Docket No. EL95–51–000]

Take notice that on October 25, 1996, Midwest Power Systems, Inc. tendered for filing a Petition for Enforcement petitioning the Federal Energy Regulatory Commission to initiate an enforcement action to enjoin the Iowa Utilities Board from implementing the final orders it issued pursuant to Iowa's Alternate Energy Production statue, Iowa Code §§ 476.41–45 (1995).

Comment date: November 13, 1996, in accordance with Standard Paragraph E at the end of this notice.

2. Acme Power Marketing, Inc. J. Aron & Company, Tennessee Power Company Wilson Power & Gas Smart, Inc., Audit Pro Incorporated, QST Energy Trading Inc. New England Ventures, Inc.

[Docket No. ER94–1530–010; ER95–34–009; ER95–581–006; ER95–751–007; ER95–878–006; ER96–553–004; ER96–1387–001 (not consolidated)]

Take notice that the following informational filings have been made with the Commission and are on file and available for inspection and copying in the Commission's Public Reference Room:

On October 11, 1996, Acme Power Marketing, Inc. filed, certain information as required by the Commission's October 18, 1994, order in Docket No. ER94–1530–000.

On October 16, 1996, J. Aron & Company filed, certain information as required by the Commission's March 1, 1995, order in Docket No. ER95–34–000.

On October 16, 1996, Tennessee Power Company filed, certain information as required by the Commission's April 28, 1995, order in Docket No. ER95–581–000.

On October 15, 1996, Wilson Power & Gas Smart, Inc. filed, certain information as required by the Commission's April 25, 1995, order in Docket No. ER95–751–000.

On October 15, 1996, Audit Pro Incorporated filed, certain information as required by the Commission's June 2, 1995, order in Docket No. ER95–878–000.

On October 15, 1996, QST Energy Trading Inc. filed, certain information as required by the Commission's March 14, 1996, order in Docket No. ER96–553–000.

On October 15, 1996, New England Ventures, Inc. filed, certain information as required by the Commission's September 6, 1996, order in Docket No. ER96–1387–000.

3. Central Maine Power Company

[Docket No. ER96–2862–000]

Take notice that on October 9, 1996, Central Maine Power Company tendered for filing an amendment in the above-referenced docket.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Atlantic City Electric Company

[Docket No. ER97–156–000]

Take notice that on October 17, 1996, Atlantic City Electric Company (ACE) tendered for filing an executed service agreement under which ACE will provide capacity and energy to Western Power Services, Inc. (Western), Virginia Power (Virginia Power) and Commonwealth Edison Company (ComEd) in accordance with the ACE wholesale power sales tariff.

ACE states that a copy of the filing has been served on Western, Virginia Power and ComEd.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. The Washington Water Power Company

[Docket No. TX97–2–000]

Take notice that on October 22, 1996, The Washington Water Power Company (WWP) filed with the Federal Energy Regulatory Commission an application requesting that the Commission order Puget Sound Power & Light Company (Puget) as a transmitting utility to provide transmission services pursuant to Section 211 et seq. of the Federal Power Act.

WWP is seeking transmission services from Puget to deliver wholesale electric power to Tosco Refining Company (Tosco) in Ferndale, Washington, pursuant to a contract between WWP and Tosco. Puget has declined to provide the service. The Service is proposed to commence on November 21, 1996 and terminate at 0000 hours, January 1, 2001, with a total capacity of up to 30 megawatts of firm transmission service.

Comment date: November 29, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Oklahoma Gas and Electric Company

[Docket No. ES97–3–000]

Take notice that on October 22, 1996, Oklahoma Gas and Electric Company filed an application, under § 204 of the Federal Power Act, seeking authorization to issue promissory notes and other evidences of indebtedness, including guarantees, from time to time, in an aggregate principal amount of not more than $400 million outstanding at any one time, during the period ending December 31, 1998, with a final maturity date no later than December 31, 1999.

Comment date: November 21, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Louisville Gas and Electric Company

[Docket No. ES97–4–000]

Take notice that on October 21, 1996, Louisville Gas and Electric Company filed an application, under § 204 of the Federal Power Act, seeking authorization to issue promissory notes and other evidences of indebtedness, including guarantees, from time to time,

in an aggregate principal amount of not more than $300 million outstanding at any one time, during the period ending December 31, 1998, with a final maturity date no later than December 31, 1999.

Comment date: November 20, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Kentucky Utilities Company

[Docket No. ES97–5–000]

Take notice that on October 23, 1996, Kentucky Utilities Company filed an application, under § 204 of the Federal Power Act, seeking authorization to issue short-term notes to banks and short-term notes in the form of commercial paper, from time to time, in an aggregate principal amount of not more than $150 million outstanding at any one time, during the period December 1, 1996 through November 30, 1998, with a final maturity date no later than December 31, 1998.

Comment date: November 21, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28212 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. ER97–179–000, et al.]

Public Service Company of Colorado, et al. Electric Rate and Corporate Regulation Filings

October 28, 1996.

Take notice that the following filings have been made with the Commission:

1. Public Service Company of Colorado

[Docket No. ER97–179–000]

Take notice that on October 22, 1996, Public Service Company of Colorado, tendered for filing a Service Agreement for Non-Firm Transmission Service between Public Service Company of Colorado and Questar Energy Trading. Public Service states that the purpose of this filing is to provide Non-Firm Transmission Service in accordance with its Open Access Transmission Service Tariff. Public Service requests that this filing be made effective August 6, 1996.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

2. Questar Energy Trading Company

[Docket No. ER97–180–000]

Take notice that on October 22, 1996, Questar Energy Trading Company (QET), tendered for filing a letter from the Executive Committee of the Western Systems Power Pool (WSPP) indicating that QET had completed all the steps for pool membership. QET requests that the Commission amend the WSPP Agreement to include it as a member.

QET requests an effective date of October 7, 1996 for the proposed amendment. Accordingly, QET requests waiver of the Commission's notice requirements for good cause shown.

Copies of the filing were served upon the WSPP Executive Committee.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. Oceanside Energy, Inc.

[Docket No. ER97–181–000]

Take notice that on October 22, 1996, Oceanside Energy, Inc. (O.E.), petitioned the Commission for acceptance of PES Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission regulations. O.E. is not affiliated with any entity which owns, operates, or controls electric power generating or transmission facilities, or that has a franchised electric power service area.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Great Bay Power Corporation

[Docket No. ER97–182–000]

Take notice that on October 21, 1996, Great Bay Power Corporation (Great Bay), tendered for filing two service agreements between Northeast Utilities Service Company and Great Bay and Montaup Electric Company and Great Bay for service under Great Bay's revised Tariff for Short Term Sales. This Tariff was accepted for filing by the Commission on May 17, 1996, in Docket No. ER96–726–000. The service agreement with Northeast Utilities Service Company is proposed to be effective October 18, 1996 and the service agreement with Montaup Electric Company is proposed to be effective October 17, 1996.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Northeast Utilities Service Company

[Docket No. ER97–183–000]

Take notice that on October 18, 1996, Northeast Utilities Service Company (NUSCO), tendered for filing a Service Agreement to provide Non-Firm Point-to-Point Transmission Service to Green Mountain Power Corporation under the NU System Companies Open Access Transmission Service Tariff No. 8.

NUSCO states that a copy of this filing has been mailed to Green Mountain Power Corporation.

NUSCO requests that the Service Agreement become effective September 10, 1996.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Portland General Electric Company

[Docket No. ER97–184–000]

Take notice that on October 18, 1996, Portland General Electric Company (PGE), tendered for filing under FERC Electric Tariff, First Revised Volume No. 2, an executed Service Agreement with Public Utility District No. 1 of Clallam County.

Pursuant to 18 CFR 35.11 and the Commission's order issued July 30, 1993 (Docket No. PL93–2–002), PGE respectfully requests the Commission grant a waiver of the notice requirements of 18 CFR 35.3 to allow the executed Service Agreement to become effective October 1, 1996.

A copy of this filing was caused to be served upon Public Utility District No. 1 of Clallam County as noted in the filing letter.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. PECO Energy Company

[Docket No. ER97–185–000]

Take notice that on October 21, 1996, PECO Energy Company (PECO), filed a Service Agreement dated October 16, 1996 with Boston Edison Company (BECO) under PECO's FERC Electric Tariff, First Revised Volume No. 4

(Tariff). The Service Agreement adds BECO as a customer under the Tariff.

PECO requests an effective date of October 16, 1996, for the Service Agreement.

PECO states that copies of this filing have been supplied to BECO and to the Pennsylvania Public Utility Commission.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Air Liquide America Corporation

[Docket No. QF96–102–000]

On October 21, 1996, Air Liquide America Corporation (Applicant), tendered for filing a supplement to its filing in this docket. No determination has been made that the submittal constitutes a complete filing.

The supplement provides additional information pertaining primarily to the technical data of the cogeneration facility.

Comment date: November 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28211 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–P

[Project No. 10805–002 Wisconsin]

Midwest Hydraulic Company, Inc.; Notice of Availability of Draft Environmental Assessment

October 29, 1996.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 F.R. 47897), the Office of Hydropower Licensing has reviewed the application for initial license for the Hatfield Hydroelectric project, located on the Black River, near Hatfield, in Jackson and Clark Counties, Wisconsin, and has prepared a Draft Environmental Assessment (DEA) for the project.

Copies of the DEA are available for review in the Public Reference Branch, Room 2–A, of the Commission's offices at 888 First Street, N.E., Washington, D.C. 20426.

Comments should be filed within 45 days from the date of this notice and should be addressed to Lois D. Cashell, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Room 1–A, Washington, D.C. 20426. Please reference Project No. 10805–002 to all comments. For further information, please contact Mary Golato at (202) 219–2804, or Ed Lee at (202) 219–2809.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28176 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP96–152–000]

Riverside Pipeline Company, L.P.; Notice of Technical Conference

October 29, 1996.

Take notice that on November 19, 1996, at 10:00 a.m., the Commission Staff will convene a technical conference in the above captioned docket at the offices of the Federal Energy Regulatory Commission, 888 1st Street NE, Washington, DC 20426. Any party, as defined in 18 CFR 385.102(c), any person seeking intervenor status pursuant to 18 CFR 385.214 and any participant, as defined in 18 CFR 385.102(b), is invited to attend.

The purpose of the conference is to discuss the resolution of issues as they pertain to the conditions of service in the rate schedules and general terms and conditions of Riverside's pro forma FERC Gas Tariff, Second Revised Volume No. 1, filed in this proceeding.

For further information, contact George Dornbusch (202) 208–0881, Office of Pipeline Regulation, Room 81–31.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28173 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG97–2–000]

Trunkline Gas Company; Notice of Filing

October 29, 1996.

Take notice that on October 15, 1996, Trunkline Gas Company (Trunkline) filed revised standards of conduct under Order Nos. 497 *et seq.*[1] and Order Nos. 566, *et seq.*[2] Trunkline states that it is revising its standards of conduct to reflect name changes of its marketing affiliates.

Trunkline states that copies of its filing are available for inspection at its offices and have been mailed to affected customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before November 13, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 96–28175 Filed 11–1–96; 8:45 am]

BILLING CODE 6717–01–M

[1] Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497–A, *order on rehearing,* 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. 30,868 (1989); Order No. 497–B, *order extending sunset date,* 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497–C, *order extending sunset date,* 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); Tenneco Gas v. FERC (affirmed in part and remanded in part), 969 F. 2d 1187 (D.C. Cir. 1992); Order No. 497–D, *order on remand and extending sunset date,* III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497–E, *order on rehearing and extending sunset date,* 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497–F, *order denying rehearing and granting clarification,* 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497–G, *order extending sunset date,* 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

[2] Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,997 (June 17, 1994); Order No. 566–A, *order on rehearing,* 59 FR 52896 (October 20, 1994), 69 FERC ¶ 61,044 (October 14, 1994); Order No. 566–B, *order on rehearing,* 59 FR 65707 (December 21, 1994); 69 FERC ¶ 61,334 (December 14, 1994).

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5646–4]

Notice of Approval of Prevention of Significant Air Quality Deterioration (PSD) and New Source Review (NSR) Permit to Mid-American Waste Systems, Inc. (NSR 4–4–10, SD 92–02)

AGENCY: Environmental Protection Agency (EPA), Region 9.

ACTION: Notice.

SUMMARY: Notice is hereby given that on October 18, 1996 the Environmental Protection Agency issued a prevention of significant deterioration/new source review (PSD/NSR) permit to the applicant named above. The PSD/NSR permit grants approval to Mid-American Waste Systems to construct and operate a solid waste landfill on the tribal lands of the Campo Band of Mission Indians.

FOR FURTHER INFORMATION CONTACT: Copies of the permit are available for public inspection upon request; address the request to: Steve Ringer (A–5–1), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1260.

SUPPLEMENTARY INFORMATION: The PSD/NSR permit requires the application of Lowest Achievable Emission Rate (LAER) for emissions of volatile organic compounds (VOCs), and Best Available Control Technology (BACT) for fine particulate matter (PM_{10}). The permit also requires Mid-American to provide emission offsets for all direct and fugitive emissions of VOCs. LAER requirements for this permit include construction of the landfill with low permeability composite liners, installation and maintenance of a landfill gas (LFG) collection system, and destruction of all collected LFG in a flaring system that will achieve a minimum VOC destruction removal efficieny (DRE) of 99.6% by weight.

BACT requirements for particulate emissions include paving, vacuum-sweeping, and watering of roads. In addition, the LFG flare is subject to certain emission limits, including allowable emission rates as follows: 0.06 lbs/mmBtu of NOx, 0.15 lbs/mmBtu of CO, and 0.005 lbs/mmBtu of PM_{10}.

The PSD/NSR permit is reviewable under Section 307(b)(1) of the Clean Air Act and 40 CFR 124.19(f)(1) in the Ninth Circuit Court of Appeals. A petition for review must be filed by January 3, 1996.

Dated: October 24, 1996.

David P. Howekamp,

Director, Air Division, Region 9.

[FR Doc. 96–28240 Filed 11–01–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5645–8]

National Environmental Justice Advisory Council, Notification of Meeting and Public Comment Period(s); Open Meeting

Pursuant to the Federal Advisory Committee Act (FACA), Public Law 92–463, notice is hereby given that the National Environmental Justice Advisory Council (NEJAC) along with the subcommittees will meet on the dates and times described below. All times noted are Eastern Standard Time. All meetings are open to the public. Due to limited space, seating at the NEJAC meeting will be on a first-come basis. Documents that are the subject of NEJAC reviews are normally available from the originating EPA office and are not available from the NEJAC. The meetings will occur at the Omni Inner Harbor Hotel, 101 W. Fayette Street, Baltimore, MD; phone number: (410) 752–1100.

The full NEJAC will convene on Tuesday, December 10 from 9:00 a.m. to 10:30 a.m. and from 6:45 p.m. to 9:00 p.m.; on Wednesday, December 11 from 1:00 p.m. to 6:00 p.m.; and on Thursday, December 12 from 9:30 a.m. to 5:00 p.m. to discuss EPA's Enforcement Roundtable, EPA's Reinvention Initiatives as they relate to environmental justice, follow-up on pending items from the May meeting, and several NEJAC new business interest items. In addition, the NEJAC will meet with EPA's Regional Environmental Justice Coordinators. There will be a 3 hour break in the NEJAC schedule on Tuesday, December 10 at 10:30 a.m. to conduct a bus tour of local environmental justice sites. A public comment period is scheduled from 7:00–9:00 p.m. on Tuesday, December 10 and from 1:00 p.m.–2:30 p.m. on Wednesday, December 11.

The six subcommittees will meet on Tuesday, December 10 from 2:00 p.m. to 6:00 p.m. and on Wednesday, December 11 from 9:00 a.m. to 12:45 p.m. Any member of the public wishing further information on the subcommittee meetings should contact the specific Designated Federal Official at the telephone number listed below.

Members of the public who wish to make a brief oral presentation should contact Tama Clare of PRC Environmental Management, Inc. no later than December 2, 1996 in order to have time reserved on the agenda. In general, each individual or group making an oral presentation will be limited to a total time of five minutes. Written comments of any length (at least 35 copies) should be received no later than December 2, comments received after that date will be provided to the Council as logistics allow. They should be sent to PRC Environmental Management, Inc., 1593 Spring Hill Road, Suite 300, Vienna, VA 22182. Telephone number is 703/287–8880 or FAX: 703/287–8843. Internet e-mail address is Claret@prcemi.com.

Subcommittee	Federal official and telephone number
Enforcement	Ms. Sherry Milan—202/564–2619.
Health & Research	Mr. Lawrence Martin—202/260–0673.
International	Ms. Lorry Frigerio—202/260–6623.
Indigenous Peoples	Ms. Elizabeth Bell—202/260–8106.
Public Participation	Mr. Robert Knox—202/564–2604.
Waste/Facility Siting	Mr. Kent Benjamin—202/260–2822

FOR FURTHER INFORMATION CONTACT: For hearing impaired individuals or non-English speaking attendees wishing to make arrangements for a sign language or foreign language interpreter, please call or fax Tama Clare of PRC Environmental Management, Inc. at Phone: 703/287–8880 or Fax: 703/287–8843.

Registration through the Internet at our World Wide Web home page can be done via the following address: http://www.prcemi.com/nejac.

Dated: October 28, 1996.

Clarice E. Gaylord,

Designated Federal Official, National Environmental Justice Advisory Council.

[FR Doc. 96–28241 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5645–6]

Ozone, Particulate Matter and Regional Haze Implementation Programs Subcommittee Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: On September 11, 1995 (60 FR 47172), the EPA announced the establishment of the Ozone, Particulate Matter and Regional Haze Implementation Programs Subcommittee under the Clean Air Act Advisory Committee (CAAAC). The CAAAC was established on November 8, 1990 (55 FR 46993) pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. app I). The purpose of the Subcommittee is to provide advice and recommendations on integrated approaches for implementing potentially new national ambient air quality standards (NAAQS) for ozone and particulate matter, as well as a regional haze program.

OPEN MEETING: Notice is hereby given that the Subcommittee for Development of Ozone, Particulate Matter and Regional Haze Implementation Programs will hold its next public meeting on Tuesday, November 19, 1996 (from 9:00 a.m. to 5:00 p.m.) and Wednesday, November 20, 1996 (from 8:00 a.m. to 4:00 p.m.).

ADDRESSES: The public meeting will be held at the Executive Tower, 1405 Curtis Street, Denver, Colorado 80202.

FOR FURTHER INFORMATION CONTACT: For further information on the Subcommittee for Development of Ozone, Particulate Matter and Regional Haze Implementation Programs, please contact Mr. William F. Hamilton, Designated Federal Officer, at 919–541-5498, or by mail at U.S. EPA, Office of Air Quality Planning and Standards, MD–12, Research Triangle Park, NC 27711. When a draft agenda is developed, a copy can be downloaded from the Ozone/Particulate Matter/ Regional Haze FACA Bulletin Board, which is located on the Office of Air Quality Planning and Standards Technology Transfer Network (OAQPS TTN) or by contacting Ms. Denise M. Gerth at 919–541-5550.

Dated: October 28, 1996.

John S. Seitz,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 96–28094 Filed 11–01–96; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5646–8]

PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of final document.

SUMMARY: This notice announces the availability of a final report titled, PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures (EPA/600/P–96/001F). The National Center for Environmental Assessment (NCEA) of the Office of Research and Development developed this report.

ADDRESSES: The document will be available on the Internet at http://www.epa.gov/ORD/WebPubs or for purchase from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; telephone 703–487–4650; facsimile 703–321–8547. The NTIS order number is PB97–104616. Copies will be available for inspection at the U.S. Environmental Protection Agency (EPA) headquarters and regional libraries and through the U.S. Government Depository Library program. The EPA Headquarters Library is located at 401 M Street, S.W., Washington, DC; the library is open Monday through Friday between 10:00 a.m. and 2:00 p.m., except for Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Jim Cogliano, National Center for Environmental Assessment/Washington Office (8602), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Telephone: 202–260–3830; facsimile: 202–260–3803; E-mail: cogliano.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The report updates the cancer dose-response assessment for polychlorinated biphenyls (PCBs) and shows how information on toxicity, disposition, and environmental processes can be considered together to evaluate health risks from PCB mixtures in the environment. Processes that chemically change PCB mixtures after release into the environment need to be considered in assessing the mixtures. Thus, guidance is given on applying a range of dose-response parameters to different exposure routes, partial lifetime exposure, and mixtures of varying composition. Intended to be brief, the document focuses on analysis and interpretation rather than a compilation of study results. The PCB report was reviewed at a public, external peer review workshop in May 1996. The review panel included experts on the carcinogenicity of PCBs from the private sector, academia, states, and other federal health agencies. This final report has been reviewed and approved by EPA's consensus review panel for inclusion on EPA's on-line Integrated Risk Information System (IRIS). A revised cancer information summary file, reflecting the quantitative and qualitative information in the final PCB report, has been loaded onto IRIS.

Dated: October 22, 1996.

Robert J. Huggett,

Assistant Administrator for Research and Development.

[FR Doc. 96–28242 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License, Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Computrex International Services, Inc., 10172 Linn Station Road, Suite 410, Louisville, KY 40223, Officers: Charles E. Harrett, President; Lisa M. Shawler, Vice President.

Advanced Shipping Agencies, Inc., 36 George Street, Bloomfield, NJ 07003, Officer: Thakor H. Bulsara, President.

Dated: October 29, 1996.

Joseph C. Polking,

Secretary.

[FR Doc. 96–28133 Filed 11–1–96; 8:45 am]

BILLING CODE 6730–01–M

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

''FEDERAL REGISTER'' CITATION OF PREVIOUS ANNOUNCEMENT: 61 FR 55000.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m.—November 6, 1996.

CHANGE IN THE MEETING: The time of the meeting has been changed to 2:00 p.m.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 96–28453 Filed 10–31–96; 3:49 pm]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 29, 1996.

A. Federal Reserve Bank of Boston (Robert M. Brady, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. UST Corp., Boston, Massachusetts; to acquire 100 percent of the voting shares and to merge with Walden Bancorp, Inc., Acton, Massachusetts, and thereby indirectly acquire The Co-operative Bank of Concord, Concord, Massachusetts, and Braintree Savings Bank, Braintree, Massachusetts.

B. Federal Reserve Bank of Cleveland (R. Chris Moore, Senior Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Provident Bancorp, Inc., Cincinnati, Ohio; to acquire 100 percent of the voting shares of South Hillsborough Community Bank, Apollo Beach, Florida.

C. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Pontiac Bancorp, Inc., Pontiac, Illinois; to acquire 100 percent of the voting shares of Bank of Dwight, Dwight, Illinois.

2. Two Rivers Bank Holding Company, Rock Valley, Iowa; to become a bank holding company by acquiring 100 percent of the voting shares of Rock Valley State Bank, Rock Valley, Iowa (in organization).

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. BOK Financial Corporation, Tulsa, Oklahoma; to acquire 100 percent of the voting shares of Park Cities Bancshares, Inc., Dallas, Texas, and thereby indirectly acquire Park Cities Corporation, Dallas, Texas; and First National Bank of Park Cities, N.A., Dallas, Texas.

2. Mancos Bancorporation, Mancos, Colorado; to merge with Southern Colorado Bank Holding Company, Pagosa Springs, Colorado, and thereby indirectly acquire Citizens Bank of Pagosa Springs, Pagosa Springs, Colorado.

Board of Governors of the Federal Reserve System, October 29, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–28131 Filed 11-1-96; 8:45 am]

BILLING CODE 6210-01-F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can ''reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices'' (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 18, 1996.

A. Federal Reserve Bank of Cleveland (R. Chris Moore, Senior Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Peoples Bancorp, Inc., Marietta, Ohio; to acquire Russell Federal Savings Bank, Russell, Kentucky, and thereby engage in operating as a savings association, pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, October 29, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96–28130 Filed 11-1-96; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL TRADE COMMISSION

[File No. 911–0008]

Montana Associated Physicians, Inc.; Billings Physician Hospital Alliance, Inc.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, two organizations of Billings, Montana physicians from negotiating or refusing to deal with third-party payers; determining the terms upon which physicians deal with such payers; or fixing the fees charged for any physicians's services. The agreement settles allegations that the respondents obstructed the entry of managed care plans into Billings, agreed on prices that they would accept from third-party payers, and otherwise acted to thwart cost-containment measures. According to the Commission, these actions resulted in higher prices and fewer health care choices for patients of Billings physicians.

DATES: Comments must be received on or before January 3, 1997.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Mark Whitener, Federal Trade Commission, H–374, 6th and Pennsylvania Ave, NW, Washington, DC 20582. (202) 326–2845. Robert F. Leibenluft, Federal Trade Commission, S–3115, 6th and Pennsylvania Ave, NW, Washington, DC 20582. (202) 326–2756.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the accompanying complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home page, on the World Wide Web, at ''http://www.ftc.gov/os/actions/htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has agreed to accept, subject to final approval, a proposed consent order settling charges that Montana Associated Physicians, Inc. (''MAPI'') and the Billings Physician Hospital Alliance, Inc. (''BPHA'') violated Section 5 of the Federal Trade Commission Act.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of either the proposed complaint or the proposed consent order, or to modify their terms in any way.

The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by MAPI or BPHA that the law has been violated as alleged in the complaint.

The Complaint

The complaint charges that MAPI restrained competition among physicians in the area of Billings, Montana, by, among other things, combining or conspiring with its respective physician members or acting as a combination of its physician members to fix the terms under which they would deal with third-party payers, and to conduct boycotts and other resistance to cost-containment efforts. The complaint further charges that MAPI was extensively involved in BPHA's formation, had the power to affect and control BPHA's dealings with third-party payers seeking contracts for physician services, and that BPHA carried on MAPI's anticompetitive conduct. The allegations set forth in the Commission's complaint are summarized below.

MAPI is an association of approximately 115 physicians in over 30 independent practices. These physicians constitute approximately 43% of all physicians in Billings, Montana. Most of the other physicians in Billings are part of a multispecialty physician group practice. MAPI's members constitute over 80 percent of all ''independent'' Billings physicians, that is, those who are not part of the multispecialty physician practice or employed by a hospital. Third-party payers seeking to contract with a Billings physician panel constituting a range of physician services must either contract with the multispecialty physician practice or with many MAPI members.

The complaint charges that MAPI was formed in 1987 in substantial part to be a vehicle for its members to deal collectively with managed care plans. At that time, there were no health maintenance organizations (HMOs) or preferred provider organizations (PPOs) operating in Billings, but physicians there were concerned that such plans would soon attempt to enter Billings, and that competitive pressure could force physicians to deal with such plans at reduced prices or on other than usual fee-for-service terms. The purpose of engaging in collective dealings through MAPI was to obtain greater bargaining power with third-party payers by presenting a united front, and thereby to resist competitive pressures to discount fees and to avoid accepting reimbursement on other than the traditional fee-for-service basis.

In 1987, MAPI began negotiating with third-party payers on behalf of its members. Members of MAPI who were approached by managed care plans told the plans to deal with MAPI. When HMO Montana, an HMO owned and operated by Blue Cross/Blue Shield of Montana, sought to contract with MAPI physicians, MAPI rejected all contracts proposed by the HMO. No member of MAPI entered into a contract with HMO Montana until 1993, after MAPI became aware of the Commission's investigation. When another health plan sought to establish the first PPO program in Billings, MAPI offered a contract to the health plan that provided

for physicians to be paid their usual fees with no discounts, and represented to the health plan that this was what MAPI's members would accept. When the health plan subsequently sought to collect current fee information from MAPI members in order to devise a proposed physician fee schedule, MAPI urged its members to submit prices higher than they were currently charging in order to inflate the fees the health plan developed for the schedule.

In addition, MAPI gathered detailed fee information from its members, enabling MAPI to determine for most physician services the prevailing fees and the maximum reimbursement allowed by Blue Cross/Blue Shield of Montana. Using this information, MAPI advised certain physicians to raise their fees, and some fees were raised in accordance with these recommendations.

In 1991, MAPI joined with Saint Vincent Hospital and Health Center in Billings to form BPHA, a physician-hospital organization. Almost all of MAPI's members joined BPHA, making MAPI members a substantial majority of BPHA's physician membership. BPHA's structure and governance gave MAPI substantial control over BPHA dealings with third-party payers regarding physician contracting, and thus allowed MAPI to continue to exercise the collective power of its physician members in BPHA's dealings with third-party payers seeking contracts.

Through BPHA's Physician Agreements, MAPI was designated as the agent of almost all BPHA physicians who were MAPI members with respect to their membership in BPHA. This agency designation gave MAPI the authority to accept or reject all contracts negotiated by BPHA with third-party payers, as well as the power to elect and remove physician members of BPHA's Board of Directors. In addition, BPHA's structure gave its physician members (most of whom were MAPI members) the ability to control BPHA's pricing and other terms of contracts for physician services.

By virtue of this structure, MAPI was able to carry on its unlawful activities through BPHA. Though payers sought to contract with BPHA for physician services, and did contract with Saint Vincent directly for hospital services, BPHA did not enter into any contract for physician services until nearly two years after its creation, after the time BPHA and MAPI became aware of the Commission's investigation.

Although MAPI and BPHA did not explicitly bar their members from dealing with managed care plans individually or on terms other than ones endorsed by MAPI or BPHA, these physicians largely dealt with such plans exclusively through MAPI and BPHA. Physician members and officials of MAPI and BPHA directed payers to deal with MAPI and BPHA rather than with individual physicians. Few physicians who were members of MAPI or BPHA participated in any managed care plans.

Neither the physician members of MAPI, nor the physician members of BPHA, have integrated their practices in any economically significant way, nor have they created efficiencies sufficient to justify their acts or practices described above.

The complaint charges that the conduct of MAPI and BPHA has injured consumers by restraining competition among physicians, fixing or increasing prices for physician services, and depriving third-party payers and patients of the benefits of competition among physicians.

The Proposed Consent Order

The proposed consent order would prohibit MAPI and BPHA from engaging in any agreement with physicians to (1) negotiate or refuse to deal with any third-party payer; (2) determine the terms upon which physicians deal with such payers; or (3) fix the fees charged for any physician's services. In addition, under Part III of the proposed consent order, MAPI is prohibited from: (1) advising physicians to raise, maintain, or otherwise adjust the fees charged for their medical services; (2) encouraging adherence to any fee schedule for physicians' services; and (3) encouraging any person to engage in any action prohibited by the order.

Notwithstanding these provisions, however, the proposed consent order would not prevent MAPI and BPHA from operating, or participating in, a legitimate joint venture. First, MAPI and BPHA respectively, if they are operating through a ''risk-sharing joint venture,'' may enter into agreements with physicians regarding terms of dealing with third-party payers, provided that the physicians participating in the venture remain free to deal individually with third-party payers. A ''risk-sharing joint venture,'' for purposes of this order, is one in which physicians who would otherwise be competitors share a substantial risk of loss from their participation in the venture.

The order's proviso permiting MAPI and BPHA to engage in joint dealing through ''risk-sharing joint ventures'' extends only to those that are ''non-exclusive,'' that is, those in which the participating physicians are available to contract with payers outside the venture. Although exclusive physician networks are not necessarily anticompetitive, they can impair competition, particularly when they include a large portion of the physicians in a market. Given the large share of the physicians in Billings that participated in MAPI and BPHA, along with evidence that as part of the challenged conduct these physicians largely refused to deal with managed care plans outside of MAPI or BPHA, the proviso does not permit exclusive risk-sharing ventures.

The proposed order allows MAPI and BPHA to operate or participate in joint ventures that involve collective price setting by competing physicians, even if those physicians do not share substantial financial risk as defined in the order, provided that they first receive the prior approval of the Commission. The order uses a prior approval provision because it is not feasible to define in an order all of the types of procompetitive joint ventures that MAPI or BPHA might seek to operate. The prior approval mechanism will allow the Commission to evaluate a specific proposal and assess its likely competitive impact. Allowing MAPI and BPHA the opportunity to seek prior approval of non-risk-sharing joint ventures will help to ensure that they are able to respond to dynamic changes in health care markets in ways that promote competition, while guarding against the recurrence of acts and practices that have restrained competition and consumer choice.

In addition, the proposed order contains a provision designed to make it clear that BPHA, as a physician-hospital organization, can take actions to facilitate contracting between its physician members and third-party payers that do not create or facilitate the kind of agreements that the order prohibits. The provision sets forth the aspects of a ''messenger model'' that would not run afoul of the order. The messenger model used here is remedial, and tailored to particular facts and circumstances.

The proposed order would also specifically permit BPHA to keep in effect contracts with third-party payers that were in effect on September 30, 1994, in order to avoid any disruption that might result from applying the order's prohibitions to those existing contractual arrangements.

Part V of the proposed order would require MAPI and BPHA to publish and distribute copies of the order and accompanying complaint. Parts VI and VII of the order impose certain reporting requirements in order to assist the Commission in monitoring compliance with the order.

The proposed consent order would terminate 20 years after the date it is issued.

Donald S. Clark,

Secretary.

Concurring Statement of Commissioner Mary L. Azcuenaga in Montana Associated Physicians, Inc.

[File No. 911–0008]

I concur in the decision to issue the complaint and accept the order for public comment and write separately to emphasize two points. First, the complaint and order do not directly challenge the organization and conduct of the Billings Physician Hospital Alliance, Inc., as a physician hospital organization (PHO), and in my view, this order should cast no shadow on the activities of PHO's. Second, although I concur in the unusual and complicated fencing-in relief in the particular circumstances of this case, in my view, this negotiated order is not, and should not be viewed as, a guide for what a PHO can and cannot do.

[FR Doc. 96–28277 Filed 11–1–96; 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION

Federal Acquisition Policy Division, FAR Secretariat Stocking Change of a Standard Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The General Services Administration/FAR Secretariat is changing the stocking of the following Standard form because of low user demand: SF 25B, Continuation Sheet for SF 24, 25, and 25A.

Since this form is now authorized for local reproduction, you can obtain the updated camera copy in two ways:

On the internet. Address: http://www.gsa.gov/forms, or;

From CARM, Attn.: Barbara Williams, (202) 501–0581.

FOR FURTHER INFORMATION CONTACT: FAR Secretariat, (202) 501–4755.

DATES: EFFECTIVE NOVEMBER 4, 1996.

Dated October 8, 1996.

Theodore D. Freed,

Standard and Optional Forms Management Officer.

[FR Doc. 96–28188 Filed 11–1–96; 8:45 am]

BILLING CODE 6820–34–M

Revision and Stocking Changes of Standard Forms

AGENCY: Public Building Service, General Services Administration.

ACTION: Notice.

SUMMARY: The General Services Administration is changing the stocking requirement of SF 118, Report of Excess Real Property, SF 118A, Buildings, Structures, Utilities, and Miscellaneous Facilities (Schedule A—Supplement to Report of Excess), SF 118B, Land (Schedule B—Supplement to Report of Excess Real Property) and SF 118C, Related Personal Property (Schedule C—Supplement to Report of Excess Real Property). These forms are revised to include metric measurements and authorized for local reproduction. Since these forms are authorized for local reproduction, you can obtain the updated camera copy in two ways.

On the Internet. Address: http://www.gsa.gov/forms, or;

From CARM, Attn.: Barbara Williams, (202) 501–0581.

FOR FURTHER INFORMATION CONTACT: Ronald Rice, (202) 501–0074. This contact is for information on completing the form only.

DATES: Effective November 4, 1996.

Dated: October 24, 1996.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 96–28166 Filed 11–1–96; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Detailed Case Data Component (DCDC) of the National Child Abuse and Neglect Data System.

OMB No.: 0980–0256.

Description: The Detailed Case Data Component of the National Child Abuse and Neglect Data System compiles automated case-level data on child maltreatment investigated by State child protective services agencies. Data are collected on reports of abuse and neglect, characteristics of victims, risk factors associated with victims and their families, and the development of polices and programs relating the child abuse and neglect at the National, State and local levels.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DCDC	56	1	110	6,160
Estimated Total Annual Burden Hours:				6,160

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Dated: October 28, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–28139 Filed 11–1–96; 8:45 am]

BILLING CODE 4184–01–M

Submission for OMB Review; Comment Request

Title: Federal Parent Locator Service.
OMB No.: 0970–0142.

Description: The Office of Child support Enforcement (OCSE) operates the Federal Parent Locator Services (FPLS), a computerized national location network which provides address and social security number information to State and local child support enforcement agencies upon request to locate parents in order to establish or enforce a child support order and to assist authorized persons in resolving parental kidnapping and child custody cases.

State and local agency requests to the FPLS can be made by tape, cartridge, electronic file transfer or by dialing-up using a personal computer. The FPLS serves as a conduit between child support enforcement offices and Federal and State agencies by conducting weekly, biweekly, or monthly matches of the collected information with various agencies and distributing the information back to the requesting State or local child support office.

Respondents: State, Local, Tribal or Federal Govt. Governments.

ANNUAL BURDEN ESTIMATE

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Standard Forms	200	24	1	4,800
Estimated Total Annual Burden Hours:				4,800

Explanation

*The specific number of annual burden hours per respondent will vary depending on individual circumstance including a States' frequency in submitting requests and their mode of submission.

*Burden hour for initial collection of information included in the submission are not considered as part of their day-to-day operation of the child support enforcement program.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork, Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: October 28, 1996.

Douglas J. Godesky,

Reports Clearance Officer.

[FR Doc. 96–28140 Filed 11–1–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96N–0298]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the voluntary collection of information for the Medical Devices Standards Activities Report, a comprehensive listing of current national and international standards for medical devices.

DATES: Submit written comments on the collection of information by January 3, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices Standards Activities Report (OMB Control Number 0910–0219—Extension)

FDA is collecting information necessary to update a comprehensive listing of current national and international standards activities in the field of medical devices. The collection of this information is authorized by section 514(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(4)(B)), which requires FDA to consult with other nationally or internationally recognized standard-setting entities, including other Federal agencies concerned with standard-setting, in carrying out its responsibility to establish special controls for medical devices. This report is used by approximately 39 standards-developing organizations to coordinate their standards activities. This coordination prevents duplication of effort and insures efficient and expeditious management of standards development. Over 700 copies of this report are used by government, hospitals, libraries, industry, private citizens, and State and local government agencies, including FDA, to keep abreast of standards development activities and current technology concerning the safety of medical devices. Without the report, there would be duplication of standards efforts by voluntary standards organizations since there is no other publication that can be easily referenced to ascertain if a certain medical device standard is being or has been developed.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
39	.5	19.5	3	58.5

There are no capital costs or operating and maintenance costs associated with this collection of information.

This collection occurs biennially and is voluntary. There are 39 national and international organizations with one report each reporting period.

Dated: October 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–28209 Filed 11–1–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93F–0273]

Lonza, Inc.; Withdrawal of Food Additive Petition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of August 12, 1996 (61 FR 41793). The document announced the withdrawal of a food additive petition (FAP 3B4392) proposing that the food additive regulations be amended to provide for the safe use of didecyldimethylammonium chloride as a slimicide used in the manufacture of paper and paperboard intended to contact food. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

In FR Doc. 96–20437, appearing on page 41793 in the Federal Register of Monday, August 12, 1996, the following correction is made: On page 41793, in the first column, in the first line, ''[Docket No. 93F–0269]'' is corrected to read ''[Docket No. 93F–0273]''.

Dated: October 16, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–28210 Filed 11–1–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. November 20, 1996, 10 a.m., and November 21, 1996, 8 a.m., Gaithersburg Hilton, Ballroom Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference FDA's Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sue Bae, KRA Corp., 301–495–1591, ext. 227. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed committee deliberations, November 20, 1996, 10 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12:30 p.m., unless public participation does not last that long; open committee discussion, 12:30 p.m. to 6 p.m.; open committee discussion, November 21, 1996, 8 a.m. to 1:30 p.m.; Jodi H. Nashman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Hotline, 1–800–

741–8138 (301–443–0572 in the Washington, DC area), Orthopedic and Rehabilitation Devices Panel, code 12521. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 8, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On the afternoon of November 20, 1996, and on the morning of November 21, 1996, the committee will discuss two separate premarket approval applications for sodium hyaluronates (also known as sodium hyaluronans and hyaluronic acid sodium salts) indicated for pain reduction and/or joint dysfunction in arthritic knees.

Closed committee deliberations. On November 20, 1996, FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 29, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96–28207 Filed 11–1–96; 8:45 am]
BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. November 19, 1996, 8 a.m., Gaithersburg Hilton, Ballroom Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Hilton. Attendees requiring overnight accommodations may contact the hotel at 301–977–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Gloria Williams, KRA Corp., 301–495–1591. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 12:30 p.m.; closed presentation of data, 12:30 p.m. to 1:30 p.m.; open committee discussion, 1:30 p.m. to 6 p.m.; Gail G. Gantt, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), General and Plastic Surgery Devices Panel, code 12519. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 8, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss general issues related to current breast biopsy devices. The committee will also discuss and vote on a premarket approval application (PMA) for a wound dressing for use in burns.

Closed presentation of data. The PMA sponsor may present to the committee trade secret and/or confidential commercial information regarding the wound dressing for burns. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. November 22, 1996, 8 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Hotel—Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301–590–0044, or 1–800–228–9290 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Alice Hall Hayes, KRA Corp., 301–495–1591, ext. 223. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed committee deliberations, 8 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m.; Michael G. Bazaral, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anesthesiology and Respiratory Therapy Devices Panel, code 12624. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 15, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. A petition has been received for reclassification of a nitric oxide administration system. The committee will discuss the reclassification from class III into class II of a system for nitric oxide administration. As part of the discussion, the committee will discuss three new devices: (1) A nitric oxide administration device; (2) a device to monitor nitric oxide gas concentration in the administration system during the administration of nitric oxide; and (3) a device to monitor nitrogen dioxide gas concentration in the administration system during the administration of nitric oxide.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial

information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 522b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 29, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–28208 Filed 11–1–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–137]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of*

Information Collection: Internal Revenue Service/Social Security Administration/Health Care Financing Administration Data Match 42 CFR 411; *Form No.*: HCFA–R–137; *Use:* Employers who are identified through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b). *Frequency:* Semi-annually; *Affected Public:* Individuals or Households, Business or other for profit, Not for profit institutions, Farms, Federal Government and State, Local or Tribal Government; *Number of Respondents:* 596,241; *Total Annual Responses:* 596,241; *Total Annual Hours Requested:* 2,325,449.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 25, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 96–28147 Filed 11–01–96; 8:45 am]

BILLING CODE 4120–03–P

[OACT–054–N]

RIN 0938–AHO8

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 1997 under Medicare's hospital insurance program (Medicare Part A). The Medicare statute specifies the formulae to be used to determine these amounts.

The inpatient hospital deductible will be $760. The daily coinsurance amounts will be: (a) $190 for the 61st through 90th days of hospitalization in a benefit period; (b) $380 for lifetime reserve days; and (c) $95 for the 21st through 100th days of extended care services in a skilled nursing facility in a benefit period.

EFFECTIVE DATE: This notice is effective on January 1, 1997.

FOR FURTHER INFORMATION CONTACT: John Wandishin, (410) 786–6389. For case-mix analysis only: Gregory J. Savord, (410) 786–6384.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish between September 1 and September 15 of each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year.

II. Computing the Inpatient Hospital Deductible for 1997

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act). This estimate is used for updating the payment rates to hospitals for discharges in the fiscal year that begins on October 1 of the same preceding calendar year and adjusted to reflect real case mix. The adjustment to reflect real case mix is determined on the basis of the most recent case mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

For fiscal year 1997, section 1886(b)(3)(B)(i)(XI) of the Act provides that the applicable percentage increase for hospitals in all areas is the market basket percentage increase minus 0.5 percent. Section 1886(b)(3)(B)(ii)(V) of the Act provides that, for fiscal year 1997, the otherwise applicable rate-of-increase percentages (the market basket percentage increase) for hospitals that are excluded from the prospective payment system are reduced by the lesser of 1 percentage point or the percentage point difference between 10 percent and the percentage by which the hospital's allowable operating costs of inpatient hospital services for cost reporting periods beginning in fiscal year 1990 exceeds the hospital's target amount. Hospitals or distinct part hospital units with fiscal year 1990 operating costs exceeding target amounts by 10 percent or more receive the market basket index percentage. The market basket percentage increases for fiscal year 1997 are 2.5 percent for prospective payment system hospitals and 2.5 percent for hospitals excluded from the prospective payment system, as announced in the Federal Register on August 30, 1996 (VOL. 61, No. 170 FR 46166). Therefore, the percentage increases for Medicare prospective payment rates are 2.0 percent for all hospitals. The average payment percentage increase for hospitals excluded from the prospective payment system is 1.96 percent. Thus, weighting these percentages in accordance with payment volume, our best estimate of the payment-weighted average of the increases in the payment rates for fiscal year 1997 is 2.0 percent.

To develop the adjustment for real case mix, an average case mix was first calculated for each hospital that reflects the relative costliness of that hospital's mix of cases compared to that of other hospitals. We then computed the increase in average case mix for hospitals paid under the Medicare prospective payment system in fiscal year 1996 compared to fiscal year 1995. (Hospitals excluded from the prospective payment system were excluded from this calculation since their payments are based on reasonable costs and are affected only by real increases in case mix.) We used bills from prospective payment hospitals received in HCFA as of July 1996. These bills represent a total of about 8.2 million discharges for fiscal year 1996 and provide the most recent case mix data available at this time. Based on these bills, the increase in average case mix in fiscal year 1996 is 1.1 percent. Based on past experience, we expect overall case mix to increase to 1.4

percent as the year progresses and more fiscal year 1996 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be increased only by that portion of the case mix increase that is determined to be real. We estimate that the increase in real case mix is about 1 percent. Since real case mix had been assumed to be increasing at about 1 percent per year in prior years, we expect this pattern to continue.

Thus, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 2.0 percent, and the real case mix adjustment factor for the deductible is 1 percent. Therefore, under the statutory formula, the inpatient hospital deductible for services furnished in calendar year 1997 is $760. This deductible amount is determined by multiplying $736 (the inpatient hospital deductible for 1996) by the payment rate increase of 1.02 multiplied by the increase in real case mix of 1.01 which equals $758.23 and is rounded to $760.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for 1997

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same calendar year. Thus, the increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in 1997, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th days of hospitalization in a benefit period will be $190 (¼ of the inpatient hospital deductible); the daily coinsurance for lifetime reserve days will be $380 (½ of the inpatient hospital deductible); and the daily coinsurance for the 21st through 100th days of extended care services in a skilled nursing facility in a benefit period will be $95 (⅛ of the inpatient hospital deductible).

IV. Cost to Beneficiaries

We estimate that in 1997 there will be about 9.2 million deductibles paid at $760 each, about 3.1 million days subject to coinsurance at $190 per day (for hospital days 61 through 90), about 1.4 million lifetime reserve days subject to coinsurance at $380 per day, and about 21.3 million extended care days subject to coinsurance at $95 per day. Similarly, we estimate that in 1996 there will be about 8.9 million deductibles paid at $736 each, about 3.0 million days subject to coinsurance at $184 per day (for hospital days 61 through 90), about 1.4 million lifetime reserve days subject to coinsurance at $368 per day, and about 20.8 million extended care days subject to coinsurance at $92 per day. Therefore, the estimated total increase in cost to beneficiaries is about $610 million (rounded to the nearest $10 million), due to (1) the increase in the deductible and coinsurance amounts and (2) the change in the number of deductibles and daily coinsurance amounts paid.

V. Waiver of Notice of Proposed Rulemaking

The Medicare statute, as discussed previously, requires publication of the Medicare Part A inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services for each calendar year. The amounts are determined according to the statute. As has been our custom, we use general notices, rather than formal notice and comment rulemaking procedures, to make such announcements. In doing so, we acknowledge that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formula used to calculate the inpatient hospital deductible and the hospital and extended care services coinsurance amounts is statutorily directed, and we can exercise no discretion in following that formula. Moreover, the statute establishes the time period for which the deductible and coinsurance amounts will apply and delaying publication of these amounts would be contrary to the public interest. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

VI. Impact Statement

This notice merely announces amounts required by legislation. This notice is not a proposed rule or a final rule issued after a proposal and does not alter any regulation or policy. Therefore, we have determined, and certify, that no analyses are required under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601 through 612), or section 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 1813(b)(2) of the Social Security Act (42 U.S.C. 1395e(b)(2)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 10, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: September 27, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–28142 Filed 11–1–96; 8:45 am]

BILLING CODE 4120–01–M

[OACT–053–N]

RIN 0938–AH45

Medicare Program; Part A Premium for 1997 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the hospital insurance premium for calendar year 1997 under Medicare's hospital insurance program (Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement. The monthly Medicare Part A premium for the 12 months beginning January 1, 1997 for these individuals is $311. The reduced premium for certain other individuals as described in this notice is $187. Section 1818(d) of the Social Security Act specifies the method to be used to determine these amounts.

EFFECTIVE DATE: This notice is effective on January 1, 1997.

FOR FURTHER INFORMATION CONTACT: John Wandishin, (410) 786–6389.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare hospital insurance program (Medicare Part A), subject to payment of a monthly premium, of certain persons who are age 65 and older, uninsured for social security or railroad retirement benefits and do not otherwise meet the requirements for entitlement to Medicare Part A. (Persons insured under the Social Security or Railroad

Retirement Acts need not pay premiums for hospital insurance.)

Section 1818(d) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services performed and for related administrative costs incurred in the following year with respect to individuals age 65 and over who will be entitled to benefits under Medicare Part A. We must then, during September of each year, determine the monthly actuarial rate (the per capita month estimated above divided by 12) and publish the dollar amount to be applicable for the monthly premium in the succeeding year. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1). The 1996 premium under this method was $289 and was effective January 1, 1996. (See 60 FR 53631, October 16, 1995.)

Section 1818(d)(2) of the Act requires us to determine and publish, during September of each calendar year, the amount of the monthly premium for the following calendar year for persons who voluntarily enroll in Medicare Part A.

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium, of certain disabled individuals who have exhausted other entitlement. These individuals are those not now entitled but who have been entitled under section 226(b) of the Act, continue to have the disabling impairment upon which their entitlement was based, and whose entitlement ended solely because they had earnings that exceeded the substantial gainful activity amount (as defined in section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the premium determined under section 1818(d)(2) of the Act for the aged will also apply to certain disabled individuals as described above.

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66, enacted on August 10, 1993) amended section 1818(d) of the Act to provide for a reduction in the monthly premium amount for certain voluntary enrollees. The reduction applies for individuals who are not eligible for social security or railroad retirement benefits but who:

- Had at least 30 quarters of coverage under title II of the Act;
- Were married and had been married for the previous 1-year period to an individual who had at least 30 quarters of coverage;
- Had been married to an individual for at least 1 year at the time of the individual's death and the individual had at least 30 quarters of coverage; or
- Are divorced from an individual who at the time of divorce had at least 30 quarters of coverage and the marriage lasted at least 10 years.

For calendar year 1997, section 1818(d)(4)(A) of the Act, specifies that the monthly premium that these individuals will pay for calendar year 1997 will be equal to the monthly premium for aged voluntary enrollees reduced by 40 percent.

II. Premium Amount for 1997

Under the authority of sections 1818(d)(2) and 1818A(d)(2) of the Act, the Secretary has determined that the monthly Medicare Part A hospital insurance premium for the uninsured aged and for certain disabled individuals who have exhausted other entitlement for the 12 months beginning January 1, 1997, is $311.

The monthly premium for those individuals entitled to a 40 percent reduction in the monthly premium for the 12-month period beginning January 1, 1997 is $187.

III. Statement of actuarial Assumptions and Bases Employed in Determining the Monthly Premium Rate

As discussed in section I of this notice, the monthly Medicare Part A premium for 1997 is equal to the estimated monthly actuarial rate for 1997 rounded to the nearest multiple of $1. The monthly actuarial rate is defined to be one-twelfth of the average per capita amount that the Secretary estimates will be paid from the Federal Hospital Insurance Trust Fund for services performed and related administrative costs incurred in 1997 for individuals age 65 and over who will be entitled to benefits under the hospital insurance program. Thus, the number of individuals age 65 and over who will be entitled to hospital insurance benefits and the costs incurred on behalf of these beneficiaries must be projected to determine the premium rate.

The principal steps involved in projecting the future costs of the hospital insurance program are (a) establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base; (b) projecting increases in payment amounts for each of the various service types; and (c) projecting increases in administrative costs. Establishing historical Medicare Part A enrollment and projecting future enrollment, by type of beneficiary, is part of this process.

We have completed all of the above steps, basing our projections for 1997 on (a) current historical data and (b) projection assumptions under current law from the Midsession Review of the President's Fiscal Year 1997 Budget. It is estimated that in calendar year 1997, 32.809 million people age 65 and over will be entitled to Medicare Part A benefits (without premium payment), and that these individuals will, in 1997, incur $122.621 billion of benefits for services performed and related administrative costs. Thus, the estimated monthly average per capita amount is $311.45 and the monthly premium is $311. The monthly premium for those individuals eligible to pay this premium reduced by 40 percent is $187.

IV. Costs to Beneficiaries

The 1997 Medicare Part A premium is about 8 percent higher than the $289 monthly premium amount for the 12-month period beginning January 1, 1996.

We estimate that there will be, in calendar year 1997, approximately 324,000 enrollees who will voluntarily enroll in Medicare Part A by paying the full premium and who do not otherwise meet the requirements for entitlement. An additional 9,000 enrollees will be paying the reduced premium. The estimated overall effect of the changes in the premium will be a cost to these voluntary enrollees of about $90 million.

V. Waiver of Notice of Proposed Rulemaking

The Medicare statute, as discussed previously, requires publication of the Medicare Part A hospital insurance premium for the upcoming calendar year during September of each year. The amounts are determined according to the statute. As has been our custom, we use general notices, rather than formal notice and comment rulemaking procedures, to make such announcements. In doing so, we acknowledge that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary because the formula used

to calculate the Part A hospital insurance premium is statutorily directed, and we can exercise no discretion in following that formula. Moreover, the statute established the time period for which the premium will apply and delaying publication of the premium amount would be contrary to the public interest. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

VI. Impact Statement

This notice merely announces amounts required by legislation. This notice is not a proposed rule or a final rule issued after a proposal, and it does not alter any regulation or policy. Therefore, we have determined and certify, that no analyses are required under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601 through 612), or section 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1818(d)(2) and 1818A(d)(2) of the Social Security Act (42 U.S.C. 1395i–2(d)(2) and 1395i–2a(d)(2)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 10, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: September 27, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–28141 Filed 11–1–96; 8:45 am]

BILLING CODE 4120–01–M

Health Resources and Services Administration

HIV Emergency Relief Grant Program

AGENCY: Health Resources and Services Administration.

ACTION: Notice of grants made to eligible metropolitan areas.

SUMMARY: (Note: On May 20, 1996, PL 104–146 reauthorized the Ryan White CARE Act of 1990. Because most of the new provisions found in Title XXVI of the Public Health Service Act did not become effective until October 1, 1996, most of the information in this notice will reflect the language of the original legislation.) The Health Resources and Services Administration (HRSA) announces that fiscal year 1996 funds have been awarded to the 49 eligible metropolitan areas (EMAs) that have been the most severely affected by the HIV epidemic. Although these funds have already been awarded to the EMAs, HRSA is publishing this notice to inform the general public of the existence of the funds. In addition, HRSA determined that it would be useful for the general public to be aware of the structure of the HIV Emergency Relief Grant Program and the statutory requirements governing the use of the funds.

The purposes of these funds are to deliver or enhance HIV-related (1) outpatient and ambulatory health and support services, including case management and comprehensive treatment services, for individuals and families with HIV disease; and (2) inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities. The HIV Emergency Relief Grant Program is authorized by Title I of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Public Law 101–381, as amended by the Ryan White CARE Act Amendments of 1996, Public Law 104–146, which amended Title XXVI of the Public Health Service Act. Funds were appropriated under Public Law 104–134.

FOR FURTHER INFORMATION, CONTACT: Individuals interested in the Title I HIV Emergency Relief Grant Program should contact the Office of the Chief Elected Official (CEO) in their locality, and may obtain information on their CEO contact by calling Anita Eichler, M.P.H., Director, Division of HIV Services, at (301) 443–6745.

SUPPLEMENTARY INFORMATION:

Availability of Funds

A total of $372,141,000 was made available for the Title I HIV Emergency Relief Grant Program. Because of the delay in the passage of fiscal year 1996 appropriations legislation for the Department of Health and Human Services and also because of the ''hold-harmless'' provisions of the the Ryan White CARE Act Amendments of 1996, the normal 50–50 split between formula and supplemental grants was affected. Below is a table showing the total award of grants made to the 49 EMAs.

Grantee	Award
Atlanta, GA	$9,208,162
Austin, TX	2,398,671
Baltimore, MD	8,364,074
Bergen-Passaic, NJ	3,369,095
Boston, MA	8,360,436
Caguas, PR	1,064,876
Chicago, IL	13,164,930
Cleveland, OH	1,384,956
Dallas, TX	7,820,653
Denver, CO	3,549,707
Detroit, MI	4,405,380
Dutchess County, NY	581,761
Ft. Lauderdale, FL	6,584,204
Ft. Worth, TX	2,255,398
Hartford, CT	3,048,467
Houston, TX	10,312,524
Jacksonville, FL	2,725,251
Jersey City, NJ	3,767,874
Kansas City, MO	2,514,291
Los Angeles, CA	26,313,561
Miami, FL	15,156,078
Middlesex-Somerset-Hunterdon, NJ	2,198,883
Minneapolis-St. Paul, MN	1,370,726
Nassau-Suffolk, NY	3,683,885
New Haven, CT	4,002,182
New Orleans, LA	2,087,199
New York, NY	92,241,697
Newark, NJ	9,725,848
Oakland, CA	4,741,595
Orange County, CA	3,492,993
Orlando, FL	3,599,489
Philadelphia, PA	10,345,478
Phoenix, AZ	2,901,602
Ponce, PR	1,685,036
Portland, OR	2,688,924
Riverside-San Bernardino, CA	4,687,432
Sacramento, CA	2,463,814
St. Louis, MO	2,587,364
San Antonio, TX	2,396,426
San Diego, CA	6,592,104
San Francisco, CA	35,172,274
San Jose, CA	2,275,044
San Juan, PR	8,199,506
Santa Rosa, CA	1,142,456
Seattle, WA	4,289,545
Tampa-St. Petersburg, FL	4,610,201
Vineland-Millville-Bridgeton, NJ	454,338
Washington, D.C.	12,763,696
West Palm Beach, FL	3,390,914

Eligible Grantees

Metropolitan areas which were eligible for grant awards under Title I were those areas for which, as of March 31, 1995, there had been reported to and confirmed by the CDC a cumulative total of more than 2,000 cases of AIDS; or, for which an award had been made prior to fiscal year 1996.

Grants were awarded to the chief elected official (CEO) of the city or urban county in each EMA that administers the public health agency providing outpatient and ambulatory services to the greatest number of individuals with AIDS.

To be eligible for assistance under Title I, the CEO was required to establish or designate an HIV health services planning council to: (1) Establish priorities for the allocation of funds within the eligible area; (2) develop a comprehensive plan for the organization and delivery of health services described in the statute that is

compatible with any State or local plan regarding the provision of health services to individuals with HIV disease; and (3) assess the efficiency of the administrative mechanism in rapidly allocating funds to the areas of greatest need within the eligible area. The planning council must include representatives of: health care providers; community-based and AIDS service organizations; social services providers; mental health services providers; local public health agencies; hospital planning agencies or health care planning agencies; affected communities, including individuals with HIV disease; non-elected community leaders; State government; and grantees receiving categorical grants for early intervention services under Title III of the CARE Act. The allocation of funds and services within the EMA must be made in accordance with the priorities established by the planning council.

To be eligible to receive a grant under Title I, the EMAs were required to submit an application containing such information as the Secretary required, including assurances adequate to ensure:

- That funds received would be utilized to supplement not supplant State funds provided for HIV-related services;
- That the political subdivisions within the EMA would maintain HIV-related expenditures at a level equal to that expended for the 1-year period preceding the first fiscal year for which the grant was received. Funds received under Title I may not be used in maintaining the required level of expenditures;
- That the EMA has an HIV health services planning council and has entered into intergovernmental agreements with any required political subdivisions and has developed or will develop a comprehensive plan for the organization and delivery of health services, in accordance with the legislation;
- That entities within the EMA that receive Title I funds will participate in an established HIV community-based continuum of care if such continuum exists within the EMA;
- That Title I funds will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity that provides health services on a prepaid basis; and
- To the maximum extent practicable, that HIV health care and support services provided with Title I assistance will be provided without regard to the current or past health condition of the individual. Such services will be provided in a setting that is accessible to low-income individuals with HIV disease, and a program of outreach will be provided to inform such individuals of such services.

General Use of Grant Funds

EMAs must use the Title I HIV Emergency Relief grants to provide financial assistance to public or nonprofit entities, for the purpose of delivering or enhancing o HIV-related outpatient and ambulatory health and support services, including case management and comprehensive treatment services, for individuals and families with HIV disease; and

- HIV-related inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities.

Services supported by the Title I grant funds must be accessible to low-income individuals and families, including women and children with HIV infection, minorities, the homeless, and persons affected by chemical dependency.

Federal Smoke-Free Compliance

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–277, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or, in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Executive Order 12372

Grants awarded for the Title I HIV Emergency Relief Grant Program are subject to the provisions of Executive Order 12372, as implemented under 45 CFR Part 100, which allows States the option of setting up a system for reviewing applications within their States for assistance under certain Federal programs. The application packages made available by HRSA to the EMAs contained a listing of States which have chosen to set up such a review system and provided a point of contact in the States for the review.

The catalog of Federal Domestic Assistance Numbers are: Formula Grants—93.915; Supplemental Grants—93.914.

Dated: October 29, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–28216 Filed 11–1–96; 8:45 am]

BILLING CODE 4160–15–P

HIV Care Grant Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grants made to States and territories.

SUMMARY: (Note: On May 20, 1996, PL 104–146 reauthorized the Ryan White CARE Act of 1990. Because most of the new provisions found in Title XXVI of the Public Health Service Act did not become effective until October 1, 1996, most of the information in this notice will reflect the language of the original legislation.) The Health Resources and Services Administration (HRSA) announces that fiscal year 1996 funds have been awarded to States and territories (hereinafter States) for the HIV Care Grant Program. Although these funds have already been awarded to the States, HRSA is publishing this notice to inform the general public of the existence of the funds. In addition, HRSA determined that it would be useful for the general public to be aware of the structure of the HIV Care Grant Program and the statutory requirements governing the use of the funds.

Funds will be used by the States to improve the quality, availability, and organization of health care and support services for individuals and families with HIV infection. The HIV Care Grant Program is authorized by Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Public Law 101–381, as amended by the Ryan White CARE Act amendments of 1996, Public Law 104–146, which amended Title XXVI of the Public Health Service Act. Funds were appropriated under Public Law 104–134.

FOR FURTHER INFORMATION, CONTACT: Individuals interested in the HIV Care Grant Program should contact the appropriate office in their State, and may obtain information on their State contact by calling Anita Eichler, M.P.H., Director, Division of HIV Services, at (301) 443–6745.

SUPPLEMENTARY INFORMATION:

Availability of Funds

A total of $198,406,000 was made available for the Title II HIV Care Grant Program. These funds have been allotted to the States according to a formula based on the number of AIDS cases reported to the Centers for Disease

Control and Prevention for the 24 months ending September 30, 1995, and a per capita income factor. In addition to the Care Grants, $51,999,164 was also awarded for the AIDS Drug Assistance Program (ADAP) to help States increase the number of HIV patients receiving drugs, including combination therapies and new drugs, and to help pay for their increasing costs. Below are two tables. The first shows the distribution of funds for the Care Grant Program by State. The second shows the distribution of funds for the ADAP by State.

CARE GRANT AWARDS

State	Amount
Alabama	$2,354,841
Alaska	250,000
Arizona	1,789,469
Arkansas	1,170,077
California	27,867,193
Colorado	1,980,699
Connecticut	2,790,149
Delaware	1,075,426
District of Columbia	2,532,524
Florida	19,716,843
Georgia	5,878,430
Hawaii	1,008,519
Idaho	250,000
Illinois	5,577,650
Indiana	2,359,737
Iowa	523,842
Kansas	867,817
Kentucky	1,148,862
Louisiana	3,306,569
Maine	458,566
Maryland	4,973,650
Massachusetts	3,776,077
Michigan	3,104,263
Minnesota	973,550
Mississippi	1,596,005
Missouri	2,504,335
Montana	110,969
Nebraska	432,455
Nevada	1,751,036
New Hampshire	265,234
New Jersey	10,181,949
New Mexico	753,940
New York	29,315,160
North Carolina	4,109,140
North Dakota	100,000
Ohio	3,885,870
Oklahoma	1,414,863
Oregon	1,330,006
Pennsylvania	6,391,896
Rhode Island	925,291
South Carolina	3,857,827
South Dakota	100,000
Tennessee	3,209,960
Texas	12,636,414
Utah	691,928
Vermont	250,000
Virginia	4,465,646
Washington	2,486,787
West Virginia	376,925
Wisconsin	1,571,609
Wyoming	100,000
Guam	4,970
Puerto Rico	7,682,087
Virgin Islands	168,945

AIDS DRUG ASSISTANCE PROGRAM AWARDS

State/territory	FY 1996 grant award
Alabama	$401,982
Alaska	38,443
Arizona	470,790
Arkansas	199,737
California	8,415,161
Colorado	528,455
Connecticut	861,629
Delaware	183,580
District of Columbia	800,064
Florida	5,503,506
Georgia	1,515,721
Hawaii	172,159
Idaho	35,657
Illinois	1,682,586
Indiana	402,818
Iowa	89,422
Kansas	183,023
Kentucky	196,116
Louisiana	773,878
Maine	78,279
Maryland	1,548,035
Massachusetts	1,059,974
Michigan	792,821
Minnesota	276,067
Mississippi	272,445
Missouri	626,791
Montana	18,943
Nebraska	73,822
Nevada	298,910
New Hampshire	66,858
New Jersey	2,953,162
New Mexico	128,701
New York	9,009,360
North Carolina	701,449
North Dakota	7,243
Ohio	782,236
Oklahoma	241,524
Oregon	354,625
Pennsylvania	1,599,571
Puerto Rico	1,685,094
Rhode Island	157,951
South Carolina	658,549
South Dakota	12,536
Tennessee	547,955
Texas	3,496,103
Utah	118,115
Vermont	29,529
Virginia	900,072
Washington	667,463
West Virginia	69,365
Wisconsin	268,824
Wyoming	13,650
Guam	0
Virgin Islands	28,415
Total	$51,999,164

Eligibility Criteria

In order to receive funding under Title II of the CARE Act, each State was required to develop:

- A detailed description of the HIV-related services provided in the State to individuals and families with HIV disease during the year preceding the year for which the grant was requested, and the number of individuals and families receiving such services; and
- A comprehensive plan for the organization and delivery of HIV health care and support services to be funded with the Title II grant, including a description of the purposes for which the State intends to use such assistance.

Each State was also required to submit an application containing such agreements, assurances, and information as the Secretary determined to be necessary to carry out this program, including an assurance that:

- The public health agency that is administering the grant for the State will conduct public hearings concerning the proposed use and distribution of the Title II grant assistance;
- The State will, to the maximum extent practicable, ensure that HIV-related health care and support services delivered with Title II assistance will be provided without regard to the current or past health condition of the individual; ensure that such services will be provided in a setting that is accessible to low-income individuals with HIV disease, and provide outreach to inform such individuals of the services available; and, in the case of a State that intends to use grant funds for the continuation of health insurance coverage, ensure that the State has established a program that assures that such amounts will be targeted to individuals who would not otherwise be able to afford health insurance coverage, that income, assets, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance, and that information concerning such criteria will be made available to the public;
- The State will provide for periodic independent peer review to assess the quality and appropriateness of health and support services provided by entities that receive Title II funds from the State;
- The State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under Title II;
- The State will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the State for the 1-year period preceding the fiscal year for which the State applied to receive a grant under Title II; and
- The State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service (1) under

any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity that provides health services on a prepaid basis.

General Use of Grant Funds

States may use the HIV Care Grant funds to:

- Establish and operate HIV care consortia within areas most affected by HIV. The statute defines a consortium as an association of one or more public, and one or more nonprofit private health care and support service providers and community-based organizations operating within areas determined by the State to be most affected by HIV disease.
- Provide home- and community-based care services for individuals with HIV disease. Funding priorities must be given to entities that provide assurances to the State that they will participate in HIV care consortia if such consortia exist within the State, and will utilize the funds for the provision of home- and community-based services to low-income individuals with HIV disease.
- Provide assistance to assure the continuity of health insurance coverage for low-income (as defined by the State) individuals with HIV disease. The State must establish a program that assures that (1) funds will be targeted to individuals who would not otherwise be able to afford health insurance coverage, and (2) income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance, and information concerning such criteria shall be made available to the public.
- Provide treatments that have been determined to prolong life or prevent serious deterioration of health for low-income individuals with HIV disease.

A State must use at least 15 percent of its grant funds to provide health and support services to infants, children, women and families with HIV disease.

At least 75 percent of the fiscal year 1996 Title II grant awarded to a State must be obligated to specific programs and projects and made available for expenditure within 120 days of the receipt of the grant by the State.

Federal Smoke-Free Compliance

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Executive Order 12372

It has been determined that the Title II HIV Care Grant Program is not subject to the provisions of Executive Order 12372 concerning inter-governmental review of Federal programs. The Catalog of Federal Domestic Assistance Number is 93.917.

Dated: October 29, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–28217 Filed 11–1–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Proposed Collection; Comment Request; Women's Health Initiative Observational Study

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which provides for an opportunity for public comment on proposed data collection projects, the Office of the Director (OD), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: Women's Health Initiative (WHI) Observational Study. Type of Information Collection Request: Revision OMB #0925–0414 Exp: 6/97 Need for Use of Information Collection: This study will be used by NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Frequency of Response: On occasion. Affected Public: Individuals and physicians. Type of Respondents: Women, next of kin, and physicians office staff. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual hours requested
OS Participants	100,000	1.06	.828	88,348
Next-of-Kin	2,682	1	.084	225
Physician's Office Staff	166	1	.084	14
Total	.....	.....	.....	88,614

The annualized cost burden is: $882,505.

The estimated annual Capital Costs, Operating Costs and/or Maintenance Costs is: $10,342,000.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

To request more information on the proposed project or to obtain a copy of the data collection plan and instruments, contact: Dr. Loretta

Finnegan, Women's Health Initiative Program Office, 7550 Rockville Pike, Room 6A09, Bethesda, Maryland 20892–9110 or call non-toll-free number (301) 402–2900, or E-mail your request, including your address to: <FinnegaL@od31em1.od.nih.gov>.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before January 3, 1997.

Dated: October 23, 1996.

Stephen Benowitz,

Executive Officer, OD.

[FR Doc. 96–28273 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for B-Cell Lymphoma Tumor Specific Antigen Studies

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company. A major goal of the CRADA is to develop strategies to isolate B-cell lymphoma tumor specific antigen. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and the timely commercialization of any products, diagnostics and treatments that result from the research.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Gary Cuchural, Office of Technology Development, National Cancer Institute-Frederick Cancer Research and Development Center, P.O. Box B, Frederick, MD 21702–1201, Telephone: (301) 846–5465, Facsimile: (301) 846–6820.

EFFECTIVE DATE: In view of the high interest in developing Anti-Cancer Vaccines in general, interested parties should notify the NCI Office of Technology Development in writing no later than December 4, 1996.

SUPPLEMENTARY INFORMATION: A major research goal of this CRADA is the development of strategies for the isolation of lymphoma derived Ig protein, including for example, the molecular cloning of Ig variable regions for expression in eukaryotic and prokaryotic cells. Another major research goal of this CRADA is the development and implementation of procedures for the GMP production of Ig protein. GMP Ig protein will be produced in sufficient quantities to support vaccine formulation studies. Vaccine formulation studies with one of several carriers, final vaccine production, and/or testing may also be among the research goals of this CRADA.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and clinical expertise and experience to the research project.
2. Planning and conducting research studies and interpreting research results.
3. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing intellectual, scientific, and regulatory expertise and experience to the research project.
2. Planning and conducting research studies and interpreting research results.
3. Providing support for CRADA-related research. Such support may include personnel and/or financial support to facilities scientific goals. Such support should include the availability of GMP manufacturing facilities for this effort, such support should also include assuming the cost of production of GMP Ig protein in sufficient quantities to support vaccine formulation studies. If vaccine formulation studies with one of several carriers, final vaccine production and/or testing are among the research goals of this CRADA, such support should also include assuming the cost of production of GMP vaccines in sufficient quantities to support these goals.
4. The experience and financial ability to support an IND.
5. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not to be limited to:

1. The ability to collaborate with NCI on research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.
2. The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
3. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
4. The demonstration of expertise in the commercial development, GMP production, marketing and sales of patient-specific products related to this area of technology.
5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.
6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.
8. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a non-exclusive license to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect and exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: October 24, 1996.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 96–28275 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development.

ADDRESSES: Licensing information and a copy of the U.S. patent applications referenced below may be obtained by

contacting Stephen Finley, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804 (telephone 301/496–7735, ext. 215; fax 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive a copy of the patent applications.

A Method for Imaging Nicotinic Acetylcholinergic Receptors in the Brain Using Radiolabeled Pyridyl 7-Azabicycloheptanes

ED London, AS Kimes, A Horti, RF Dannals, M Kassiou (NIDA) Serial No. 08/642,636 filed 06 May 96

The current invention embodies the use of radiolabeled analogs of epibatidine to noninvasively image and quantify levels of nicotinic acetylcholine receptors in a living mammalian brain, using Positron Emission Tomography or other nuclear medicine methods. As nicotinic acetylcholine receptors have been implicated in various neuropathological and physiological disorders, including Alzheimer's disease, the invention may represent a powerful new method for the noninvasive diagnosis of Alzheimer's disease and other disorders. In addition, the method embodied in the invention may prove valuable for use in monitoring the progression of various disorders and in determining the efficacy of drug therapy protocols used in the treatment of these disorders. (portfolio: Central Nervous System—Diagnostics, in vivo)

Identification of an Allelic Ser_{857}–Asn_{857} Variation of the Human Delayed Rectifier Potassium Channel DRK1 (KCNB1 locus)

D Goldman, AW Bergen, CM Mazzanti, S Michelini (NIAAA) Serial No. 60/020,348 filed 24 Jun 96

The DRK1 potassium channel is voltage sensitive such that as phosphorylation of the protein is increased the current is reduced, thereby increasing the cell's excitability. The amino- and carboxyl-terminal regions of DRK1 are located in the cytoplasm. A new, but naturally occurring substitution of the human delayed rectifier potassium channel DRK1 (KCNB1 locus) was mapped to chromosome 20q13.2. The nonconservative substitution occurs at position 857 in the carboxy terminal region of the protein. Transmembrane sequences of the rat and human DRK1 have been shown elsewhere to be identical, but have different pharmacological and conductance differences. The substitution of cytoplasmic serine to asparagine may effectively remove a possible phosphorylation site which could result in increased excitability of the cell or effect the function of the protein by altering the conformation, thereby accounting for the pharmacological and conductance changes. The DRK1 was mapped to the same locus as the dominantly inherited EEG trait difference, a low voltage alpha trait difference (20q13.3–13.3), but no correlation could be found between the substitution and the low voltage alpha trait. (portfolios: Central Nervous System—Therapeutics, psychotherapeutics; Central Nervous System—Diagnostics; Central Nervous System—Research Materials).

Dated: October 28, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 96–28274 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors Clinical Trials Review Working Group, November 25–26, 1996 at the Doubletree Hotel, Rockville, Maryland.

The meeting will be open to the public on November 25, 1996 from 8 am to 2 pm for discussions of methods to maximize the exchange of information and collaboration between laboratory and clinical scientists and between the pharmaceutical industry and NCI funded researchers, and on November 26 from 8 am to 8:30 am for introductory remarks and welcome.

The meeting will be closed to the public on November 25, 1996 from 2 pm to approximately 6 pm and on November 26 from 8:30 am to approximately 6 pm for discussion of confidential issues relating to the review, discussion and evaluation of individual programs and projects conducted by the Clinical Trials Extramural Program. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and personal information including consideration of personnel qualifications and performance, the competence of individual investigators and similar matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Information pertaining to the meeting may be obtained from Dr. John S. Cole, III, Executive Secretary, National Cancer Institute Clinical Trials Review Working Group, National Cancer Institute, 6130 Executive Blvd., EPN, Rm. 540, Bethesda, MD 20892 (301–496–1718).

Individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations should contact Dr. Cole in advance of the meeting.

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28266 Filed 11–1–96; 8:45 am]

BILLING CODE 4101–01–M

National Cancer Institute; Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Cancer Institute Frederick Cancer Research and Development Center Advisory Committee.

The open portion of the meeting will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person in advance of the meeting.

Committee Name: Frederick Cancer Research and Development Center Advisory Committee.

Date: December 17–18, 1996.

Place: Frederick Cancer Research and Development Center, Building 549, Executive Board Room.

Open: December 17—8:30 a.m.–11:00 a.m.

Agenda: Discussion of administrative matters such as future meetings, budget, and information items related to the operation of the NCI Frederick Cancer Research and Development Center.

Closed: December 17—11 a.m. to 5:00 p.m. December 18—8:30 a.m. to 5:00 p.m.

Agenda/Purpose: Discussion of previous site visit report and response for the Core Support Services with Science Applications International Corporation. The majority of the closed session will be devoted to a site review of the Molecular Virology and Carcinogenesis Laboratory under contract with ABL-Basic Research.

Contact Person: Cedric W. Long, Ph.D., Frederic Cancer Research and Development Center, P.O. Box B, Frederick, MD 21702, Telephone: 301–846–1108.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(2)(4) and 552b(c)(6), Title 5 U.S.C. The report and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the programs, disclosure of

which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28267 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Cancer Institute (NCI) Board of Scientific Advisors Prevention Program Review Working Group, December 17, 1996 at the Crystal Gateway Marriott, Arlington, VA.

The meeting will be closed to the public on December 17, 1996 from 8:30 AM to approximately 5:30 PM for discussion of confidential issues relating to review, discussion and evaluation of individual programs and projects conducted by the NCI Prevention Program. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and personal information including consideration of personnel qualifications and performance, the competence of individual investigators and similar matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Information pertaining to the meeting may be obtained from Dr. Jack Gruber, Executive Secretary, National Cancer Institute Prevention Program Review Working Group, National Cancer Institute, 6130 Executive Blvd., EPN, Rm. 540, Bethesda, MD 20892 (301–496–9740).

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28268 Filed 11–1–96; 8:45 am]

BILLING CODE 4101–01–M

National Cancer Institutes; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Cancer Institute Special Emphasis Panel (SEP):

Name of SEP: Community Clinical Oncology Program.

Date: December 16–18, 1996.

Time: December 16—7 pm; December 17–18—8 am.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ray Bramhall, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 643, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–3428.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of individual grant applications.

Name of SEP: Minority-Based Community Clinical Oncology Program.

Date: January 13–14, 1997.

Time: January 13—7 pm; January 14—8 am.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ray Bramhall, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 643, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–3428.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of individual grant applications.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28269 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Center for Human Genome Research; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following teleconference:

Agenda/Purpose: To review and evaluate grant applications and/or contract proposals.

Name of Committee: National Center for Human Genome Research Special Emphasis Panel 02.

Date: November 12, 1996.

Time: 12:00 pm.

Place: NIH, Building 38A, Room 609, 9000 Rockville Pike, Bethesda, Maryland.

Contact Person: Rudy Pozzatti, Ph.D., Office of Scientific Review, National Center for Human Genome Research, National Institutes of Health, Building 38A, Room 604, Bethesda, Maryland 20892, (301) 402–0838.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The applications and/or contract proposals, and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: October 29, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28263 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Heart Attack Alert Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute on Tuesday, December 10, 1996, from 8:30 a.m. to 1:00 p.m. at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland, 20814 (301) 897–9400.

The entire meeting is open to the public. The Coordinating Committee is meeting to define the priorities, activities, and needs of the participating groups in the National Heart Attack Alert Program. Attendance by the public will be limited to space available.

For detailed program information, agenda, list of participants, and meeting summary, contact: Ms. Mary Hand, Coordinator, National Heart Attack Alert Program, Office of Prevention, Education and Control; National heart, Lung, and Blood Institute; National Institutes of Health, Building 31, Room 4A–18, 31 Center Drive MSC 2480, Bethesda, Maryland 20892–2480 (301) 496–1051.

Dated: October 25, 1996.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96–28256 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of Meeting

Notice is hereby given of the meeting of the National High Blood Pressure Education Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute on Friday, November 22, 1996, from 8:30 a.m. to 1:00 p.m., at the Bethesda Mariott Hotel, 5151 Pooks Hill, Bethesda, Maryland 20814 (301) 987–9400.

The entire meeting is open to the public. The Coordinating Committee is meeting to define the priorities, activities, and needs of the participating groups in the National High Blood Pressure Education Program. Attendance by the public will be limited to space available.

For the detailed program information, agenda, list of participants, and meeting summary, contact: Dr. Edward J. Roccella, Coordinator, National High Blood Pressure Education Program, Office of Prevention, Education and Control, National Heart, Lung, and Blood Institute, National Institute of Health, 31 Center Drive MSC 2480, Bethesda, Maryland 20892, (301) 496–1051.

Dated: October 25, 1996.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96–28257 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Asthma Education and Prevention Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute on Monday, November 18, 1996, from 8:30 a.m. to 1:00 p.m. at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland, 20814 (301) 897–9400.

The entire meeting is open to the public. The Coordinating Committee is meeting to define the priorities, activities, and needs of the participating groups in the National Asthma Education and Prevention Program. Attendance by the public will be limited to space available.

For detailed program information, agenda, list of participants, and meeting summary, contact: Mr. Robinson Fulwood, Coordinator, National Asthma Education and Prevention Program, Office of Prevention, Education and Control; National Heart, Lung, and Blood Institute; National Institutes of Health, Building 31, Room 4A–03, 31 Center Drive MSC 2480, Bethesda, Maryland 20892, (301) 496–0554.

Dated: October 25, 1996.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96–28258 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute on Drug Abuse (NIDA) Initial Review Group meetings:

Purpose/Agenda: To evaluate and review grant applications.

Name of Committee: Health Services Research Subcommittee.

Date: November 13–14, 1996.

Time: 8:30 a.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Raquel Crider, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: Treatment Research Subcommittee.

Date: November 13–15, 1996.

Time: 8:30 a.m.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Kesinee Nimit, M.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: AIDS Biomedical and Clinical Research Subcommittee.

Date: November 19–20, 1996.

Time: 8:30 a.m.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Gamil Debbas, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–2620.

This notice is being published less than 15 days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Name of Committee: AIDS Behavioral Research Subcommittee.

Date: December 3–4, 1996.

Time: 8:30 a.m.

Place: Sheraton Washington Hotel, 2660 Woodley Road at Connecticut, N.W., Washington, DC 20000.

Contact Person: William C. Grace, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

The meetings will be closed in accordance with provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Scientist Development, Research Scientist Development, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health)

Dated: October 29, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28262 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Mental Retardation.

Date: November 25, 1996.

Time: 8:30 a.m.–5:00 p.m.

Place: 6100 Executive Boulevard, 6100 Building, Room 5E01, Rockville, Maryland 20852.

Contact Person: Hameed Kahn, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, 6100 Building, Room 5E01, Rockville, Maryland 20852, Telephone: 301–496–1485.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. [93.864, Population Research and No. 93.865, Research for Mothers and Children, National Institutes of Health])

Dated: October 29, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28264 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of General Medical Sciences, Special Emphasis Panel (SEP) meeting:

Committee Name: Special Emphasis Panel—Anesthesiology.

Date: November 14, 1996.

Time: 7:00 a.m.—adjournment.

Place: Penn Tower Hotel, Civic Center Blvd. at 34th Street, Philadelphia, PA 19104.

Contact Person: Irene A. Eckstrand, Ph.D., 45 Center Drive, Room 2AS–25P, Bethesda, MD 20892–6200, 301–594–0943.

Purpose: To review an Anesthesiology application.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences: 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS])

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28265 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following advisory committee meeting of the National Institute of General Medical Sciences:

Committee Name: MARC (Minority Access to Research Careers) Special Emphasis Panel.

Date: December 3, 1996.

Time: 9:30 a.m.—adjournment.

Place: Telephone Conference, 45 Center Drive, Bethesda, MD 20892–6200.

Contact Person: Richard I. Martinez, Ph.D., Scientific Review Administrator, NIGMS, 45 Center Drive, Room 1AS–19G, Bethesda, MD 20892–6200, 301–594–2849.

Purpose: To review cooperative agreement (U13) applications submitted in response to the RFA.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS])

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28271 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Preclinical Evaluation of Therapies for Cryptosporidium Parvum Infections.

Date: December 9, 1996.

Time: 8:30 a.m.

Place: Solar Bldg., Rm. 1A01, 6003 Executive Boulevard, Bethesda, MD 20892–7610, (301) 402–0747.

Contact Person: Dr. Sayeed Quraishi, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C22, Bethesda, MD 20892–7610, (301) 496–7465.

Purpose/Agenda: To evaluate contract proposals.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28272 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on December 9, 1996. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on December 9, 1996, at approximately 9 a.m., and will adjourn at approximately 5 p.m. The meeting will be open to the public to discuss Proposed Actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496) and other matters to be considered by the Committee. The Proposed Actions to be discussed will follow this notice of meeting. Attendance by the public will be limited to space available. Members of the public wishing to speak at this meeting may be given such opportunity at the discretion of the Chair.

Ms. Debra W. Knorr, Biotechnology Program Advisor, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone (301) 496–9838, FAX (301) 496–9839, will provide materials to be discussed at this meeting, roster of committee members, and substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Knorr in advance of the meeting. A summary of the meeting will be available at a later date.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs.

Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and

international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: October 28, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–28270 Filed 11–1–96; 8:45 am]

BILLING CODE 4140–01–M

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615–331–5300

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931 / 334–263–5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866 / 800–433–2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787 / 800–242–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–227–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414–355–4444 / 800–877–7016

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5784

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–549–8263 / 800–833–3984 (formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

CORNING Clinical Laboratories, 4771 Regent Blvd., Irving, TX 75063, 800–526–0947 (formerly: Damon Clinical Laboratories, Damon/MetPath)

CORNING Clinical Laboratories, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220–3610, 800–284–7515 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories)

CORNING Clinical Laboratories, 4444 Giddings Road, Auburn Hills, MI 48326, 800–444–0106 / 810–373–9120 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath)

CORNING Clinical Laboratories Inc., 1355 Mittel Blvd., Wood Dale, IL 60191, 630–595–3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)

CORNING Clinical Laboratories, South Central Divison, 2320 Schuetz Rd., St. Louis, MO 63146, 800–288–7293 (formerly: Metropolitan Reference Laboratories, Inc.)

CORNING Clinical Laboratory, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5000 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)

CORNING National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–1485 / 800–522–9235, (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science)

CORNING Clinical Laboratories, 7470–A Mission Valley Rd., San Diego, CA 92108–4406, 800–446–4728 / 619–686–3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT), CORNING Nichols Institute)

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652 / 417–269–3093 (formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P.O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045 / 847–688–4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941–418–4700 / 800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180 / 206–386–2672 (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267

Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784 / 915–563–3300 (formerly: Harrison & Associates Forensic Laboratories)

Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051

LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913–888–3927 / 800–728–4064 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Specialists, Inc., 113 Jarrell Dr., Belle Chasse, LA 70037, 504–392–7961

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave.,

Marshfield, WI 54449, 715–389–3734 / 800–331–3734
MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38118, 901–795–1515/800–526–6339
Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43614, 419–381–5213
Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302–655–5227
MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800–832–3244 / 612–636–7466
Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317–929–3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800–752–1835 / 309–671–5199
MetroLab-Legacy Laboratory Services, 235 N. Graham St., Portland, OR 97227, 503–413–4512, 800–237–7808(x4512)
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, Minnesota 55417, 612–725–2088
National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805–322–4250
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440–0972, 541–687–2134
Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400 / 800–541–7891
PharmChem Laboratories, Inc., 1505–A O'Brien Dr., Menlo Park, CA 94025, 415–328–6200 / 800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817–595–0294 (formerly: Harris Medical Laboratory)
Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–338–4070 / 800–821–3627
Poisonlab, Inc., 7272 Clairemont Mesa Blvd., San Diego, CA 92111, 619–279–2600 / 800–882–7272
Premier Analytical Laboratories, 15201 I–10 East, Suite 125, Channelview, TX 77530, 713–457–3784 / 800–888–4063 (formerly: Drug Labs of Texas)
Presbyterian Laboratory Services, 1851 East Third Street, Charlotte, NC 28204, 800–473–6640
Puckett Laboratory, 4200 Mamie St., Hattiesburgh, MS 39402, 601–264–3856 / 800–844–8378
Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804–378–9130
Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76504, 800–749–3788
S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505–244–8800 / 800–999–LABS
Sierra Nevada Laboratories, Inc., 888 Willow St., Reno, NV 89502, 702–334–3400
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91045, 818–877–2520 / 800–877–2520
SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 352–787–9006 (formerly: Doctors & Physicians Laboratory)
SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 847–447–4379 / 800–447–4379 (formerly: International Toxicology Laboratories)
SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800–523–0289 / 610–631–4600 (formerly: SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301 (formerly: SmithKline Bio-Science Laboratories)
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219–234–4176
Southwest Laboratories, 2727 W. Baseline Rd., Suite 6, Tempe, AZ 85283, 602–438–8507
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee St., Oklahoma City, OK 73102, 405–272–7052
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305–593–2260
TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818–226–4373 / 800–966–2211 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)
UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800–492–0800 / 818–996–7300 (formerly: MetWest-BPL Toxicology Laboratory)
UTMB Pathology-Toxicology Laboratory, University of Texas Medical Branch, Clinical Chemistry Division, 301 University Boulevard, Room 5.158, Old John Sealy, Galveston, Texas 77555–0551, 409–772–3197

The following laboratory withdrew from the National Laboratory Certification Program on October 24, 1996:

Laboratory Corporation of America, 21903 68th Ave. South, Kent, WA 98032, 206–395–4000 (Formerly: Regional Toxicology Services)

The following laboratory withdrew from the National Laboratory Certification Program on June 30, 1996:

Laboratory Corporation of America Holdings, 1120 Stateline Rd., Southaven, MS 38671, 601–342–1286 (Formerly: Roche Biomedical Laboratories, Inc.)

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 96–28276 Filed 11–1–96; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–020–06–5440–A137; AZA–29495]

Notice of Realty Action, Recreation and Public Purposes (R&PP) Act Classification and Conveyance; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Amendment to Sale of Public Land in Pima County.

SUMMARY: This document contains a modification to the notice published Tuesday, June 18, 1996 (FR Doc. 96–15378) on page 30916 in the **SUMMARY** section. The land description should be changed to read as follows:

Gila and Salt River Meridian, Arizona

T. 13 S., R. 5 W.,
Sec. 24, S½SW¼SW¼SW¼.

ADDRESSES: Phoenix Field Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027.

FOR FURTHER INFORMATION CONTACT: Bob Hale, Realty Specialist, at the address shown above or telephone at (602) 780–8090.

Dated: October 24, 1996.

G. L. Cheniae,

Field Manager, Phoenix Field Office.

[FR Doc. 96–28150 Filed 11–01–96; 8:45 am]

BILLING CODE 4310–32–P

[WY–989–1050–00–P]

Filing of Plats of Survey; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Wyoming State Office, Cheyenne, Wyoming, thirty (30) calendar days from the date of this publication.

Sixth Principal Meridian, Wyoming

T. 13 N., R. 104 W., accepted September 30, 1996
T. 50 N., R. 99 W., accepted September 30, 1996

If protests against a survey, as shown on any of the above plats, are received prior to the official filing, the filing will be stayed pending consideration of the protest(s) and or appeal(s). A plat will not be officially filed until after disposition of protest(s) and or appeal(s). These plats will be placed in the open files of the Wyoming State Office, Bureau of Land Management,

5353 Yellowstone Road, Cheyenne, Wyoming, and will be available to the public as a matter of information only. Copies of the plats will be made available upon request and prepayment of the reproduction fee of $1.10 per copy.

A person or party who wishes to protest a survey must file with the State Director, Bureau of Land Management, Cheyenne, Wyoming, a notice of protest prior to thirty (30) calendar days from the date of this publication. If the protest notice did not include a statement of reasons for the protest, the Protestant shall file such a statement with the State Director within thirty (30) calendar days after the notice of protest was filed.

The above-listed plats represent dependent resurveys, subdivision of sections.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, P.O. Box 1828, 5353 Yellowstone Road, Cheyenne, Wyoming 82003.

Dated: October 23, 1996.

John P. Lee,

Chief, Cadastral Survey Group.

[FR Doc. 96–28148 Filed 11–1–96; 8:45 am]

BILLING CODE 4310–22–M

Bureau of Reclamation

[INT–DES–96–46]

Draft Programmatic Environmental Impact Statement; Availability and Notice of Public Hearings

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability and notice of public hearings on the draft programmatic environmental impact statement; INT–DES–96–46.

SUMMARY: The Gila River Indian Community (Community) and the Bureau of Reclamation (Reclamation) have prepared a Draft Programmatic Environmental Impact Statement (PEIS) on the Pima-Maricopa Irrigation Project (Project) in compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, and other applicable environmental laws. The purpose of the draft PEIS is to assist in decisionmaking by the Commissioner of Reclamation regarding the approval of construction-related expenditures of funds authorized for the Central Arizona Project (CAP) to implement portions of the Project within the constraints of law. Any project that involves a major Federal action, such as Federal funding, permitting or approval, must comply with NEPA.

This draft PEIS describes four alternatives for rehabilitation of 66,000 acres and new development of 80,330 acres of irrigated agricultural lands. The proposed action is to rehabilitate San Carlos Indian Irrigation Project (SCIIP) facilities and build new facilities both on and off the Reservation. Ultimate project size would be 146,330 acres which will enable the Gila River Indian Community to better utilize water supplies and provide additional economic employment opportunities. A No Federal Action alternative is also described.

The Community is the Project proponent and is responsible for the preparation of this draft PEIS through a Self-Governance Agreement with Reclamation. Reclamation is responsible for disbursing CAP-related Federal funds and functions as the lead Federal agency for the Project. The Bureau of Indian Affairs (BIA) is a cooperating agency in this process because of its trust responsibility and administration of SCIIP.

DATES: A 60-day public review period begins with the publication of this notice. Written comments on the draft PEIS should be submitted to the Bureau of Reclamation.

Public hearings on the draft PEIS will be held on the following dates at the locations indicated.

- December 3, 1996, Sacaton, Arizona: Tribal Council Chambers, Corner of Pima and Main Street, Sacaton, AZ 85247, 7:00–9:00 p.m.
- December 4, 1996, Laveen, Arizona: District 6 Service Center, Corner of St. Johns Road and 51st Avenue, Laveen, AZ 85339, 7:00–9:00 p.m.
- December 5, 1996, Coolidge, Arizona: Coolidge Adult Center, 250 South 3rd Street, Coolidge, AZ 85228, 7:00–9:00 p.m.
- December 5, 1996, Phoenix, Arizona: Quality Inn—South Mountain, 5121 East La Puente Street, Phoenix AZ 85044, 1:00–3:00 p.m.

ADDRESSES: Written comments on the draft PEIS and requests for copies should be addressed to: Mr. Bruce D. Ellis (PXAO–1500), Bureau of Reclamation, PO Box 9980, Phoenix, AZ 85068. Copies may also be requested by telephone at (602) 870–6760.

Copies of the draft PEIS are available for inspection at the address above and also at the following locations:

- Office of the Commissioner, Bureau of Reclamation, Room 7612, 1849 C Street, NW., Washington DC 20240
- Reclamation Service Center, Bureau of Reclamation, Library, Room 167, Building 67, Denver Federal Center, Denver CO 80225
- Lower Colorado Regional Office, Bureau of Reclamation, Library, Room M117, Nevada Highway and Park Street, Boulder City NV 89005

Libraries

Arizona Department of Library Archives and Public Records, Phoenix AZ
Phoenix Public Library, Phoenix AZ
Chandler Public Library, Chandler AZ
Florence Public Library, Florence AZ
Coolidge Public Library, Coolidge AZ
Arizona Collection, Hayden Library, Arizona State University, Tempe AZ
University of Arizona, Main Library, Tucson AZ
Ms. Rebecca Burke, Government Document Service, Arizona State University, Tempe AZ
Ms. Holly Amegen, Tucson AZ

FOR FURTHER INFORMATION CONTACT: Mr. Bruce D. Ellis (PXAO–1500), Bureau of Reclamation, PO Box 9980, Phoenix, AZ 85068; telephone: (602) 870–6760.

SUPPLEMENTARY INFORMATION: The Gila River Indian Community (Community) proposes to construct a common-use irrigation system to deliver water to 146,330 acres within the Gila River Indian Reservation (Reservation) and to rehabilitate SCIIP Joint Works facilities. The Proposed Action, known as the Project, represents a component of the Community's Master Plan for Land and Water Use (Franzoy Corey, 1985). The Master Plan identifies the Community's major goals and preferences for improving and developing Reservation land and water resources.

The Project would support the continued role of agriculture as a primary element of the Community's traditional economy and way of life. The Project would enhance economic growth, development and self-sufficiency of the Community. The Project has the potential to significantly improve the standard of living for Community members.

The Community is the Project proponent and is responsible for the preparation of this draft PEIS through a Self-Governance Agreement with Reclamation. Reclamation is responsible for disbursing CAP-related Federal funds and functions as the lead Federal agency for the Project. The Bureau of Indian Affairs (BIA) is a cooperating agency in this process because of its trust responsibility and administration of SCIIP.

Hearing Process Information

The purpose of the hearings is to allow the public an opportunity to present their views and comments on the environmental impacts of the proposed project.

Those wishing to request time to make comments prior to the hearing dates should write or call the Bureau of Reclamation, Phoenix Area Office. The address and telephone number are listed on the previous page. Requests should be received on or before November 26, 1996, and should indicate at which session the speaker wishes to appear. Speakers will be called upon to present their comments in the order in which their requests were received by the Bureau of Reclamation. Requests to speak may also be made at each session, and speakers will be called after the advance requests. Oral comments will be limited to 5 minutes per individual.

Written comments, for inclusion in the hearing record, from those unable to attend the hearing or wanting to supplement their oral presentation should be received at the Bureau of Reclamation Phoenix Area Office by December 15, 1996.

Dated: October 23, 1996.

V. LeGrand Neilson,

Assistant Regional Director.

[FR Doc. 96–28229 Filed 11–1–96; 8:45 am]

BILLING CODE 4310–94–P

National Park Service

National Capital Area; Mary McLeod Bethune Council House National Historic Site Advisory Commission; Notice of Public Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Mary Mcleod Bethune Council House National Historic Site Advisory Commission will be held on November 8, 1996, at 11:00 a.m., at the National Park Service National Capital Area 1100 Ohio Drive, S.W., Washington, D.C. 20242.

The Commission was authorized on December 11, 1991, by Public Law 102–211, for the purpose of advising the Secretary of the Interior in the development of a General Management Plan for the Mary McLeod Bethune Council House National Historic Site.

The Member of the Commission are as follows: Dr. Dorothy I. Height; Ms. Barbara Van Blake; Ms. Brenda Girton-Mitchell; Dr. Savanna C. Jones; Dr. Bettye J. Gardner; Dr. Bettye Collier-Thomas; Mr. Eugene Morris; Dr. Rosalyn Terborg-Penn; Mrs. Bertha S. Waters; Dr. Frederick Stielow; Dr. Shelia Flemming; Dr. Ramona Edelin; Mrs. Romaine B. Thomas; Ms. Brandi Lynette Creighton; and Dr. Janette Hoston Harris.

The purpose of this meeting will be to discuss commission Bylaws, rules and regulations, and general business. The meeting will be open to the public. Any person may file with the commission a written statement concerning the matters to be discussed. Persons who wishing further information concerning this meeting or wish to file a written statement or testify at the meeting may contact Ms. Marta C. Kelly, the Federal Liaison Officer for the commission, at (202) 332–1233. Minutes of the meeting will be available for public inspection 4 weeks after the meeting at the Bethune Council House National Historic Site.

Dated: October 29, 1996.

Richard E. Powers,

Field Director, National Capital Area.

[FR Doc. 96–28280 Filed 11–01–96; 8:45 am]

BILLING CODE 4310–70–M

Subsistence Resource Commission Meeting

SUMMARY: The Superintendent of Cape Krusenstern National Monument and Kobuk Valley National Park and the Chairpersons of the Subsistence Resource Commissions for Cape Krusenstern National Monument and Kobuk Valley National Park announce a forthcoming joint meeting of the Cape Krusenstern National Monument and Kobuk Valley National Park Subsistence Resource Commissions.

The following agenda items will be discussed:

(1) Call to order and welcome by Chairs.

(2) Moment of silence.

(3) Roll call/confirmation of quorum.

(4) Membership status report.

(5) Introduction of guests.

(6) Review agenda.

(7) Approval of minutes from last meeting (August 18, 1993).

(8) Election of officers (Chair and Vice Chair).

(9) Superintendent's report: a. NPS Subsistence Issue Paper report.

(10) Agency and public comments.

(11) Old business: a. Review Secretarial response to hunting plan recommendations.

(12) New business: a. Hunting plan work session.

(13) Set time and place of next SRC meeting.

(14) Adjournment.

DATES: The meeting will be held Tuesday and Wednesday, November 12–13, 1996. The meeting will begin at 8 a.m. and conclude around 5 p.m. each day.

LOCATION: The meeting will be held at the Alaska Technical Center, Kotzebue, Alaska.

FOR FURTHER INFORMATION CONTACT: Dave Spirtes, Superintendent, Cape Krusenstern National Monument and Kobuk Valley National Park, P.O. Box 1029, Kotzebue, Alaska 99752. Phone (907) 442–3890.

SUPPLEMENTARY INFORMATION: The Subsistence Resource Commissions are authorized under Title VIII, Section 808, of the Alaska National Interest Lands Conservation Act, Pub. L. 96–487, and operate in accordance with the provisions of the Federal Advisory Committees Act.

Robert D. Barbee,

Field Director.

[FR Doc. 96–28279 Filed 11–01–96; 8:45 am]

BILLING CODE 4310–70–M

Fish and Wildlife Service

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

PRT–821343

Applicant: Wolf Timbers, Bolivar, Ohio (Martin J. Huth, President).

The applicant requests a permit to obtain two captive-bred wolf pups (*Canis lupus*) in interstate commerce. The applicant has applied for a permit to obtain and maintain these wolves and their progeny for the purpose of conservation education in support of recovery of the species. The proposed transaction is requested to occur between the States of Indiana and Ohio. The animals and their progeny would be maintained as a captive pack at the applicant's facility in Bolivar, Ohio.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Division of Ecological Service Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Division of Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/725–3536 x250); FAX: (612/725–3526).

Dated: October 22, 1996.

John A. Blankenship,

Assistant Regional Director, IL, IN, MO (Ecological Services), Region 3, Fort Snelling, Minnesota.

[FR Doc. 96–28204 Filed 11–1–96; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Water Act

In accordance with Departmental policy and 28 CFR 50.7, notice is hereby given that on October 11, 1996, two consent decrees in *United States* v. *City of Erie et al.*, Civil Action No. 94–281E were lodged with the United States District Court for the Western District of Pennsylvania.

These consent decrees settle claims brought pursuant to section 309 (b) and (d) of the Clean Water Act (the ''Act''), 33 U.S.C. 1319 (b) and (d), for civil penalties and injunctive relief for failure to comply with applicable pretreatment standards. The two consent decrees lodged with the Court on October 11, 1996 settle claims brought by the United States against Erie Coke Corporation and Presque Isle Plating. Under the first of these two Consent Decrees, Erie Coke Corporation has agreed to pay a civil penalty of $450,000 and to come into full compliance with all applicable pretreatment requirements pursuant to a compliance schedule contained in the decree. Under the terms of the second consent decree, Presque Isle Plating has agreed to pay a civil penalty of $20,000, based on its limited ability to pay, and to maintain full compliance with all applicable pretreatment requirements.

The Department of Justice will receive comments relating to the proposed consent decrees for a period of thirty days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *City of Erie et al.*, DOJ Ref. No. 90–5–1–1–5064. The proposed consent decrees may be examined at the office of the United States Attorney, Western District of Pennsylvania, 633 U.S. Post Office and Courthouse, 7th Avenue and Grant Street, Pittsburgh, Pennsylvania. Copies of the consent decrees may also be examined and obtained by mail at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005 (202–624–0892) and the offices of the Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. When requesting a copy by mail, please enclose a check in the amount of $6.50 for the Erie Coke Corporation agreement or $6.00 for the Presque Isle Plating agreement (twenty-five cents per page reproduction costs) payable to the ''Consent Decree Library.''

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–28155 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Lodging of Consent Decree Pursuant to the Clean Water Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on October 21, 1996, a proposed Consent Decree in *United States* v. *Jefferson County, Alabama, Jefferson County Commission and the State of Alabama*, Case No. 93–G–2492–S was lodged with the United States District Court for the Northern District of Alabama. The consent decree provides for extensive rehabilitation to the entire Jefferson County wastewater collection system and the County's ten wastewater treatment facilities. The consent decree also provides for the recovery of a $750,000 civil penalty against Jefferson County, Alabama and the Jefferson County Commission (hereinafter ''the County'') under Section 309 (b) and (d) of the Clean Water Act (''CWA'' or ''Act''), 33 U.S.C. 1319 (b) and (d).

In addition, the consent decree requires the County to perform a Supplemental Environmental Project (''SEP'') valued at $30 million. The SEP involves the acquisition of riparian properties or ''Greenways'' for the purpose of reducing or eliminating non-point source pollution into the Cahaba and Black Warrior River systems in Jefferson County and generally enhancing the water quality of those river systems. A secondary benefit of the SEP shall be to protect, restore, and enhance aquatic and stream corridor habitats of the river systems.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Jefferson County, Alabama, Jefferson County Commission and the State of Alabama*, D.J. Ref. 90–5–1–1–4195.

The proposed Consent Decree may be examined at the Office of the United States Attorney, Northern District of Alabama, 200 Robert S. Vance Federal Building and Courthouse, 1800 5th Avenue, North, Room 200, Birmingham, Alabama 35203–2198 and at Region 4, Office of the Environmental Protection Agency, 100 Alabama Street, SW., Atlanta, Georgia 30303, and at the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005. In requesting a copy, please enclose a check in the amount of $34.25 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Joel Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–28154 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Notice of Lodging of Consent Decree Pursuant to the Clean Air Act

Notice is hereby given that on August 29, 1996, a proposed Consent Decree was lodged with the United States District Court for the District of Alaska in *United States* v. *Ketchikan Pulp Company*, Civil Action No. A96 313 CIV. The proposed Consent Decree settles claims asserted by the United States at the request of the United States Environmental Protection Agency (''EPA'') in a complaint filed on the same day. The United States filed its complaint pursuant to Section 113 of the Clean Air Act (''CAA'' or ''Act''), 42 U.S.C. § 7413(b). The complaint requested the assessment of civil penalties against defendant Ketchikan Pulp Company (''KPC'') for the following: (1) violations of the CAA's prevention of significant deterioration (''PSD'') program as set forth in Part C of Title I, 42 U.S.C. § 7471 *et seq.*, and in the regulations promulgated thereunder, 40 CFR § 52.21; and (2) violations of a Compliance Order issued by EPA Region 10 under Section 113 of the CAA, 42 U.S.C. § 7413(a). The United States alleges that the violations occurred in connection with the construction and operation of equipment at KPC's Annette Hemlock Sawmill which is located on the Annette Island Indian Reservation in southeast Alaska.

Under the proposed Consent Decree, KPC will pay a civil penalty of $359,000 to the United States to resolve EPA's claims as set forth in the Complaint. In

addition, KPC maintains responsibility for complete compliance with all federal or state laws, regulations, and permits applicable to the Sawmill.

The Department of Justice will receive written comments relating to the proposed Consent Decree for thirty (30) days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, U.S. Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Ketchikan Pulp Company*, DOJ #90–5–2–1–1957. The proposed Consent Decree may be examined at the Region 10 Office of EPA, 7th Floor Records Center, 1200 Sixth Avenue, Seattle, WA 98101. A copy of the Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005 (202) 624–0892. In requesting copies, please enclose a check in the amount of $3.50 (25 cents per page copy cost) payable to the ''Consent Decree Library.''

Joel Gross,

Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–28153 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as Amended, and the Resource Conservation and Recovery Act

Consistent with Departmental policy, 28 CFR 50.7, 38 FR 19029, and 42 U.S.C. 9622(d), notice is hereby given that on October 21, 1996, a proposed consent decree in *United States* v. *LAR Labs, Inc. f/k/a Pfaltz & Bauer, Inc.*, Civil Action No. 396–CV–00305 PCD, was lodged with the United States District Court for the District of Connecticut. This proposed consent decree resolves the United States' claims under the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6909 *et seq.* and the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9601 *et seq.*, on behalf of the United States Environmental Protection Agency (''EPA'') against defendant LAR Labs, Inc. (''LAR''), formerly known as Pfaltz & Bauer, Inc., relating to LAR's former facility in Waterbury, Connecticut (''the Facility'').

Under the terms of the Consent Decree, LAR shall pay a total of $225,000, as follows: $94,000, or 100 percent, of EPA response costs incurred in overseeing response actions undertaken by LAR in response to an Administrative Order pursuant to Section 106 of CERCLA, 42 U.S.C. 9606, and $131,000 for civil penalties for violations of RCRA pursuant to Section 3008(g) of RCRA, 42 U.S.C. 6928(g). In addition, LAR shall undertake certain injunctive relief, including conducting an environmental audit at the Facility and providing hazardous waste management training for employees of the Facility.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *LAR Labs Inc., f/k/a Pfaltz & Bauer, Inc.*, Civil Action No. 396–CV–00305 PCD, DOJ Ref. Number 90–7–1–793.

The proposed consent decree may be examined at the Office of the United States Attorney, District of Connecticut, 915 Lafayette Boulevard, Bridgeport, Connecticut, 06604; at Region I, Office of the Environmental Protection Agency, One Congress Street, Boston, Massachusetts, 02203; and, at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005. In requesting a copy, please send a check (there is a 25 cent per page reproduction cost) in the amount of $6.15 payable to the Consent Decree Library.

Bruce S. Gelber,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–28157 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Notice of Lodging of Joint Stipulation Pursuant to the Clean Water Act

Consistent with Departmental policy, 28 CFR 50.7, notice is hereby given that a proposed joint stipulation in *United States v. Puerto Rico Aqueduct and Sewer Authority*, Civil Action No. 83–0105(cc), was lodged on October 7, 1996 with the United States District Court for the District of Puerto Rico. Defendant Puerto Rico Aqueduct and Sewer Authority (''PRASA'') is the owner and operator of sewage treatment plants throughout Puerto Rico. In operating thirty-one of these facilities, PRASA violated its National Pollutant Discharge Elimination System (''NPDES'') permits issued pursuant to the Clean Water Act.

Under the proposed joint stipulation, PRASA commits to a study to determine which of the thirty-one wastewater plants still subject to the 1985 Order will require advanced wastewater treatment (''AWT'') in order to achieve compliance with final NPDES permit limitations and for those plants so requiring AWT, a compliance schedule for construction of facilities. In addition, PRASA will pay the United States $375,000 in penalties, thus resolving all outstanding United States claims for stipulated penalties for PRASA's violations of the 1985 Order up through March 1996. PRASA also agrees to remain in compliance with the Clean Water Act and is subject to stipulated penalties for any violations of the proposed joint stipulation.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed joint stipulation. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States v. Puerto Rico Aqueduct and Sewer Authority*, D.J. reference #90–5–1–1–1793.

The proposed joint stipulation may be examined at the Office of the United States Attorney for the District of Puerto Rico, Federal Office Building, Carlos E. Chardon Avenue, Hato Rey, Puerto Rico; the Region II Office of the Environmental Protection Agency, 290 Broadway Avenue, New York, New York; and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005, (202) 624–0892. A copy of the proposed joint stipulation may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. In requesting a copy, please enclose a check in the amount of $3.75 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environment Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96–28156 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Bell Communications Research, Inc.

Notice is hereby given that, on August 23, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Bell Communications Research, Inc. (''Bellcore'') has filed written notifications on behalf of Bellcore; Lucent Technologies, Inc. (''Lucent''); Rockwell International Corporation (''Rockwell''); Southwestern Bell Technology Resources, Inc. (''TRI''); Tektronix, Inc. (''Tektronix''); and Washington University in St. Louis (''WUSTL'') simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are Bellcore, Morristown, NJ; Lucent, Breinigsville, PA; Rockwell, Newbury Park, CA; TRI, Austin, TX; Tektronix, Beaverton, OR; and WUSTL, St. Louis, MO.

Bellcore, Rockwell, TRI, Tektronix, and WUSTL enter into Articles of Collaboration with AT&T effective April 7, 1994, establishing a consortium to engage in a collaborative research effort of limited duration in order to gain further knowledge and understanding in the area of SONET/ATM self-healing ring technology and to better understand the applications of such technology for telecommunications networks, particularly exchange and exchange access service networks. On June 24, 1996, as a result of the restructuring of AT&T, Lucent replaced and assumed the rights and responsibilities of AT&T as a member of the consortium. The nature and objectives of the consortium remain unchanged.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–28160 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Corporation for National Research Initiatives—Cross Industry Working Team Project

Notice is hereby given that, on July 31, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Corporation for National Research Initiatives (''CNRI'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in the membership of the Cross Industry Working Team Project (''XIWT''). The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the following additional parties have become Primary Members of XIWT: Corning, Inc., Corning, NY; Lucent Technologies, Inc., Warren, NJ; Ameritech Corporation, Chicago, IL. The following additional party has become an Associate Member of XIWT: Philips Research Briarcliff, Briarcliff Manor, NY. The following parties have discontinued membership in XIWT: Pacific Bell; and NYNEX Science & Technology.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and CNRI intends to file additional written notifications disclosing all changes in membership. On September 28, 1993, CNRI filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on December 17, 1993 (58 FR 66022). The last notification was filed with the Department on October 24, 1995. A notice was published in the Federal Register pursuant to Section 6(b) of the Act on April 25, 1996 (61 FR 18409).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–28162 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Enterprise Computer Telephony Forum

Notice is hereby given that, on August 16, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Enterprise Computer Telephony Forum (''ECTF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Amarex Technology, Inc., New York, NY; NEC America, Inc., Irving TX; and Lucent Technologies, Columbus, OH have become Principal Members. Dinatel and Motorola are no longer Principal Members. The following parties have become Auditing Members: CTI Market Solutions, Menlo Park, CA; Digital Systems International, Redmond, WA; Garex AS, Oslo, NORWAY; ITEC Telecom, Bogota, COLOMBIA; Lernout & Hauspie Speech Products, Burlington, MA; Nationsbank, Charlotte, NC; Technology Marketing Products, Berkeley, CA; and UCA&L, Buffalo, NY. Alcatel is no longer an Auditing Member.

No other changes have been made in the membership, nature or objectives of ECTF. Membership remains open, and ECTF intends to file additional written notifications disclosing all changes in membership.

On February 20, 1996, ECTF filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on May 13, 1996 (61 FR 22074).

The last notification was filed with the Department on April 17, 1996. A notice was published in the Federal Register pursuant to Section 6(b) of the Act on June 12, 1996 (61 FR 29769).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–28161 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ITT Aerospace Communications Division of ITT Industries, Inc.

Notice is hereby given that, on August 19, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), ITT Aerospace Communications Division of ITT Industries, Inc. (''ITT A/CD'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture.

The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are ITT A/CD, Ft. Wayne, IN; Honeywell Technology Center, Minneapolis, MN; David Sarnoff Research Center, Princeton, NJ; and MCS, Inc., Boston, MA.

ITT A/CD and the above identified parties entered into a collaborative research agreement, in June 1996, to perform a Technology Development project under DARPA's Technology Reinvestment Program (TRP) for the purpose of developing a handheld terminal capable of transmitting and receiving multimedia communications. The terminal will assist civilian consumers and military commanders who need mobile access to information.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–28159 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Network Management Forum

Notice is hereby given that, on September 9, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* (''the Act''), the Network Management Forum (''the Forum'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes to its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the identities of the new members to the venture are as follows: Applecom Systems Ltd., Herzelia, ISRAEL; Architel Systems Corporation, Toronto, Ontario, CANADA; Clarify, Inc., San Jose, CA; GIE COFIRA, Montrouge, FRANCE; Microtec, Santa Clara, CA; Open Management Software, Inc., Newark, CA; Optus Vision Pty. Ltd., Chatswood, New South Wales, AUSTRALIA; Softwire Corporation, Larkspur, CA; Template Software, Inc., Herndon, VA; and UH Communications Aps, Ballerup, DENMARK are Associate Members. EFP-The Franco-Polish School of New Information and Communication Technology, Poznan, POLAND; DETECON, Deutsche Telepost Consulting Gmbh, Darmstadt, GERMANY; and ETRI, Taejon, KOREA are Affiliate Members.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and the Forum intends to file additional written notifications disclosing all changes in membership.

On October 21, 1988, the Forum filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on December 8, 1988 (53 FR 49615).

The last notification was filed with the Department on June 6, 1996. A notice was published in the Federal Register pursuant to Section 6(b) of the Act on August 14, 1996 (61 FR 42268).

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–28163 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Petroleum Environmental Research Forum Project No. 96–01

Notice is hereby given that, on October 9, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301, *et seq.* (''The Act''), the participants in the Petroleum Environmental Research Forum (''PERF'') Project No. 96–01, titled ''Treating Refinery/Petrochemical Wastewater Using Media Systems,'' have filed written notifications simultaneously with the Attorney General and with the Federal Trade Commission disclosing: (1) the identities of the parties; and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the current participants in PERF Project No. 96–01 are: Exxon Research & Engineering Company, Florham Park, NJ; Shall Development Company, Houston, TX; Conoco, Inc., Houston, TX; Phillips Petroleum Company, Bartlesville, OK; BP Exploration & Oil Company, Cleveland, OH; and Elf Antar, Inc., Paris, FRANCE.

The nature and objective of the research program performed in accordance with PERF Project No. 96–01 is to demonstrate the effectiveness and benefits of media systems (with an emphasis on suspended media) for the biotreatment of refinery and petrochemical wastewater.

Participation in this Project will remain open to interested persons and organizations until the final Project Completion Date, which is presently anticipated to occur approximately twelve (12) months after the Project commences. The parties intend to file additional written notifications disclosing all changes in membership in this Project.

Information regarding participation in Petroleum Environmental Research Forum (''PERF'') Project No. 96–01 may be obtained from Ms. Amy M. Feith, Engineering Department, Exxon Research & Engineering Company, P.O. Box 181, Florham Park, NJ 07932–0101.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96–28158 Filed 11–1–96; 8:45 am]

BILLING CODE 4410–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 96–133]

NASA Advisory Council, Advisory Committee on the International Space Station (ACISS); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Advisory Committee on the International Space Station.

DATES: November 6, 1996, 1:00 p.m. to 3:00 p.m. and November 7, 1996, 10:00 a.m. to 12:00 p.m.

ADDRESSES: Waterfront Hilton, 21100 Pacific Coast Highway, Huntington Beach, CA 92648.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce Luna, Code M–4, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–1101.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Committee Recommendations on ISS Budget

—Committee Recommendations on Commercialization Planning

—Space Station Electrical Power System Briefing

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: October 29, 1996.

Alan M. Ladwig,

Associate Administrator for Policy and Plans, National Aeronautics and Space Administration.

[FR Doc. 96–28250 Filed 11–1–96; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Administration.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that (1) propose the destruction of records not previously authorized for disposal, or (2) reduce the retention period for records already authorized for disposal. NARA invites public comments on such schedules, as required by 44 U.S.C. 3303a(a).

DATES: Request for copies must be received in writing on or before December 19, 1996. Once the appraisal of the records is completed, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

ADDRESSES: Address requests for single copies of schedules identified in this notice to the Records Appraisal and Disposition Division (NIR), National Archives and Records Administration, College Park, MD 20740. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in the parentheses immediately after the name of the requesting agency.

SUPPLEMENTARY INFORMATION: Each year U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records requires the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about the disposition process will be furnished to each requester.

Schedules Pending

1. Department of Commerce, Patent and Trademark Office (N1–241–96–4). Updated chapter of a comprehensive schedule, including records of the Patent Assignment and Certification Division, and related program offices.

2. Department of Energy, Savannah River Operations Office (N1–434–96–12). Routine administrative and general facilities records from the Savannah River Site and the Dana Plant.

3. Department of Justice (N1–60–94–9). Litigation case files relating to tax matters arising before the Court of Federal Claims and tax matters involving assessments against the United States.

4. Department of State, All Foreign Service Posts (N1–84–96–4). The Citizen Services System (CSS) maintained by Consular Sections.

5. Department of Treasury, Bureau of Public Debt (N1–53–97–1). Office of Administration records.

6. Bureau of Alcohol, Tobacco, and Firearms (N1–436–96–3). Outputs of the Weapons, Application, and Importation Tracking System (WAITS) and Firearms and Explosives Import System (FEIS). (Master files will be preserved.)

7. Competitiveness Policy Council (N1–220–96–14). Administrative files and records of Subcouncils (exclusive Subcouncil final reports).

8. Federal Housing Finance Board (N1–485–95–1). On-line working data files of the District Banks Information Management System.

9. Panama Canal Commission (N1–185–96–6). Routine informational services and public relations records.

10. Securities and Exchange Commission (N1–266–97–2). One time disposal of computer output microfiche created from data stored in the EDGAR system, which is scheduled for transfer to the National Archives.

Dated: October 24, 1996.

James W. Moore,

Assistant Archivist for Records Administration.

[FR Doc. 96–28146 Filed 11–01–96; 8:45 am]

BILLING CODE 7515–01–M

NATIONAL SCIENCE FOUNDATION

Submission for OMB Review: Comment Request

Title of Proposed Collection: National Science Foundation Proposal Evaluation Process.

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Science Foundation (NSF) will publish periodic summaries of proposed projects. Such a notice was published at Federal Register 29432, dated June 10, 1996. No public comments were received.

The materials are now being sent to OMB for review. Send any written comments to Desk Officer: OMB No. 3145–0100, OIRA, Office of Management and Budget, Washington, DC 20503. Comments should be received by December 1, 1996.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use

of automated collection techniques or other forms of information technology.

Proposed Project: Separately budgeted current fund expenditures on research and development in the sciences and engineering performed by universities and colleges and their affiliated federally funded research and development ceners—A mail survey, the Survey of Scientific and Engineering Expenditures at Universities and Colleges, originated in fiscal year (FY) 1954 and has been conducted annually since FY 1972. The survey is the academic expenditure component of the NSF statistical program that seeks to ''provide a central clearinghouse for the collection, interpretation, and analysis of data on the availability of, and the current and projected need for, scientific and technical resources in the United States, and to provide a source of information for policy formulation by other agencies of the Federal government'' as mandated in the National Science Foundation Act of 1950. The proposed project will continue the current survey cycle for three to five years. The FY 1996 and FY 1997 will be a statistical sample of approximately 518 institutions and FY 1998 a full survey population of about 700 institutions. The survey is conducted as a full survey population every 5 years and as a statistical sample in each of the 4 intervening years. These institutions account for over 95 percent of the Nation's academic R&D funds. The survey has provided continuity of statistics on R&D expenditures by source of funds and by science & engineering (S&E) field, with separate data requested on current fund expenditures for research equipment by S&E field. Statistics from the survey are published in NSF's annual publication series Academic Science and Engineering R&D Expenditures and are available electronically on the World Wide Web.

The survey will be mailed primarily to the administrators at the Institutional Research Offices. To minimize burden, institutions are provided with (in addition to paper copy) an automatic survey questionnaire (ASQ) diskette, pre-loaded with the institutions previous years data and a complete program for editing and trend checking. Respondents are encouraged to submit their response via the ASQ diskette or electronically via internet. Approximately 60% responded via ASQ or electronically to this voluntary survey in FY 1994 and a total response rate of 90.6% was obtained. Burden estimates are as follows:

Total number of institutions	Doctorate-granting	Masters-granting	Bachelors degree or below
	Burden hours		
FY 1992—480	20.8	12.0	4.4
FY 1993—700	21.0	8.1	5.2
FY 1994—518	21.6	7.7	4.3

Dated: October 29, 1996.

Herman G. Fleming,

NSF Clearance Officer.

[FR Doc. 96–28132 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

National Science Board; Nominations for Membership

The National Science Board (NSB) is the policymaking body of the National Science Foundation (NSF). The Board consists of 24 members appointed by the President, with the advice and consent of the Senate, for six-year terms, in addition to the NSF Director *ex officio.* Section 4(c) of the National Science Foundation Act of 1950, as amended, states that: ''The persons nominated for appointment as members of the Board (1) shall be eminent in the fields of the basic, medical, or social sciences, engineering, agriculture, education, research management, or public affairs; (2) shall be selected solely on the basis of established records of distinguished service; and (3) shall be so selected as to provide representation of the views of scientific and engineering leaders in all areas of the Nation.''

All of the members whose terms expire in May 1998 are eligible for reappointment. Current NSB membership is as follows:

Terms Expire May 10, 1998

Dr. F. Albert Cotton, Distinguished Professor, Department of Chemistry, Texas A&M University, College Station, TX

Dr. Charles E. Hess, Director of International Programs Office, University of California, Davis, CA

Dr. John E. Hopcroft, Joseph Silbert Dean of Engineering, Cornell University, Ithaca, NY

Dr. Shirley Malcom, HEAD, Directorate for Education and Human Resources Programs, American Association for the Advancement of Science, Washington, D.C.

Dr. James L. Powell, President and Director, Natural History Museum of Los Angeles County, 900 Exposition Boulevard, Los Angeles, CA

Dr. Frank H.T. Rhodes, President Emeritus, Cornell University, Ithaca, NY

Dr. Ian M. Ross, President-Emeritus, AT&T Bell Laboratories, Inc., 101 Crawfords Corner Road, Holmdel, NJ

Dr. Richard N. Zare, (Chairman, National Science Board), Marguerite Blake Wilbur Professor of Chemistry, Department of Chemistry, Stanford University, Stanford, CA

Terms Expire May 10, 2000

Dr. Sanford Greenberg, Chairman and CEO, TEI Industries, Inc., Washington, D.C.

* Dr. Jane Lubchenco, Wayne and Gladys Valley Professor of Marine Biology and Distinguished Professor of Zoology, Oregon State University, Corvallis, OR

Dr. Eve L. Menger, Director, Characterization Science and Services, Corning, Inc., Corning, NY

Dr. Claudia I. Mitchell-Kernan, Vice Chancellor, Academic Affairs and Dean, Graduate Division, Office of the Chancellor, University of California, Los Angeles, CA

Dr. Diana Natalicio, (Vice Chairman, National Science Board), President, The University of Texas at El Paso, El Paso, TX

Dr. Robert M. Solow, Institute Professor Emeritus, Department of Economics, Massachusetts Institute of Technology, Cambridge, MA

Dr. Warren M. Washington, Senior Scientist and Head, Climate Change Research Section, National Center for Atmospheric Research, Boulder, CO

Dr. John A. White, Jr., Regents' Professor and Dean of Engineering, Eugene C. Gwaltney Professor, Georgia Institute of Technology, Atlanta, GA

Terms Expire May 10, 2002*

Dr. John A. Armstrong, IBM Vice President for Science and Technology (Retired), Amherst, MA
Dr. Mary K. Gaillard, Professor of Physics, University of California, Berkeley, Berkeley, CA
Dr. M.R.C. Greenwood, Chancellor, University of California Santa Cruz, Santa Cruz, CA
Dr. Stanley V. Jaskolski, Vice President, Eaton Corporation, Eaton Center, Cleveland, OH
Dr. Eamon M. Kelly, President, Tulane University, New Orleans, LA
Dr. Vera Rubin, Staff Member, Department of Terrestrial Magnetism, Carnegie Institution of Washington, Washington, D.C.
Dr. Bob H. Suzuki, President, California State Polytechnic University, Pomona, CA
Dr. Richard Tapia, Professor, Department of Computational and Applied Mathematics, Rice University, Houston, TX

Member Ex Officio

Dr. Neal F. Lane, Director, National Science Foundation, Washington, D.C.

The Board and the Director solicit and evaluate nominations for submission to the President. Nominations accompanied by biographical information may be forwarded to the Chairman, National Science Board, 4201 Wilson Boulevard, Arlington, VA, 22230, no later than January 3, 1997.

Any questions should be directed to Mrs. Susan E. Fannoney, Staff Assistant, National Science Board (703/306–2000).

* NSB nominee pending U.S. Senate confirmation.

Dated: October 29, 1996.

Richard N. Zare,

Chairman, National Science Board.

[FR Doc. 96–28120 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Astronomical Sciences (1186); Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces that the Special Emphasis Panel in Astronomical Sciences (1186) will be holding panel meetings for the purpose of reviewing proposals submitted to the Stellar Astronomy and Astrophysics Program in the area of Astronomical Sciences. In order to review the large volume of proposals, panel meetings will be held on November 19–20 (2) and November 21–22 (3). All meetings will be closed to the public and will be held at the National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia, from 8:30 AM to 5:00 PM each day.

Contact Person: Dr. Eileen Friel, Program Director, Stellar Astronomy and Astrophysics, Division of Astronomical Sciences, National Science Foundation, Room 1045, 4201 Wilson Boulevard, Arlington, VA 22230, (703) 306–1825.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28123 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name and Committee Code: Special Emphasis Panel in Biological Sciences (#1754).

Date and Time: November 20–22, 1996, 8:00 a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Room 680, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Fred Stollnitz, Program Director, Research Experiences for Undergraduates, Room 615, National Science Foundation, 4201 Wilson Boulevard, VA 22230. Telephone: (703) 306–1413.

Minutes: May be obtained from contact person listed above.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate proposals submitted in response to the Research Experiences for Undergraduates program announcement (NSF 96–102).

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28128 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Biomolecular Structure and Function; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Advisory Panel for Biomolecular Structure and Function—(1134) (Panel B).

Date and Time: Monday, Tuesday, and Wednesday, November 18, 19, & 20, 1996 8:30 a.m. to 6:00 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Room 390, Arlington, VA 22230.

Type of Meeting: Closed.

Contact Person: Dr. Kamal Shukla, Program Director for Molecular Biophysics, Room 655, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230. (703/306–1444).

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate research proposals submitted to the Molecular Biophysics Program as part of the selection process for awards..

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28122 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Chemistry; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Chemistry (1191).

Date and Time: November 22, 1996 from 7:30 a.m. to 4:00 p.m.

Place: Room 1020, NSF, 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Closed.

Contact Person: Dr. Joseph Reed, Program Director for Chemistry Research Instrumentation and Facilities (CRIF) Program, Room 1055, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1849.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the National Science Foundation for financial support.

Agenda: To review and evaluate Chemistry Research Instrumentation and Facilities

proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28124 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Computer and Computation Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Computer and Computation Research (1192).

Date and Time: November 18 and 22, 1996 from 8:30 a.m. to 5:00 p.m.

Place: Room 320, 330, 340 and 360, NSF 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Closed.

Contact Person: Dr. S. Kamal Abdali, Program Director for Numeric, Symbolic, and Geometric Computation Program, CCR, Room 1145, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone (703) 306–1912.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the National Science Foundation for financial support.

Agenda: To review and evaluate Numeric, Symbolic and Geometric Computation proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28126 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Cross Disciplinary Activities; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L.92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Cross Disciplinary Activities (1193).

Date and Time: November 19, 1996, from 8:30 am to 5:00 pm.

Place: Rooms 1120 and 1150, NSF 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Closed.

Contact Person: Dr. Harry Hedges, Program Director for Cross Disciplinary Activities, Room 1160, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1980.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to the National Science Foundation for financial support.

Agenda: To review and evaluate CISE Research Experiences for Undergraduates' proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28125 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Geosciences (1756).

Date and Time: Monday, November 18 to Friday, November 22, 1996; 8:30 am—5:00 pm.

Place: Rooms 310, 320, 330, 340, National Science Foundation, 4201 Wilson Blvd., Arlington, VA.

Type of Meeting: Closed.

Contact Person: Dr. Michael R. Reeve, Section Head, Division of Ocean Sciences, Ocean Sciences Research, Room 725, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1582.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Ocean Sciences Research Section proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28129 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Human Resource Development; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Human Resource Development (#1199).

Date and Time: November 18 and 19, 1996, 8:30 a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Arlington, VA. Room 370 (November 18), Room 950 (November 19).

Type of Meeting: Closed.

Contact Person: Lawrence Scadden & Mary Kohlerman, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306–1636.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Programs for Persons with Disabilities proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28121 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Social and Political Science; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation (NSF).

Name: Advisory Panel for Social and Political Science (#1761).

Date and Time: November 21–22, 1996; 9:00 a.m. to 5:00 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 920, Arlington, VA 22230.

Contact Person: Dr. Frank Scioli and Dr. Rick Wilson, Program Directors for Political Science, National Science Foundation. Telephone: (703) 306–1761.

Agenda: To review and evaluate the political science proposals as part of the selection process for awards.

Date and Time: December 16–17, 1996; 9:00 a.m. to 5:00 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 970, Arlington, VA 22230.

Contact Person: Dr. Harmon Hosch, Program Director, Law and Social Science, National Science Foundation. Telephone (703) 306–1762.

Agenda: To review and evaluate the Law and Social Science Proposals as a part of the selection process for awards.

Date and Time: December 12–13, 1996; 9:00 a.m. to 5:00 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 370, Arlington, VA 22230.

Contact Person: Dr. William S. Bainbridge and Dr. Patricia White, Program Directors for Sociology, National Science Foundation. Telephone (703) 306–1756.

Agenda: To review and evaluate the Sociology proposals as a part of the selection process for awards.

Type of Meetings: Closed.

Purpose of Meeting: To provide advice and recommendations concerning support for research proposals submitted to the NSF for financial support.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 28, 1996.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 96–28127 Filed 11–1–96; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Notice of Pending Submittal to the Office of Management and Budget (OMB) for Review

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. The title of the information collection: Application for License to Export Nuclear Material and Equipment, NRC Form 7

2. Current OMB approval number: 3150–0027

3. How often the collection is required: On occasion; for each separate request for a specific export license and for exports of incidental radioactive material using existing general licenses.

4. Who is required or asked to report: Any person in the U.S. who wishes to export: (a) nuclear material and equipment subject to the requirements of a specific license; (b) radioactive waste subject to the requirements of a specific license; and (c) incidental radioactive material that is a contaminant of shipments of more than 100 kilograms of non-waste material using existing NRC general licenses.

5. The number of annual respondents: 153

6. The number of hours needed annually to complete the requirement or request: 330 hours (2.2 hours per response)

7. Abstract: Any person in the U.S. wishing to export nuclear material and equipment requiring a specific authorization or radioactive waste requiring a specific authorization must file an application for a license on NRC Form 7. The application will be reviewed by the NRC and by the Executive Branch, and if applicable statutory, regulatory, and policy considerations are satisfied, the NRC will issue a license authorizing the export.

A completed NRC Form 7 must also be filed by any person in the U.S. wishing to use existing NRC general licenses for the export of incidental radioactive material before the export takes place (if the total amount of the shipment containing the incidental radioactive material exceeds 100 kilograms). The form is reviewed by the NRC to ensure that the NRC is informed before the fact of these kinds of shipments and to allow NRC to inform other interested parties, as appropriate, including import control authorities in interested foreign countries.

Submit, by January 3, 1996, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street NW., (lower level), Washington, DC. Members of the public who are in the Washington, DC area can access this document via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library), NRC subsystem at FedWorld, 703–321–3339. Members of the public who are located outside of the Washington, DC area can dial FedWorld, 1–800–303–9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703–487–4608.

Comments and questions may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–6 F33, Washington, DC 20555–0001, or by telephone at 301–415–7233, or by Internet electronic mail at BJS1@NRC.GOV.

Dated at Rockville, Maryland, this 29th day of October 1996.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 96–28225 Filed 11–01–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–317, 50–318, and 72–8]

Baltimore Gas and Electric Company; (Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 and the Independent Spent Fuel Storage Installation); Order Approving Transfer of Licenses for Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 and the Independent Spent Fuel Storage Installation

I

Baltimore Gas and Electric Company (BGE) is the licensee for Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, and the associated Independent Spent Fuel Storage Installation. BGE has the exclusive responsibility for the construction, operation, and maintenance of Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 and the Independent Spent Fuel Storage Installation, as reflected in Operating License Nos. DPR–53, DPR–69 and Material License No. SNM–2505 of the U.S. Nuclear Regulatory Commission (NRC) issued on July 31, 1974 and November 30, 1976, and November 25, 1992, respectively. The facility is located on the western shore of the Chesapeake Bay, in Calvert County, Maryland.

II

By letter dated April 5, 1996, BGE submitted its request for approval pursuant to Sections 50.80, 50.90, 72.50, and 72.56 of Title 10 of the Code of Federal Regulations, of the transfer of and amendments to Operating Licenses Nos. DPR–53 and DPR–69 and Material License No. SNM–2505 for Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 and the Independent Spent Fuel Storage Installation. On May 22, 1996, June 12, 1996, and July 15, 1996, notices of the proposed actions were published in the Federal Register (61 FR 25697, 29771, 36914).

The license transfers and amendments are requested in connection with a pending merger between BGE and Potomac Electric Power Company (PEPCO) into Constellation Energy Corporation. The proposed license transfers would transfer authority to possess and operate Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 and the Independent Spent Fuel Storage Installation (ISFSI) from BGE to Constellation Energy Corporation. The proposed amendments would change the licenses to reflect the transfer of the licenses by substituting Constellation Energy Corporation in place of BGE as licensee for Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, and the ISFSI.

The technical qualifications of Constellation Energy Corporation to carry out its responsibilities under the operating licenses will be the same as those of BGE. The transfer of the operating licenses to Constellation Energy Corporation involves no significant changes to either the technical organization or staff responsible for operating the facility. Both before and after the transfer, essentially the same BGE nuclear organization and staff will be responsible for the operation and maintenance of Calvert Cliffs. The transfer requires no change in the numbers and qualifications of personnel who operate Calvert Cliffs. Although specific individuals may join or leave the nuclear staff, the technical and administrative abilities will remain essentially unchanged.

The Constellation Energy Corporation management directly responsible for Calvert Cliffs will be experienced BGE Nuclear Managers. The transfer involves no changes in the training program or procedures applicable to the Calvert Cliffs operating organization. The current Calvert Cliffs personnel training program and operating organization are set forth in the updated final safety analysis report for Calvert Cliffs. Given that Constellation Energy Corporation management directly responsible for Calvert Cliffs will be BGE Nuclear Managers, the transfer will result in no adverse impact with respect to technical qualifications.

BGE proposes to restructure itself by merging with PEPCO. The company formed as a result of the merger would be Constellation Energy Corporation, which is currently a subsidiary of BGE and PEPCO formed for the purpose of consummating the merger and would become the owner and operating licensee for the two-unit Calvert Cliffs Nuclear Power Plant, as well as the ISFSI.

BGE indicates that the purpose of the merger is

> * * * to achieve benefits for BGE's and PEPCO's shareholders, customers and communities that would not be available if they were to remain separate companies. The benefits are expected to be achieved through significant reduction in operating costs (estimated at approximately $1.3 billion in nominal dollars, net of costs to achieve, over a 10-year period) * * *. (Application dated April 5, 1996 to Transfer and Amend Operating License Nos. DPR–53 and DPR–69, and ISFSI license SNM–2505, Calvert Cliffs Nuclear Power Plant, Attachment 1, p. 5.)

BGE indicates that Constellation Energy Corporation will be an ''electric utility'' as defined in 10 CFR 50.2. That is, Constellation Energy Corporation will continue to be engaged in the generation, transmission, and distribution of electricity and will remain subject to the rate regulatory authority of the Maryland Public Service Commission, the District of Columbia Public Service Commission, and the Federal Energy Regulatory Commission. Based on the information provided in BGE's application, the staff finds that there will be no near-term substantive change in Constellation Energy Corporation's financial ability to contribute to the operations and decommissioning of its Calvert Cliffs units as a result of the proposed merger. Thus, pursuant to 10 CFR 50.33(f), Constellation Energy Corporation is exempt from further financial qualifications review as an electric utility. The staff finds that the financial information provided in BGE's application for transfer of SNM–2505, as required by 10 CFR 72.22(e), demonstrates that funding for operation and decommissioning of the ISFSI will not be adversely affected by the merger.

Based on the above, the staff concludes that Constellation Energy Corporation will be financially qualified with respect to holding the licenses for the Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 and the Independent Spent Fuel Storage Installation.

The Calvert Cliffs Nuclear Power Plant received its construction permit (CP) prior to enactment of Section 105 of the Atomic Energy Act. Nuclear plants that received CPs prior to enactment of Section 105 in December 1970 were issued 104b licenses rather than 103 commercial licenses and were grandfathered for purposes of antitrust review. Consequently, the staff is not conducting a significant change antitrust review as a result of the proposed merger involving BGE and PEPCO.

BGE has asserted that Constellation Energy Corporation will not be owned, controlled or dominated by an alien, foreign corporation or foreign government and will not be acting as an agent or representative of any other person.

On the basis of a review of the information in the letter of April 5, 1996, and other information before the Commission, the NRC staff finds that the transfer of the Calvert Cliffs Nuclear Power Plant, Units No. 1 and No. 2 and Independent Spent Fuel Storage Installation operating licenses to Constellation Energy Corporation, will not adversely affect protection of public health and safety or the common defense and security. Therefore, the NRC staff concludes that Constellation Energy Corporation is qualified to be the holder of the licenses, subject to conditions set forth herein and the transfer of the licenses is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission. An environmental assessment and finding of no significant impact was published in the Federal Register on October 10, 1996 (61 FR 53241).

III

Accordingly, pursuant to Sections 161b, 161i, and 184 of the Atomic Energy Act of 1954, as amended, 42 USC §§ 2201(b), 2201(i), and 2234, and 10 CFR 50.80 and 10 CFR 72.50, It is hereby Ordered that the Commission consents to the proposed transfer of the licenses described herein between BGE and Constellation Energy Corporation subject to the following: (1) amendments to the licenses described herein, consistent with the contents of and reflecting this Order, must be issued and become effective as of the date of issuance; (2) should the transfer of the licenses not be consummated by December 31, 1997, this Order shall become null and void, provided, however, on application and for good cause shown, such date may be extended.

IV

Any person adversely affected by this Order may file a request for a hearing with respect to issuance of the Order. Any person requesting a hearing shall set forth with particularity how such person's interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is to be held, the Commission will issue an Order designating the time and place of such hearing.

The issue to be considered at any such hearing will be whether this Order should be sustained.

Any request for a hearing must be filed with Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Chief Docketing and Services Section, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Copies should also be sent to the Office of the General Counsel and to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to J. E. Silbert, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street NW., Washington, DC 20037.

This Order is effective upon issuance. For further details with respect to this action, see the application dated April 5, 1996, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Calvert County Library, Prince Frederick, Maryland 20678.

Dated at Rockville, Maryland, this 18th day of October 1996.

For the Nuclear Regulatory Commission.

Frank J. Miraglia, Jr.,

Acting Director, Office of Nuclear Reactor Regulation.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 96–28222 Filed 11–1–96; 8:45 am]

BILLING CODE 7590–01–P

[Docket No. 50–262]

Brigham Young University (Brigham Young University L–77 Research Reactor); Order Terminating Facility License

By application dated June 28, 1990, as supplemented on July 2, 1991, and March 9, 1992, Brigham Young University (BYU or the licensee) requested from the U.S. Nuclear Regulatory Commission (the Commission) authorization to dismantle and dispose of the component parts of the BYU L–77 Research Reactor located on the licensee's campus in Provo, Utah. The July 2, 1991, letter contained a request that upon completion of decommissioning, authorization be given for termination of Facility License No. R–109. A ''Notice of Proposed Issuance of Orders Authorizing Disposition of Component Parts and Terminating Facility License,'' was published in the Federal Register on August 1, 1991 (56 FR 36851). No requests for a hearing were received. By Order dated July 23, 1992 (57 FR 33979), the Commission authorized dismantling of the facility and disposition of component parts as proposed in the decommissioning plan of the licensee. By letter dated April 15, 1994, as supplemented on May 30, October 9, and December 7, 1995, the licensee submitted the Decommissioning Survey for the L–77 Research Reactor.

The reactor fuel has been removed from the core and was shipped to a Department of Energy (DOE) facility. The reactor facility has been completely dismantled and all requirements pertaining to residual radioactivity, personnel and external radiation exposure, and fuel disposition have been satisfied. The termination radiation survey and associated documentation demonstrate that the facility and site are suitable for release. Confirmatory radiological surveys verified that the facility complied with the recommended regulatory guidance for release of the facility for unrestricted use. Accordingly, the Commission has found that the licensee decommissioned the facility in accordance with the approved decommissioning plan and the facility has been dismantled and decontaminated pursuant to the Commission's Order dated July 23, 1992. The component parts and fuel have been disposed of in accordance with the Commission's regulations in 10 CFR Chapter I, and in a manner not inimical to the common defense and security, nor to the health and safety of the public. Therefore, on the basis of the application filed by BYU, and pursuant to Sections 104 and 161 b, and i, of the Atomic Energy Act of 1954, as amended, and in accordance with 10 CFR 50.82(b)(6), Facility License No. R–109 is terminated as of the date of this Order. In accordance with 10 CFR Part 51, the Commission has determined that the issuance of this termination Order will have no significant environmental impact. The Environmental Assessment and Finding of No Significant Impact was published in the Federal Register on October 28, 1996 (61 FR 55672).

For further details with respect to this action see (1) the application for termination of Facility License No. R–109, dated July 2, 1991, as supplemented, (2) the Commission's Safety Evaluation related to the termination of the license, (3) the Environmental Assessment and Finding of No Significant Impact, and (4) the ''Notice of Proposed Issuance of Orders Authorizing Disposition of Component Parts and Terminating Facility License,'' published in the Federal Register on August 1, 1991 (56 FR 36851). Each of these items is available for public inspection at the Commission Public Document Room, 2120 L Street, N.W., Washington, D.C. 20037.

Copies of items 2, 3, and 4 may be obtained upon request from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555–0001, Attention: Director, Division of Reactor Program Management.

Dated at Rockville, Maryland this 29th day of October 1996.

For the Nuclear Regulatory Commission.

Thomas T. Martin,

Director, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 96–28224 Filed 11–1–96; 8:45 am]

BILLING CODE 7590–01–P

Notice of Issuance of Branch Technical Position on Screening Methodology for Assessing Prior Land Burials of Radioactive Waste Authorized Under Former 10 CFR 20.304 and 20.302 for Interim Use and Comment

SUMMARY: This notice is to advise the public of the U.S. Nuclear Regulatory Commission's issuance of a Branch Technical Position (BTP) which provides a screening methodology that the staff finds acceptable to determine the need for further characterization and/or remediation of prior low-level radioactive waste disposal conducted under the provisions of former 10 CFR 20.304 and 20.302.

Burial of certain quantities of radioactive waste in soil, by licensees, without prior NRC approval, was authorized on January 29, 1959 (22 FR 548). This authorization was codified in former 10 CFR 20.304. On January 28, 1981, the NRC concluded that it was inappropriate to continue generic authorizations of burials pursuant to 10 CFR 20.304 without regard to factors such as location of burial, concentrations of radioactive material, form of packaging, and notification of NRC. Therefore, NRC rescinded 10 CFR

20.304 (45 FR 71761). As of January 28, 1981, licensees wishing to perform on-site disposal of the type previously authorized under 10 CFR 20.304 were required to obtain prior NRC approval in accordance with 10 CFR 20.302.

Disposals made pursuant to former 10 CFR 20.304 and 20.302 at facilities licensed under 10 CFR Parts 30, 40, and 70, and that have been unused for NRC licensed operations for a period of 24 months, are subject to the requirements of the ''Final Rule on Timeliness in Decommissioning Nuclear Facilities'' (59 FR 36026, effective August 15, 1994) (hereinafter called the ''Timeliness Rule''). Licensees who have unused outside areas (e.g., burial areas) containing elevated levels of licensed radioactive materials, are required to notify NRC, that they are in possession of these areas and must begin following a schedule for decommissioning these areas. For timing provisions related to decommissioning, see 10 CFR 30.36(d), 40.42(d), 70.38(d), and 72.54(d).

On August 19, 1996, NRC published Information Notice 96–47 ''Recordkeeping, Decommissioning Notifications for Disposal of Radioactive Waste by Land Burial Authorized under Former 10 CFR 20.304, 20.302, and Current 20.2002.'' This notice re-emphasized NRC's position that former burials are covered under the Timeliness Rule, outlined the decommissioning schedule required by the rule, and stated that NRC would develop a screening methodology for assessing former burials. This screening methodology is being issued as a draft BTP and is attached to this notice.

Because of the deadlines associated with the Timeliness Rule, this BTP is being issued for public use and comment for 90 days. At the end of the 90 day period, the comments received will be evaluated to determine if the BTP should be revised. Since there is a possibility that the comments could result in a substantial change to the BTP, NRC will not make any decisions regarding the assessment of prior burials until after the comments can be evaluated.

All comments should be addressed to Heather Astwood, Mail Stop T–7F–27, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A copy of the BTP is also located in the NRC's Public Document Room, 2120 L Street NW., Washington, DC 20555. A copy is also on the NRC homepage which can be accessed at www.nrc.com.

FOR FURTHER INFORMATION CONTACT: Heather Astwood, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T–7F–27, Washington, DC 20555, telephone (301) 415–5819.

Dated at Rockville, MD this 25th day of October 1996.

For the U.S. Nuclear Regulatory Commission.

Michael F. Weber,

Chief, Low-Level Waste and Decommissioning Projects Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

Draft—Branch Technical Position

Screening Methodology for Assessing Prior Land Burials of Radioactive Waste Authorized Under Former 10 CFR 20.304 and 20.302

October 1996

Low-Level Waste and Decommissioning Projects Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards

Table of Contents

Draft—Screening Methodology for Assessing Prior Land Burials of Radioactive Waste Authorized Under Former 10 CFR 20.304 and 20.302

1.0 Purpose

This Branch Technical Position (BTP) provides a screening methodology that the staff finds acceptable to determine the need for further characterization and/or remediation of prior low-level radioactive waste disposals conducted under the provisions of former 10 CFR 20.304 and 20.302. This BTP is intended to be a final evaluation for former burials. Decisions made based on this BTP are not expected to change because of the issuance of future rules or standards.

2.0 Introduction

Burial of certain quantities of radioactive waste in soil, by licensees, without prior NRC approval, was authorized on January 29, 1959 (22 *FR* 548). This authorization was codified in former 10 CFR 20.304. On January 28, 1981, NRC concluded that it was inappropriate to continue generic authorizations of burials pursuant to 10 CFR 20.304 without regard to factors such as location of burial, concentrations of radioactive material, form of packaging, and notification of the Nuclear Regulatory Commission. Therefore, NRC rescinded 10 CFR 20.304 (45 FR 71761). As of January 28, 1981, licensees wishing to perform on-site disposals of the type previously authorized under 10 CFR 20.304 were required to obtain prior NRC approval in accordance with 10 CFR 20.302.

On May 21, 1991, 10 CFR Part 20 was revised (56 FR 23360) and 10 CFR 20.302 was replaced by 20.2002. According to 10 CFR 20.1008(b), licensees were required to comply with the new 10 CFR 20.2002 exclusively on January 1, 1994. The requirements of 10 CFR 20.2002 are similar to the original requirements in former 10 CFR 20.302, with the addition of requirements for submitting analyses and procedures for maintaining doses within established dose limits and as low as reasonably achievable (ALARA).

Disposals made pursuant to former 10 CFR 20.304 and 20.302 at facilities licensed under 10 CFR Parts 30, 40, and 70, and that have been unused for NRC licensed operations for a period of 24 months, are subject to the requirements of the ''Final Rule on Timeliness in Decommissioning Nuclear Facilities'' (59 *FR* 36026, effective August 15, 1994) (hereinafter called the ''Timeliness Rule''). Licensees who have unused outside areas (e.g., burial areas) containing elevated levels of licensed radioactive materials, are required to notify NRC, that they are in possession of these areas and must begin following a schedule for decommissioning these areas. For timing provisions related to decommissioning, see 10 CFR 30.36(d), 40.42(d), 70.38(d), and 72.54(d).

The evaluations required before the Commission terminates a license or releases a former burial area from a license related to disposed material were discussed in the supplemental information to the final rule on the ''General Requirements for Decommissioning Nuclear Facilities'' (53 FR 24021), published June 27, 1988. In the statement of considerations for the final rule, NRC stated that it ''. . . will take a hard look at the extent to which the site has been previously used to dispose of low-level radioactive waste by land burial and decide what remedial measures, including removal of such soil off-site, are appropriate before the site can be released for unrestricted use and the license terminated.''

On August 19, 1996, NRC published Information Notice 96–47 ''Recordkeeping, Decommissioning

Notifications for Disposals of Radioactive Waste by Land Burial Authorized under Former 10 CFR 20.304, 20.302, and Current 20.2002.'' This notice re-emphasized NRC's position that former burials are covered under the Timeliness Rule, outlined the decommissioning schedule required by the rule, and stated that NRC would develop a screening methodology for assessing former burials.

3.0 Discussion

During decommissioning, NRC will evaluate disposals authorized under former 10 CFR 20.304 and 20.302, to determine whether they are acceptable for release for unrestricted use, based on their potential impact on the health and safety of the public. The acceptability of a disposal will depend on the potential for significant exposure to members of the public who may, at some time in the future, develop and use the disposal site for a private residence, farm, business, or other purpose.

This methodology is intended to be used by the licensee as a screening tool to determine which burial sites, in general, are acceptable for release for unrestricted use, recognizing that exceptions may be identified by NRC and/or the licensee. This screening tool will be based on the total activity disposed of in the burial ground and the potential for that activity to produce a significant dose to a member of the public. Although this methodology estimates doses, they are very conservative estimates. Actual doses produced by a site would be a fraction of the doses estimated using this screening.

For those sites which pass this screening, in general, the staff will require no further characterization or remediation effort. Those sites that do not pass the screening would require more detailed analysis. This may consist of site characterization and dose assessments by the licensee and NRC. Remediation may also be necessary. This is not to say that sites that do not pass the screening will be required to remediate. This process is intended to screen out simple sites with small inventories. More detailed evaluations can then be performed for the more complex sites, or sites with unique circumstances (i.e., no records, or burial located under a building). It is recognized that spot concentrations in the waste may exceed NRC's radiological criteria for decommissioning (57 FR 13389, ''Action Plan to Ensure Timely Cleanup of Site Decommissioning Management Plan Sites''), but the overall risk to the public is limited by the total inventory, site characteristics, or other factors. It is also recognized that these burials may not be the only residual activity contained at a site. This screening is intended to evaluate the risks posed by an on-site burial independent of any other evaluations of dose contributions from other areas of the site. A facility which contains larger quantities of contamination would be required to complete a site and facility characterization program and a detailed dose assessment that accounts for doses from all sources. Because such a site/facility could conceivably have residual contamination levels that result in doses that are just below the unrestricted release criterion, it is not justified to exclude a former burial site or sites. Therefore, this screening cannot be used for sites that have surface soil or building contamination outside of what is contained in the burial site and sites where members of the public would be exposed concurrently to both the burial and other residual radioactivity. It is restricted for use at those sites where a former burial is expected to be the only source of residual contamination at time of decommissioning.

The Timeliness Rule, published August 15, 1994, outlines a schedule for licensees to follow in performing decommissioning activities and requires licensees to notify NRC of plans to meet this schedule. It also requires licensees to decommission portions of their site, including ''unused outdoor areas,'' which have not been used for a period of 24 months. These outdoor areas include former 10 CFR 20.304 and 20.302 disposals, and are, therefore, subject to the Timeliness Rule.

There are several issues associated with the assessment of prior burials. Many licensees considered these burials to be permanent disposals at the time of placement. Licensees did not budget the time nor monetary resources to evaluate these sites at the time of decommissioning. There is also a concern about the cost benefit of evaluating these sites for decommissioning. Many universities and hospitals disposed of small quantities of wastes associated with research and medical applications. The cost to characterize and remediate small burials of byproduct materials may outweigh the hazards avoided. However, some burials may pose greater risks to the public, such as those containing significant quantities of source and special nuclear material wastes. At these sites, characterization and/or remediation may be needed and costs of remediation will be considered for sites that are below 100 mrem/yr and have an adequate ALARA analysis. In addition, there are concerns about the quantity and quality of available disposal records. At the time of decommissioning, complete records of 10 CFR 20.304 and 20.302 disposals are necessary for NRC to evaluate the acceptability of the disposals. Former 10 CFR 20.401(c)(3) stated that records of disposals made pursuant to 10 CFR 20.302 and 20.304 should be maintained until NRC authorizes their disposition. However, for many of the older sites, these records are scarce or unavailable. The sites that have no burial records, may be required to evaluate and/or characterize the burials. Then, if NRC determines that the site does not pose a risk to the public, the site could be released for unrestricted use. If, however, it is determined that the site could pose a significant risk, the licensee may be required to remediate the burial. This analysis is based on the radiological risks associated with the burial. If the burial areas require characterization and/or remediation, other applicable local, state, or federal radiological and non-radiological regulations should be considered.

To help alleviate some of these concerns, the staff developed this screening methodology to determine which former burials require additional characterization and assessment and which burials are acceptable for unrestricted use. To perform this screening, the licensee will need a copy of Part 20, Appendix B, and NUREG–1500 ''Working Draft Regulatory Guide on Release Criteria for Decommissioning: NRC Staff's Draft for Comment.'' [1] The NRC will defer decisions on releasing former burials based on this methodology until this draft is finalized.

4.0 Regulatory Position

4.1 Scope

The methodology of this BTP applies to prior burials of radioactive material that were buried under 10 CFR 20.304 and 20.302. This methodology is not intended to be applied to burial sites that are currently in use or to evaluate former or proposed burials under 10 CFR 20.2002. The final rule on ''Decommissioning Recordkeeping and License Termination: Documentation Additions,'' was issued on July 26, 1993 (58 *FR* 39628), and requires a single document listing: (1) All areas outside restricted areas where current and previous wastes have been buried, (as documented under 10 CFR 20.2108); and (2) other information necessary to ensure that decommissioning is carried

[1] NUREGs can be ordered by calling (202) 512–1800.

out in accordance with the NRC's regulations. Therefore, for disposals made pursuant to 10 CFR 20.2002, waste disposal records should be sufficiently accurate and complete to demonstrate acceptability for release in accordance with recordkeeping and decommissioning requirements. In addition, recent approvals of 10 CFR 20.2002 disposal requests have been based on the assumption that the site would be released for unrestricted use. Guidance for evaluating these burials is contained in NUREG–1101, ''Onsite Disposal of Radioactive Waste.'' As stated previously, this screening is intended to be used for sites in which the former burial is expected to be the only source of residual contamination at the time of decommissioning. This screening is based only on the radiological risks associated with the burial. If the burial areas require characterization and/or remediation, or contain hazardous and/or mixed wastes, other applicable local, state, or Federal radiological and non-radiological regulations should be considered.

This screening is intended to be used by both the licensee and NRC to determine the ultimate disposition of the burial ground. Licensees will perform the screening calculations, NRC staff will review the calculations and make a final determination if the site passes the screening. If the NRC's review indicates the site passes the screening, no further evaluation or characterization of the site will generally be required. The site can be removed from the license, if that is the wish of the licensee, and the site will not need to be revisited during license termination. Those sites that do not pass this screening will require more detailed analysis to assess potential radiological risks. The amount of analysis required beyond this screening depends on the complexity of the site, the amount of available site characterization information and site characteristics, and will be determined on a case-by-case basis.

4.2 Screening Methodology

4.2.1 General Approach

This methodology consists of three steps. The first step involves collecting information on the materials which were buried at the site. The other two involve conservative dose assessments using this historical information to determine the possible consequences from human exposure to the buried material. The Step 2 calculations are performed first because they require a minimal amount of information about the site, and are easy to perform. If a site passes Step 2, there is no need to collect additional information required to perform Step 3 calculations because Step 2 is more conservative. If the site does not pass Step 2, then Step 3 calculations should be performed. If a site fails both Steps 2 and 3, this site requires more detailed analysis to determine whether it poses an unacceptable risk to the public.

4.2.2 Step 1—Records Review

The first step for the licensee should be a review of the burial records. These records should indicate the activity and types of isotopes that were disposed of at the site and the time period for those disposals. All available and relevant records should be used to develop a complete inventory for the burial area. The total activity of each isotope in the entire burial site should be determined and converted into microcuries (μCi). This total inventory should be adjusted to account for radioactive decay which has occurred since the time of burial.

It may be difficult to find records for some of the older burials. Many of these sites may have had several changes in management or location of record storage, and the records may have been misplaced or lost. If no records are available, this methodology can be performed using the original possession limits contained in the license for the site for the actual or reasonable estimate of time in which the trench was in operation and estimating the throughput resulting from the licensed activity during that time. This approach would most likely overestimate the quantities in the burial site because the activity disposed of in a burial is typically only a fraction of the activity allowed to be possessed under the license based on NRC staff experience. This will only be allowed for estimating the total inventory for use in Step 2. If there are no records, the trench size could not be determined, and, therefore, Step 3 could not be implemented. If using the original possession limits results in not passing this screening criteria, the licensee should consult with NRC for case-by-case guidance for evaluating the site. The maximum quantity that was allowed to be buried in the trenches under rescinded 10 CFR 20.304, Appendix C cannot be used as an estimate for the quantity of isotopes in the trenches because NRC has identified instances in decommissioning burial sites where disposal limits were exceeded. Without some evidence (i.e., disposal records) that these guidelines were followed, the licensee and NRC can have little confidence in the trench inventory.

If no records are available and the use of license limits result in a failure at Step 2, the licensee can take some intrusive samples of the burial ground to determine the general type and concentration of isotopes at the site and then perform this screening. The level of characterization necessary (i.e., number of samples) will be determined on a case-by-case basis in consultation with NRC staff. NRC draft ''Branch Technical Position on Site Characterization for Decommissioning Sites,'' dated November 1994, contains a description of the type of site characterization information that could be required. After Step 1 is complete and the total activity for each isotope in the burial site is estimated, the licensee should continue with Step 2.

4.2.3 Step 2—Groundwater Pathway

Following the general screening model approach described in NCRPM Report No. 123, this step assumes that the total activity for each isotope is leached into the minimum quantity of water needed to meet a family of four's average use in one-year (91 m^3). Therefore, the activity of each isotope (after decay) should be divided by 9.1E7 milliliters (ml) to obtain a concentration (C) for each isotope as follows:

$$C\ \mu Ci/ml = \frac{\text{total inventory}\ (\mu Ci)}{9.1E7\ ml} \quad (1)$$

The concentration of each isotope can be compared to the effluent release criteria contained in Part 20, Appendix B, Table 2, Column 2 for water. The concentrations contained in this table are estimated to produce a dose of approximately 50 mrem/yr assuming an individual consumes 2 liters/day. Because Appendix B lists concentrations in μCi/ml for isotopes which result in a dose of 50 mrem, this concentration/dose ratio can be used to estimate the dose produced from a different concentration of that isotope. The potential dose from the estimated concentration for the isotopes in the burial can be estimated as follows:

$$D\,mrem/yr = \frac{(C\ \mu Ci/ml)(50\,mrem/yr)}{(B\ \mu Ci/ml)} \quad (2)$$

where:

C=the concentration of a burial site isotope in groundwater μCi/ml;

B=the Appendix B, Table 2, Col. 2 concentration for the same isotope; and

D=the dose from exposure to this isotope.

This calculation should be performed for all isotopes in the burial site. After the doses are estimated for each isotope,

the doses should be totaled. If the total dose is less than the 100 mrem/yr screening level, the site passes Step 2 and, in general, the site will require no additional evaluations. If the dose is greater than the 100 mrem/yr screening level, then the analyses of Step 3 should be performed.

Note: Step 3 CANNOT be used for isotopes with atomic numbers of 88 or higher. Step 3 uses draft NUREG–1500, which is currently undergoing revisions for these isotopes. If a site contains these isotopes, licensees should consult with NRC staff for case-by-case guidance for evaluating these sites. If a site passes Step 2, then it passes the screening. If a site contains isotopes with atomic weight greater than 88, and it fails Step 2, then the site fails the screening and must be evaluated on a case-by-case basis.

4.2.4 Step 3—Exhumation Concentration

In this step, it is assumed that the total inventory of the site is evenly distributed throughout the burial trenches. Most burial sites consist of several burial trenches located at the same site. The activity of each isotope should be divided by the total grams of material in the trenches. This will produce a trench concentration (μCi/gram of waste) for each isotope. This calculation should only consider the specific burial area containing the waste and contaminated soils. It should not include the soil cap, if one is present, or the 6 feet of clean soil which was required to be placed between burials conducted under the provisions of 10 CFR 20.304. For example, if a 100 m^3 site contained 6 burial trenches with each one having a volume of 10 m^3, the total inventory would be assumed to be evenly distributed over the volume of the trenches (60 m^3), not the volume of the site (100 m^3). For sites where the volume of the trenches cannot be reasonably determined, licensees should consult with NRC staff for case-by-case guidance for evaluating these sites.

This step of the methodology assumes that a member of the public builds a house directly on the burial site. The Draft Environmental Impact Statement developed for 10 CFR Part 61, ''Licensing Requirements for Land Disposal of Radioactive Waste,'' dated September 1981 (NUREG–0782), contains information concerning the dilution of waste caused by exhumation of a building foundation. Appendix G of NUREG–0782 contains the inadvertent intruder scenario and states that the waste concentration should be reduced by a factor of 4 to account for dilution during excavation (the contaminated material would be mixed with the clean cover material as well as the clean soil surrounding the burial). This concentration should be converted into picocuries per gram (pCi/g) for comparison with NUREG–1500 values. NUREG–1500, Appendix A, Table A–1, ''Total Dose'' column contains the total dose calculated using a residential scenario, with default assumptions, and is based on 1 Pci/g of an isotope. To calculate a screening dose for the burial site, the above calculated exhumed concentration can be multiplied by the Appendix A values.

$$D\ \text{mrem/yr} = C\ \text{pCi/g} \frac{A\ \text{mrem/yr}}{\text{pCi/g}} \quad (3)$$

where

C=the concentration of a single isotope in the burial ground;
A=the NUREG–1500 Appendix A, Table A–1 dose for the same isotope; and
D=the dose from exposure to this isotope.

This calculation should be performed for all isotopes in the burial site. After the doses are estimated for each isotope, the doses should be totaled. If the total estimated dose is less than the 100 mrem/yr screening level, the site passes the screening and no further analysis is generally necessary for the site; however, extenuating circumstances may warrant further review. If the estimated dose is greater than 100 mrem/yr screening level, the site fails this screening analysis and the licensee will be required to perform additional site-specific analyses (Section 4.3.5). Example calculations are provided in Appendix C.

4.2.5 Results

If the site passes one of the steps above, the site would generally not require any further characterization or remediation. The licensee should submit the results of this screening, including a description of the site, as known, and copies of the calculations performed for this screening. This should be submitted to NRC, along with a statement concerning the licensee's intention to take no further actions at the site. In accordance with recordkeeping requirements, the licensee will be required to maintain these records until the NRC authorizes their disposal. Assuming that the licensee submitted the notification and analysis in a timely manner (as described in IN 96–47), NRC would then issue a letter stating that the licensee has complied with the Timeliness Rule and that the former burial is suitable for unrestricted release. It will then be determined by NRC and the licensee when the burial site would be released. This BTP is intended to be a final evaluation for former burials. Decisions made based on this BTP are not expected to change because of the issuance of future rules such as NRC's radiological criteria for license termination.

There may be instances where the licensee's calculations indicate the site passes the screening, but NRC determines the site requires more evaluation to consider additional hazards that may be associated with the waste. This would include sites which contain both radioactive and hazardous wastes. This methodology may determine the site is suitable for release based on the radioactive materials alone. However, the presence of hazardous chemical wastes may warrant additional evaluation to ensure protection of the public and the environment. This could also include sites where it is known the burial will be excavated in the future (i.e., the burial is in the path for a future road), sites with very limited burial records, and sites where there is other residual contamination outside of the burial area.

If the site fails Step 3 above, the licensee will be required to perform more specific characterization of the site. The details of the characterization process and the level of detail required will be determined on a case-by-case basis. NRC draft ''Branch Technical Position on Site Characterization for Decommissioning Sites,'' dated November 1994, contains a description of the type of site characterization information that could be required. In some cases, if the characterization information indicates that total activity in the burial site is less than the activity originally used in the screening method, this more realistic total activity can be used in the screening methodology. If the site then passes the screening using this new activity, the site would not require further evaluation. If the site fails again, then the licensee will have to work with NRC staff to develop a plan for additional actions to be taken at the site. Evaluations beyond this methodology may require site characterization information and a dose assessment. More detailed assessment of the environmental transport and potential doses should be conducted in accordance with Policy and Guidance Directive PG–8–08, ''Scenarios for Assessing Potential Doses Associated with Residual Radioactivity.'' In such cases, sites will be acceptable for unrestricted release, if projected doses are a small fraction of 100 mrem/yr and ALARA, considering corrective actions. The staff will consider the magnitude of the projected dose, and existing radiological criteria for decommissioning, in conjunction with

the objectives of keeping residual contamination levels ALARA, to determine if the waste may pose a significant risk to the public and the burial requires remediation.

It should be noted that the results of this screening are most affected by the quantity and quality of the records available to determine total inventory, and the assumptions used in determining the trench concentration. Slight variations in the trench size could be the difference between a site failing or passing the methodology.

4.3 Dose Screening Level and Basis

This methodology uses the public dose limit of 100 mrem/yr in Part 20 as a screening level for determining if a site poses a significant risk to the public. Although this is higher than the dose levels previously imposed for on-site burials (i.e., a few mrem/yr), the staff believes this is appropriate for screening these sites because of the high degree of conservatism built into the methodology and limitations of existing information.

Following the general screening model approach described in the National Council on Radiation Protection and Measurements (NCRPM) Report No. 123, dated January 22, 1996, Step 2 of this methodology assumes the total inventory in the burial ground is leached into the minimum quantity of water needed to meet the average water use of a family of four for 1 year (91 m^3). The dose is then calculated assuming an individual member of the family drank 2 liters/day of the 91 m^3 for 1 year. The use of 91 m^3 is also the screening default value used in NUREG/CR–5512, ''Residual Radioactive Contamination From Decommissioning'' (Table 6.22).

NRC staff analysis in NUREG–1500, Table A–1 contains estimated annual total effective dose equivalent factors. These dose factors indicate that there are cases, in which the inhalation of an isotope in a residential scenario would produce a larger dose than the ingestion of an equal amount of activity. It also indicates that the direct exposure pathway for some isotopes may be more limiting than either the ingestion or inhalation pathway. However, Appendix A, of this BTP, contains an analysis which demonstrates that the ingestion scenario, as used in this methodology, is so restrictive that inhalation and direct exposure calculations are not necessary.

The staff considers the assumptions used in this ingestion scenario to overestimate likely doses to potential members of the public, such as: (1) There has been no migration from the burial so that the total inventory originally placed in the burial remains; (2) the entire inventory leaches into the groundwater in a one-year period; (3) someone moves onto the site, and places a well near the burial ground that would capture all of the contaminated water; (4) there is no sorption of the radionuclide during transport and only limited dilution and dispersion; (5) a single individual drinks only well water from the site for that year. As shown in the example given later in this section, more likely doses to a hypothetical individual would be a small fraction of the doses estimated in this methodology and would likely be in the range of a few millirem per year if the dose using this methodology is less than 100 mrem/yr.

Step 3 of this methodology assumes that a farmer lives on top of the burial ground at some point in the future. This scenario also contains several conservative assumptions such as: (1) There has been no migration from the burial so that the total inventory originally placed in the burial remains; (2) that an intruder inadvertently digs into the waste and brings the entire inventory to the surface; and (3) the intruder fails to recognize the waste. These are assumptions used in developing the exhumed concentrations. There are also several conservative assumptions contained in the dose conversion factors developed for soils in NUREG–1500, which are used in this step to estimate screening doses.

NUREG–1500 uses a family farm scenario, in which an individual lives on the site, drinks water from an on-site well, and ingests 25 percent of his/her food from a garden, on-site. The resident's house and garden are assumed to be in the contaminated area, and the garden alone is assumed to be 2500 m^2 (NUREG/CR–5512, Table 6.23). Therefore, to contain the house and garden, the contaminated area has to be larger than 2500 m^2. Many of the on-site disposals that have been reviewed by NRC in the past have had areas less than 2500 m^2. These sites are generally too small to contain a house and a garden, and, since they are smaller than those used in NUREG–1500, would likely produce a smaller dose than predicted using NUREG–1500 values. Therefore, based on the conservative assumptions used in both estimating the soil concentration, and estimating the doses, the actual doses produced from a site are expected to be a small fraction of the screening doses predicted using this methodology.

The following example of a Cs-134 burial is used to illustrate the level of conservatism in these scenarios. Assuming a burial contains 270 µCi[2] of Cs-134, the resulting dose for the ingestion scenario in Step 2 equals approximately 160 mrem/yr. If this same inventory is evenly distributed in a trench which is 5m x 2m x 1m, the exhumation concentration is calculated to be 4.2 pCi/g Cs-134 based on Step 3. Using NUREG–1500, this results in a dose of approximately 13 mrem/yr. As an independent check, a RESRAD analysis was also performed using a concentration of 4.2 pCi/g Cs-134 and a contaminated zone area of 5m x 2m, but no other site specific information. This analysis produced a dose of 7 mrem/yr (assuming no soil cover and that the groundwater was within 2 meters of the bottom of the burial). Therefore, although the scenarios in this methodology can predict elevated doses, they are only for screening purposes and do not necessarily reflect actual doses which could be produced from the site. The projected doses calculated using a more rigorous approach are a small fraction of 100 mrem/yr screening level.

Appendix A—Analysis of Other Pathways

There are only a limited number of isotopes for which the inhalation pathway is more limiting than the ingestion pathway for the residential scenario in NUREG–1500, Appendix A, Table A–1. For all of these, however, the direct exposure pathway is even more limiting than either the inhalation or ingestion pathways. The staff created the ingestion pathway scenario used in this methodology to be so restrictive, that even for isotopes which are primarily an external hazard (e.g., Co-60), the dose produced, based on ingestion, is higher than one produced using an external scenario, as in NUREG–1500.

Based on calculations performed using Step 3 of this BTP and the RESRAD, version 5.1, the dose modeling code, Step 2 of this methodology produces a higher screening dose, and, therefore, is more restrictive than the other two methods. Since both Step 3 and RESRAD consider all pathways, including direct exposure, in the dose calculations, if Step 2 doses are high then the other pathways do not need to be considered independently. To demonstrate this, it was assumed that there was a burial trench which

[2] NRC's standard metrification policy is to place metric units first, followed by non-metric units in parentheses. However, the supporting tables for this BTP (i.e., 10 CFR Part 20, Appendix B) are presented in non-metric units, therefore, for comparison purposes non-metric units are used in this BTP. A conversion table is contained in Appendix B.

contained a total activity of 270 μCi of Co–60. Co–60 was chosen because NUREG–1500 indicates it produces the largest external dose per pCi/g. It was assumed that the entire inventory of the burial was contained in a relatively small trench, with an area of 10 m^2 and depth of 1 meter. This area was used to be consistent with the contaminated zone area used in the Step 3 screening of this BTP. It was assumed that the groundwater was within 1 meter of the bottom of the burial, and that there was no cover on the material. If the total activity is used in Step 2, a screening dose of 48 mrem/yr is estimated. Step 3 of the screening estimates a dose of approximately 40 mrem/yr, and a RESRAD analysis predicts 18 mrem/yr. A RESRAD analysis using more site specific parameters (i.e., cover thickness, depth to groundwater) would likely reduce this dose even further.

Appendix B—Metric Conversion Table

Quantity	From	To metric	Multiply by
Activity	Ci (curie)	MBq (becquerel)	37,000.0
Dose equivalent	rem	Sv (sievert)	0.01
Length	ft (feet)	m (meter)	0.3048
Volume	ft^3	m^3	0.02831685
Volume	gal (gallon)	L (liter)	3.785412

Appendix C—Sample Calculations

1.0 Example Site No.1

This site contains 1–3 animal carcasses that were tagged with 41 millicuries (mCi) Cs–134, 10.5 Mci Fe–55, 60 Mci Zn–65, 2.7 Mci Co–60 and 25 Mci I–125. These animals were placed in a 5m×2m×1m burial pit in 1980.

1.1 Step 1—Records Review

No burial records were available to determine how many of the tagged animals were placed in the pits. There were records on the number of animals tagged, and the maximum activity that was used to tag these animals. Therefore, the maximum activity of each isotope was used to estimate the total inventory. The burial has been in place for 15 years, which is sufficient time for Zn–65 and I–125 to decay to insignificant activities. Therefore, they can be excluded from consideration. The calculated activities for the remaining isotopes are adjusted for decay.

Isotope	μCi
Cs–134	270
Fe–55	233
Co–60	376

1.2 Step 2—Groundwater Pathway

The total inventory for each isotope was divided by 9.1E7 ml (91 m3) of groundwater. This represents the concentration in μCi/ml of that isotope which could be ingested by a person in 1 year.

Isotope	μCi	μCi/ml(water)
Cs–134	270	2.9E–6.
Fe–55	233	2.5E–6.
Co–60	376	4.1E–6.

This concentration was then compared to Part 20, Appendix B, Column 2, limits. These limits represent concentrations in effluent releases which could cause doses of approximately 50 mrem/yr assuming ingestion of 2 liters per day. The Appendix B ratio of concentration to dose was used to determine roughly the dose that could be produced from the waste concentrations in groundwater. For example,

$$D\ \text{mrem/yr} = \frac{(2.9\text{E-}6\ \mu\text{Ci/ml Cs-}134)(50\ \text{mrem/yr})}{(9\text{E-}7\ \mu\text{Ci/ml Cs-}134)}$$

161 mrem/yr from Cs–134

This calculation was preformed for the remaining two isotopes and the results are included in the following table.

APPENDIX B

Isotope	μCi	μCi/ml	μCi/ml/50 mrem/yr	mrem/yr
Cs–134	270	2.9E–6	9E–7	161
Fe–55	233	2.5E–6	1E–4	1.25
Co–60	376	4.1E–6	3E–6	68

The doses were summed and the result was a dose of over 230 mrem/yr. This dose exceeds the 100 mrem/yr screening level, and, therefore, this site fails Step 2 of the screening methodology. Since this burial did not contain any isotopes greater than atomic number 88, Step 3 was performed.

1.3 Step 3—Exhumation Concentration

In this step, the total inventory was averaged over the volume of the burial ground, which is 5 m x 2 m and 1 meter deep or equivalent to 1.6E7 grams of waste and soil assuming a soil density of 1.6 g/cm3 to determine an average concentration (activity per cm3). This concentration is then converted into pCi/g for comparison with NUREG–1500 values in Table A–1 and divided by 4 to represent expected dilution from cover material and clean soil on the sides during exhumation.

$$\text{Trench Concentration} = \frac{(270\ \mu\text{Ci Cs-134})(1\text{E}6\ \text{pCi}/\mu\text{Ci})}{(1.6\text{E}7\ \text{g})}$$

Trench Concentration = 17 pCi/gram

$$\text{Exhumation Concentration} = \frac{17\ \text{pCi/g}}{4}$$

Exhumation Concentration = 4.2 pCi/g

Isotope	pCi	pCi/gram
Cs–134	2.7E8	4.2
Fe–55	2.3E8	3.5
Co–60	3.8E8	5.7

These concentrations were then compared to NUREG–1500 values in Table A–1, Column 9, for the total dose in mrem/yr, as follows:

D mrem/yr = (4.2 pCi/g Cs–134)(3.06 mrem/yr), where NUREG–1500 relates 3.06 mrem/yr to 1 pCi/g Cs–134

D = 12.8 mrem/yr from Cs–134

This calculation was performed for the remaining two isotopes, and the results are summarized in the following table.

NUREG–1500

Isotope	pCi	pCi/gram	mrem/yr/pCi/g	mrem/yr
Cs–134	2.7E8	4.2	3.06	12.8
Fe–55	2.3E8	3.5	1.65E–3	0.006
Co–60	3.8E8	5.7	5.06	28.78

Based on the above calculations, the total dose is approximately 40 mrem/yr and is less than 100 mrem/yr. Therefore, this site passes screening Step 3 and does not require any further characterization nor remediation.

2.0 Example Site No. 2

This site contains process waste from the manufacture of uranium fuel. The burial contains approximately 3 curies of uranium in several trenches. The material was placed in trenches throughout the 1960s.

2.1 Step 1—Records Review

Burial records were available and reviewed to determine that approximately 3 curies of uranium were disposed of in trenches. For this example, it was assumed that there was 0.5 curies of U–234 and 2.5 curies U–238. Approximately 27 years have passed since the time of the last burial, which is insufficient time for either uranium to have decayed. Therefore, they cannot be excluded from consideration, and the calculations will be performed with the quantities cited above.

Isotope	µCi
U–234	5E5
U–238	2.5E6

2.2 Step 2—Total Activity Ingested From Groundwater

The total inventory for each isotope was divided by 9.1E7 ml (91 m3) of groundwater. This represents the concentration in µCi/ml of that isotope that could be ingested by a person in 1 year.

Isotope	µCi	µCi/ml
U–234	5E5	0.005
U–238	2.5E6	0.027

This concentration was then compared to Part 20, Appendix B, Column 2, limits. These limits represent concentrations in effluent releases that could cause doses of approximately 50 mrem/yr. The Appendix B ratio of concentration to dose was used to determine, roughly, the dose that could be produced from the waste concentrations in groundwater. For example,

$$\text{D mrem / yr} = \frac{(0.005\ \mu\text{Ci/ml U-234})(50\ \text{mrem/yr})}{(3\text{E-}7\ \mu\text{Ci/ml U-234})}$$

8E5 mrem/yr from U–234

This calculation was performed for the remaining two isotopes, and the results are included in the following table.

Isotope	µCi	µCi/ml	App B µCi/ml	mrem/yr
U–234	5E5	0.005	3E–7	8E5
U–238	2.5E6	0.027	3E–7	4.5E6

The doses are well over the 100 mrem/yr screening level, and, therefore, this site fails Step 2 of the screening methodology.

2.3 Step 3—Exhumation Concentration

This site contains isotopes that have atomic numbers greater than 88, and, therefore, cannot be used in Step 3. Since this site failed Step 2 and cannot be used in Step 3, this site fails this screening methodology.

[FR Doc. 96–28223 Filed 11–01–96; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for OMB Review; Comment Request for Revision of Information Collection; SF 2809

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13, May 22, 1995), this notice announces that the Office of Personnel Management will submit to the Office of Management and Budget a request for reclearance of the following information collection. SF 2809, Health Benefits Registration Form, is used by annuitants under Federal retirement systems other than the Civil Service Retirement System and the Federal Employees Retirement System and by the former spouses of Federal employees and annuitants to register for and change enrollment in the Federal Employees Health Benefits Program. SF 2809 is needed to verify entitlement and to effect premium withholdings.

Approximately 9,000 SF 2809 forms will be processed each year from former spouses and annuitants from other retirement systems. Each form takes approximately 30 minutes to complete. The annual estimated burden is 4,500 hours.

For copies of this proposal, contact Jim Farron on (202) 418–3208, or E-mail to jmfarron@mail.opm.gov

DATES: Comments on this proposal should be received on or before December 4, 1996.

ADDRESSES: Send or deliver comments to—

Kenneth H. Glass, Chief, Insurance Operations Division, Retirement and Insurance Service, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3415, Washington, DC 20415–0001

and

Joseph Lackey, OPM Desk Office, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW, Room 3002, Washington, DC 20503.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Mary Beth Smith-Toomey, Management Services Division, (202) 606–0623.

U.S. Office of Personnel Management.

Lorraine A. Green,

Deputy Director.

[FR Doc. 96–28219 Filed 11–1–96; 8:45 am]

BILLING CODE 6325–01–M

The National Partnership Council Meeting

AGENCY: Office of Personnel Management.

ACTION: Notice of meeting.

TIME AND DATE: 1:00 p.m., November 13, 1996.

PLACE: OPM Conference Center, Room 1350, Theodore Roosevelt Building, 1900 E Street, NW., Washington, DC 20415–0001. The conference center is located on the first floor.

STATUS: This meeting will be open to the public. Seating will be available on a first-come, first-served basis. Individuals with special access needs wishing to attend should contact OPM at the number shown below to obtain appropriate accommodations.

MATTERS TO BE CONSIDERED: There will be a presentation of National Partnership Council (NPC) information on the World Wide Web and a discussion of the NPC's strategic action plan for calendar year 1997.

CONTACT PERSON FOR MORE INFORMATION: Michael Cushing, Director, Center for Partnership and Labor-Management Relations, Office of Personnel Management, Theodore Roosevelt Building, 1900 E Street, NW., Room 7H28, Washington, DC 20415–0001, (202) 606–0010.

SUPPLEMENTARY INFORMATION: We invite interested persons and organizations to submit written comments. Mail or deliver your comments to Michael Cushing at the address shown above. To be considered at the November 13 meeting, written comments should be received by November 8.

Office of Personnel Management

James B. King,

Director.

[FR Doc. 96–28218 Filed 11–1–96; 8:45 am]

BILLING CODE 6325–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–37885; File No. SR–CBOE–96–55]

Self-Regulatory Organizations; Order Granting Permanent Approval of a Pilot Program Proposed by Chicago Board Options Exchange, Incorporated Relating to its System for Suspending the Retail Automatic Execution System for Equity Options in the Event of News Announcements Near the Close of Trading

October 29, 1996.

I. Introduction

On August 14, 1996, the Chicago Board Options Exchange, Incorporated (''CBOE''), filed a proposed rule change with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b-4 thereunder,[2] to seek permanent approval of a program for suspending the Exchange's automatic execution system in the event of news announcements near the close of trading, as described in Interpretation and Policy .01 under CBOE Rule 6.6.

Notice of the proposal was published for comment and appeared in the Federal Register on August 21, 1996.[3] On October 17, 1996, the Exchange filed with the Commission, Exhibit A to the proposal which sets forth the text of the proposed rule change.[4] No comment letters were received on the proposed rule change. This order approves the Exchange's proposal.

II. Description of the Proposal

The Exchange proposes to make permanent the Exchange's system that suspends its Retail Automatic Execution System (''RAES'') in the event of news announcements near the close of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] The Commission concurrently granted accelerated approval of the Exchange's request to extend the program pending consideration of the request for permanent approval. *See* Securities Exchange Act Release No. 37577 (August 15, 1996), 61 FR 43281 (''Release No. 37577'').

[4] Exhibit A was mistakenly omitted from the original proposal. The exhibit reflects minor and non-substantive changes to Interpretation and Policy .01 under CBOE Rule 6.6. The changes to the text of the proposed rule, as originally proposed in SR–CBOE–96–37, merely eliminate words associated with the pilot status of the program. *See* Letter from Michael Meyer, Attorney, Schiff Hardin & Waite, to John Ayanian, Attorney, Office of Market Supervision (''OMS''), Division of Market Regulation (''Market Regulation''), Commission, dated October 15, 1996 (''CBOE Letter'').

trading, as described in Interpretation .01 under CBOE Rule 6.6.[5]

The automatic RAES suspension system is designed to respond to the problem presented when issuers of stocks underlying options make significant news announcements during the ten minutes after the close of trading in stocks when options continue to trade.[6] The system monitors news wires during this period, and automatically suspends RAES in options on stocks that are the subject of such announcements in order to prevent automatic executions at prices that do not reflect the news. This program has been in place on a pilot basis since July 1, 1996.

Based on its experience with the pilot operation of the system, the Exchange has now determined to propose its adoption on a permanent basis. During the first four weeks of the pilot operation of the system, the Exchange believes that it performed as intended to suspend RAES in particular classes of options each time there was a news announcement pertaining to an underlying stock during the period of time when options continued to trade after the close of trading in underlying stocks. The Exchange submitted a report of the operation of the pilot from July 1, 1996 through July 26, 1996 to the Commission. The report shows that during this period, RAES was suspended a total of 90 times and was reinstated after suspension 36 times. Although the news announcements covered a range of subjects, at least 15 were earnings reports, evidencing that many issuers continue to release such news after the close of stock trading while options continue to be traded. Of the 90 suspensions, 26 were in classes in which there were RAES-eligible orders after the suspension. Of the 132 RAES-eligible orders in these classes, 69 were executed after RAES was reactivated (63 of which related to a single suspension and subsequent reactivation of RAES in connection with the release of earnings for IBM), and 63 were rerouted as follows: to PAR terminals (30 orders), to printers at the post (4 orders), to members' booths (22 orders), or to the limit order book (7 orders). Forty-five of these rerouted orders (71%) were filled in the auction market. Eighteen orders during the pilot period expired unfilled. The orders that expired unfilled were marketable limit orders submitted at or after the close of stock trading, that were not longer marketable in the auction market following the RAES suspension for the subject options classes.[7] The Exchange believes that the system appears to have worked as intended to prevent the execution of these orders at inappropriate prices, while permitting most orders to be executed at prices established in the auction market. The Exchange notes that reactivation of RAES was generally not a significant factor in the execution of these orders (with the one exception of the IBM orders noted above), because most had already been executed in the auction market by the time RAES was reactivated.

III. Commission Finding and Conclusions

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Section 6(b)(5) of the Act.[8] Specifically, the Commission finds that the Exchange's proposal strikes a reasonable balance between the Commission's mandates under Section 6(b)(5) to remove impediments to and perfect the mechanism of a free and open market and a national market system, while protecting investors and the public interest.

The Commission believes that the proposed rule change provides a reasonable method of suspending RAES for a limited period in a particular options class that is subject to a news announcement near the close of trading in the underlying security. The Commission notes that the Exchange has not reported any significant problems with the operation of the system to date. Upon reviewing the Exchange's report regarding the operation of the system during the pilot, the Commission believes that the proposed system should help to prevent the execution of trades at inaccurate quotes while continuing to ensure prompt and accurate execution of customer orders in the particular class subject to a news announcement.

The Commission also believes that the proposed rule change is reasonable because during the time when options continue to be traded after the close of trading in the primary market for underlying stocks (1) RAES executions will still be available in classes of options not subject to news announcements; and (2) orders for an options class subject to a news announcement that would have been routed to RAES will be automatically re-routed to a PAR workstation, a floor broker printer in the trading crowd, or to the appropriate member firm booth, where they can be immediately executed at the then current price. Accordingly, the Commission believes that the Exchange's electronic Order Routing System should provide small investors an efficient and effective method for order execution in circumstances where RAES is turned off pursuant to this proposed rule change.

The Commission expects the Exchange to monitor the system and ensure that (1) the system responds to *news* announcements, and if the system responds to an item disseminated over the wires that is not ''news'' related, that RAES operations for the particular options class will be resumed as soon as possible;[9] (2) if there is enough time before the close of options trading, and if options prices have been adjusted to reflect the current state of the market, that Floor Officials will resume RAES operations for the subject options class; and (3) market orders and marketable limit orders that are still marketable, receive efficient and accurate executions after being re-routed in the manner described above.

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[5] The 30-day pilot was proposed in File No. SR–CBOE–96–37. *See* Securities Exchange Act Release No. 37380 (June 28, 1996). The pilot was extended for an additional 15 days in File No. SR–CBOE–96–53. *See* Securities Exchange Act Release No. 37505 (July 31, 1996). The pilot was then extended pending Commission review of the Exchange's request for permanent approval. *See* Release No. 37577, *supra* note 3.

[6] CBOE may soon propose reducing to five minutes the time when options continue to trade after the close of stock trading. So long as options trade for any period of time after the close of stock trading, CBOE believes it would need to maintain the system for suspending RAES in the event of news announcements during this period. Only if options trading and stock trading close concurrently would there be no need for such a system. CBOE does not support concurrent closings because this would not allow time for closing options prices to be determined based on closing stock prices, or for participants to open or close options positions for hedging purposes based on closing stock prices. For a more detailed discussion of the reasons for continuing to trade options after the close of trading in the primary markets for underlying stocks and the problems this presents for RAES, *see* the discussion in SR–CBOE–96–37, which proposed the initial 30-day pilot in the system that is the subject of this filing, notice of which was given in Securities Exchange Act Release No. 37380 (June 28, 1996).

[7] Telephone conversation between Mike Meyer, Attorney, Schiff Hardin & Waite, and Holly Smith, Associate Director, and John Ayanian, Attorney, OMS, Market Regulation, Commission, on August 15, 1996.

[8] 15 U.S.C. 78f(b)(5).

[9] For example, block transactions in a given stock are sometimes disseminated by a news service. When this occurs near or after the close of trading, the identification of the stock triggers an automatic suspension of RAES under the system. The CBOE has indicated that in such circumstances, RAES will be immediately reactivated, if time remains before the close of options trading. *See* CBOE Letter, *supra* note 4.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (File No. SR–CBOE–96–55) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–28181 Filed; 11–1–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–37878; File No. SR–CBOE–96–64]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the Chicago Board Options Exchange, Inc., Relating to Listing and Delisting Standards for Debt Securities

October 28, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''), 15 U.S.C. § 78s(b)(1), notice is hereby given that on October 22, 1996, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. CBOE submitted Amendment No. 1 to the filing on October 25, 1996 to clarify rule language.[1] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to revise its standards for the listing and delisting of debt securities to conform to those of other securities exchanges. The text of the proposed rule change is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to permit the Exchange to conform the Exchange's listing and delisting standards for debt securities to those of the American Stock Exchange (''AMEX'') and New York Stock Exchange (''NYSE''). The Exchange proposes to revise the listing and delisting standards set forth in Rule 31.5 so that the listing and delisting standards are substantially similar to those that now exist for the NYSE and AMEX. The Commission approved substantially similar standards for listing bonds and debentures for the AMEX and NYSE in Securities Exchange Act Release No. 36594 (December 14, 1995) (''Release No. 36594'') (approval of AMEX proposal to revise debt listing standards) and Securities Exchange Act Release No. 34019 (May 5, 1994) (approval of NYSE proposal to revise debt listing standards). The NYSE and the AMEX stated that the purpose of the revisions to their debt listing standards was to facilitate the exchange listing of debt securities and to provide debtholders with a transparent auction market for secondary trading.

Original Listing Standards

CBOE Rule 31.5 provides that the Exchange will consider listing bonds and debentures if: (1) the issuer meets the net worth and earnings criteria for equity issues (Rule 31.5A) and appears to be able to satisfy interest and principal when due; (2) the issuer meets the size and earnings criteria applicable to issuers listing common stock; and (3) the issue has an aggregate market value and principal amount of at least $5 million for issuers that have common stock listed on the Exchange, AMEX or NYSE, or at least $20 million and 100 holders for issuers that do not have securities listed on the Exchange, AMEX or NYSE.[1]

The Exchange proposes to replace its listing criteria for debt securities with standards similar to those of AMEX and the NYSE. Under the proposed standards, if an issuer has equity securities listed on the Exchange, AMEX or NYSE, and is in ''good standing,'' [2] the Exchange will ordinarily list that issuer's debt securities as long as the debt issue has an aggregate market value or principal amount of at least $5 million. If the issuer does not have equity securities listed on the Exchange, AMEX or NYSE, the Exchange will rely on the analyses of nationally recognized securities rating organizations (''NRSROs''), such as Standard & Poor's or Moody's.[3]

Specifically, the Exchange proposes to make the following changes to Rule 31.5 of the Exchange's rules:

A. Eliminate the requirement that an issuer of debt satisfy net worth and earnings standards applicable to issuers listing common stock. [Proposed Rule 31.5.C.(1)].

B. Eliminate the requirement that an issuer demonstrate that it is able to satisfy interest and principal when due. [Proposed Rule 31.5.C.(1)].

C. Permit the Exchange to list a debt issue if it has an aggregate market value or principal amount of at least $5 million. [Proposed Rule 31.5.C.(1)].

D. Permit the Exchange to list debt securities that are issued or guaranteed by an issuer which has equity securities listed on the Exchange, AMEX or NYSE. [Proposed Rule 31.5.C.(2)(a)]. Alternatively, the issuer of debt securities may list on the Exchange if a majority interest of the issuer of debt is directly or indirectly owned, or under common control with the issuer of equity securities listed on the Exchange, AMEX or NYSE. [Proposed Rule 31.5.C.(2)(b)].

E. Eliminate the public distribution requirement that listed and non-listed issuers have at least 100 holders. [Proposed Rule 31.5.C.(2)].

F. In lieu of the criteria specified in D above, permit the Exchange to list the debt securities of an issuer if an NRSRO has assigned a current rating to the debt security that is no lower than an S&P Corporation ''B'' rating (i.e., B- or better) or the equivalent rating of another NRSRO. A ''B'' rating indicates that the debt issuer currently has the capacity to meet interest payments and principal repayments, and that such capacity is not dependent upon favorable business, financial or economic conditions. If no NRSRO has assigned a rating to the issue, an NRSRO must have currently

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[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

[1] *See* Letter from Janet Angstadt, Schiff Hardin & Waite, to Michael Walinskas, SEC, dated October 25, 1996.

[1] CBOE's listing and delisting standards for common stock are substantially identical to those of AMEX.

[2] An issuer is in ''good standing'' if the issuer is in compliance with the relevant Exchange, AMEX or NYSE standards for continued listing.

[3] As noted by the AMEX in its proposed rule filing, the Exchange will not conduct a review to determine whether the issuer satisfies its original equity listing guidelines or, as the case may be, those of the AMEX or NYSE.

assigned either an investment grade rating (i.e., an S&P or equivalent rating no lower than ''BBB−'') to a senior issue or a rating that is no lower than an S&P) ''B'' rating (or equivalent) to a pari passu or junior issue. [Proposed Rule 31.5.C.(21)(d)].

Suspension and Delisting Policies

Exchange Rule 31.94 sets forth the minimum criteria which a security must meet to continue to be listed on the Exchange. Under Exchange Rule 31.94 as proposed, the Exchange will consider delisting a debt issue if (1) its aggregate market value or principal amount is less than $400,000 or (2) if the debt issuer is unable to meet its obligations on the listed debt securities. The standards in Rule 31.94(b)(iii) will permit, but not require, the delisting of the bond or debenture if the debt issuer fails to meet the criteria set forth in the rule. Consistent with policy statements adopted by the Amex, in applying these standards, the Exchange will normally not delist the debt if there is value in the security and continued Exchange trading is in the best interests of investors. However, if an issuer is unable to meet its financial obligations and there is minimal or no value in the security, the Exchange will give serious consideration to delisting the bond issue.

As stated in Rule 31.94.C, the criteria set forth in the rule in no way restricts the Exchange's right to delist a security, and the Exchange may at any time delist a security from listing when in its opinion such security is unsuitable for continued trading on the Exchange. The determination of whether a debt security is suitable for exchange trading would include whether or not there were sufficient holders of the debt security.

In the case of debt securities which are convertible into equity securities, the Exchange proposes to review the continued listing of the debt security when the underlying equity security is delisted. The Exchange will delist the convertible bond when the underlying equity security is no longer subject to real-time trade reporting or if the Exchange delists the underlying equity security for violation of certain specified Exchange rules related to corporate governance (Exchange Rules 31.9—31.14).

Listing Procedures

The Exchange also proposes to reduce the number of supporting documents that an applicant must file in support of its debt listing application. In proposing similar changes, the AMEX stated that its review of the listing process revealed that ''several documents were either unnecessary, duplicative or unduly burdensome to issuers.''[4] The Exchange proposes the following changes to conform Exchange procedures to those of the AMEX:

A. *Form 5—Distribution of Bonds.* Since the Exchange is proposing to eliminate the requirement that debt securities have 100 holders, Form 5 will no longer be necessary.

B. *Trustee's Certificate.* The Exchange currently requires a certificate from the trustee which shows (i) acceptance of the trust; (ii) that the securities have been issued in accordance with the terms of the indenture; (iii) what disposition has been made of securities redeemed or refunded; (iv) that pledged collateral has been deposited; and (v) what disposition has been made of prior obligations. In its filing proposing revisions to the Trustee's Certificate, the AMEX stated that ''[i]ssuers often complain that it is unduly burdensome for them to obtain the trustee's certificate because many trustees are reluctant to certify the issuer-specific information'' required by Items (ii)–(v).[5] Therefore, the AMEX proposed to require that the certificate show only the trustee's acceptance of the trust. The Exchange proposes to conform its practice to that of the AMEX and therefore require that the certificate show only the trustee's acceptance of the trust.

C. *Listing Resolution.* The Exchange currently requires bond issuers to obtain a resolution of the board of directors authorizing the filing of the listing application. In its filing proposing revisions to the listing resolution, the AMEX stated that ''[t]his requirement is often burdensome to comply with, and can delay a listing if the company's board is not scheduled to meet for a month or more.'' The AMEX further stated that ''[t]he requirement to obtain a listing resolution is essentially ceremonial in nature and does not serve any significant purpose.''[6] The Exchange proposes to conform its practice to that of the AMEX.

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act in general and furthers the objectives of Section 6(b)(5) in particular in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change, as amended: (1) does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) was provided to the Commission for its review prior to the filing date,[7] the rule change proposal, as amended, has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(e)(6) thereunder.

A proposed rule change filed under Rule 19b–4(e) does not become operative prior to thirty days after the date of filing or such shorter time as the Commission may designate if such action is consistent with the protection of investors and the public interest. CBOE has requested that the Commission accelerate the implementation of the proposed rule change so that it may take effect prior to the thirty days specified under Rule 19b–4(e)(6)(iii). In particular, the Commission believes the proposal qualifies as a ''noncontroversial filing'' in that the proposed amendments do not significantly affect the protection of investors or the public interest and do not impose any significant burden on competition. In making this determination, the Commission notes that the rule change makes CBOE's debt listing standards almost identical to those of other exchanges, which were approved and found by the Commission to be consistent with Section 6(b)(5) of the Act.[8] Accordingly, the Commission finds that the proposed rule change, as amended, is consistent with the protection of investors and the public interest and therefore has determined to

[4] *See* Release No. 36594.

[5] Id.

[6] Id.

[7] Although there is usually a five day pre-filing requirement for rule changes submitted pursuant to Rule 19b–4(e)(6), subsection (iii) authorizes the Commission to shorten this pre-filing requirement.

[8] *See, e.g.,* Release No. 36594.

make the proposed rule change operative as of the date of this order.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provsisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to File No. SR–CBOE–96–64 and should be submitted by November 25, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–28182 Filed 11–1–96; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–37876; File No. SR–CBOE–96–15]

Self-Regulatory Organizations; Chicago Board Options Exchange, Inc.; Order Approving a Proposed Rule Change Relating to the Placing of Orders Over the Outside Telephone Lines at the Equity Trading Posts

October 28, 1996.

I. Introduction

On March 12, 1996, the Chicago Board Options Exchange, Inc. (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposal to amend its Regulatory Circular governing the use of member-owned or Exchange-owned telephones located at the equity trading post on the floor of the Exchange. The proposed rule change was published for comment and appeared in the Federal Register on April 8, 1996.[3] No comments were received. This order approves the proposal.

II. Description of the Proposal

CBOE Rule 6.23[4] currently prohibits orders of any type to be entered via outside telephone lines at equity option trading posts.[5] The rule change would amend this prohibition by permitting market makers only to place orders with floor brokers over the outside telephone lines at equity option trading posts.[6] The policy for use of the telephones at the equity posts will remain unchanged in every other respect. Thus, for example, customers will not be permitted to place orders over the telephones located at the equity posts.

In its filing, the Exchange stated that the purpose of the proposed rule change was to permit market makers to transmit their orders more efficiently even when they need to be off the floor to attend to personal or Exchange business. The Exchange stated in its filing that this change will be particularly useful to those members of the Exchange that are often requested to attend meetings on Exchange matters during the trading day.

Orders of market makers placed over the outside telephone lines pursuant to the amended policy will be counted as off-floor orders for purposes of determining a market maker's compliance with the 80% requirement of Rule 8.7. Pursuant to Interpretation .03 of Rule 8.7, Obligations of Market-Makers, a market maker must execute in-person 80% of his total transactions to receive market maker treatment for off-floor orders. An order that receives market maker treatment is entitled to certain benefits, such as favorable margin treatment under Federal Reserve Board Regulation T; therefore, there is an incentive for market makers to satisfy the 80% requirement. Also, Interpretation .03 of Rule 8.7 states that the off-floor orders for which a market maker receives market maker treatment shall be effected for the purpose of hedging, reducing risk of, rebalancing, or liquidating open positions of the market maker. Finally, Interpretation .03 to Rule 8.7 also requires a market maker, at a minimum, to execute at least 25% of his total transactions in-person.

As with the current policy governing the use of telephones at the equity trading posts, the Exchange intends to monitor compliance with these conditions by means of customary floor surveillance procedures, including reliance on surveillance by Floor Officials and Exchange employees. In addition, the Exchange will review on a weekly basis clearance data, as it does now, to assure that a market maker meets the 80% in-person requirement.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Section 6(b)(5) of the Act,[7] in that it is designed to promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, prevent fraudulent and manipulative acts and practices, and, in general, to protect investors and the public interest; and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Commission believes that the proposed rule change may allow market makers more efficient access to equity option posts when they are off the Exchange floor temporarily which could potentially enhance liquidity. In this context, under CBOE Rule 8.7(a), any orders placed by a market maker over the outside telephone lines at the equity post should constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market. As noted above, the other requirements of Rule 8.7 should also help to ensure that access to place orders over the outside telephone lines

[9] 17 CFR 200.30–3(a)(12) (1994).

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 37050 (March 29, 1996), 61 FR 15542.

[4] Exchange Rule 6.23 prohibits members from establishing or maintaining any telephone or other wire communications between their offices and the Exchange floor, and it authorizes the Exchange to direct the discontinuance of any communication facility terminating on the Exchange floor.

[5] *See* Securities Exchange Act Release No. 33701 (March 2, 1994), 59 FR 11336 (March 10, 1994) (order approving the Exchange's equity options telephone policy).

[6] Currently, the Exchange permits market makers to place orders with floor brokers via intra-floor lines.

[7] 15 U.S.C. § 78f(b)(5) (1988).

will not be used as a method to avoid standing in the crowd and fulfilling market making duties.

The Commission notes that the policy does differentiate between market makers and customers in that the amended policy will continue to prohibit customers from placing orders with floor brokers over the outside telephone lines. By contrast, customers are permitted direct telephone access to enter orders with floor brokers in the trading crowds of certain CBOE index options.[8] However, the Commission believes that it is not unreasonable for CBOE to prohibit customers from placing orders directly with floor brokers in equity options trading crowds. The CBOE has represented to the Commission that CBOE members may not wish that their customers receive direct phone access to equity crowds because equity options tend to be used more widely by retail customers: direct phone access may inhibit member firms' ability to discharge their customer suitability and margin obligations.[9] Furthermore, member firms do not commonly station a floor-broker in each equity trading crowd on the floor.[10] Floor brokers commonly are responsible for representing orders in multiple crowds, which means that customers are less likely to be able to direct orders to a particular floor broker in a particular crowd.[11]

Furthermore, CBOE offers automated systems that permit member firms to ensure that customer orders are swiftly routed to the floor of the exchange.[12] Approximately 70% of customer orders are routed through CBOE's Order Routing System (''ORS''), which provides an electronic interface between the Exchange's trading systems and the member firms' order transmission systems.[13] In summary, because customer orders can be transmitted quickly to the post through other means, direct customer telephone access may cause compliance problems for members firms while offering uncertain access to the trading crowd and because the Commission has not received any comments about alleged unfair discriminatory effects objecting to the proposed rule change, the Commission believes it is reasonable to conclude that the amended telephone policy is not presently designed to permit unfair discrimination.[14]

The Commission expects the CBOE to maintain surveillance procedures that are adequate to ensure that market makers do not use the amended telephone policy to avoid standing in their respective crowds or to assume de facto an appointment in an option traded at another post. In addition, the Commission believes that the 80% in-person requirement will serve to discourage market makers from utilizing the amended telephone policy to avoid standing in their respective crowds or to assume de facto an appointment in an option traded at another post.

IV. Conclusion

For the reasons discussed above, the Commission finds that the proposal is consistent with the Act, and, in particular, Section 6 of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[15] that the proposed rule change (File No. SR–CBOE–96–15) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–28183 Filed 11–1–96; 8:45 am]

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[8] *See* Letter from Mary L. Bender, Senior Vice President, CBOE, to Sharon Lawson, Senior Special Counsel, Division of Market Regulation, Commission, dated October 18, 1996 (available in Commission's Public Reference Room).

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *See id.*

[13] *See id.* ORS routes customer orders that qualify for firm quote guarantees to the Retail Automatic Execution System (''RAES''), which automatically and instantaneously executes such orders. According to CBOE, approximately 1 out of 5 customer orders at the CBOE are executed through RAES. ORS routes pre-opening market orders and limit orders, and limit orders at least one price tick away from the same-side market quote to the Exchange's Electronic Book. Finally, ORS routes market orders not eligible for firm quote guarantees and limit orders ''near'' the market quote to the trading crowd. Such orders are delivered either to printers or to Public Automated Routing (''PAR'') System touch screen terminals in the trading pit. According to CBOE, the capabilities of the PAR workstation allows customer orders routed through it to ''enjoy turnaround time second only to RAES.''

[14] *See Timpinaro* v. *SEC,* 2 F.3d 453, 457 (D.C. Cir. 1993) (finding that the Act prohibits only unfair discrimination, not all discrimination).

[15] 15 U.S.C. § 78s(b)(2) (1988).

[16] 17 CFR 200.30–3(a)(12).

[Release No. 34–37881; File No. SR–OCC–96–09]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Approval of a Proposed Rule Change Relating to the Valuation of Government Securities

October 28, 1996.

On July 18, 1996, The Options Clearing Corporation (''OCC'') filed a proposed rule change (File No. SR–OCC–96–09) with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Act'').[1] On August 22, 1996, OCC filed an amendment to the proposed rule change.[2] Notice of the proposal was published in the Federal Register on September 12, 1996, to solicit comments from interested persons.[3] No comments were received. As discussed below, this order approves the proposed rule change.

I. Description

The proposed rule change modifies the valuation methodology on deposits of government securities for margin and clearing fund purposes and expands the category of government securities eligible for deposit to include maturities greater than ten years. Presently, OCC values government securities at either: (1) the lesser of par value or 100% of the current market value for maturities of less than one year or (2) the lesser of par value of 95% of the current market value for maturities between one and ten years.

Government securities were defined by Section 1 of Article 1 of OCC's By-laws as securities issued or guaranteed by the United States or Canadian government or by any other foreign government acceptable to OCC and maturing within ten years. The amendment deletes the ten year restriction.

The proposed rule change also amends Section 3 of Article VIII of OCC's By-laws and Rule 604 of OCC's Rules to establish a new schedule of haircuts.[4] Pursuant to the amendments, Government securities deposited as either clearing fund or margin will be valued at: (1) 99.5% of the current market value for maturities of less than one year; (2) 98% of the current market value for maturities between one and five years; (3) 96.5% of the current market value for maturities between five and ten years; and (4) 95% of the current market value for maturities in excess of ten years.

II. Discussion

Since the early 1980's, OCC has revalued Government securities on a monthly basis. Because OCC is now

[1] 15 U.S.C. § 78s(b) (1988).

[2] Letter from Michael G. Vitek, OCC, to Jerry Carpenter, Assistant Director, Division of Market Regulation, Commission (August 19, 1996).

[3] Securities Exchange Act Release No. 37645 (September 5, 1996), 61 FR 48194.

[4] Article III, Section 3 sets forth the allowable forms of contributions to the clearing fund. Rule 604 set forth the allowable forms of margin deposits.

ready to revalue Government securities on a daily basis and to include the valuation in its overall daily assessment of clearing member margin and clearing fund deposits, OCC believes the par value methodology and prohibition on deposits of securities with maturities beyond ten years are overly conservative and no longer necessary to protect OCC from risk associated with value changes in margin and clearing fund deposits.

Before setting the haircut levels, OCC reviewed the haircut policies of other derivative clearing houses and analyzed recent historical volatilites of government securities. OCC collected daily data since 1990 on government securities of various maturities across the yield curve and analyzed this historical volatility for the setting of margin intervals within OCC's Theoretical Intermarket Margin System. The proposed haircut levels should adequately cover more than 99% of the movements of all days since 1990.

Section 17A(b)(3)(F) of the Act requires that a clearing agency's rules be designed to ensure the safeguarding of securities and funds in its custody or control or for which it is responsible. [5] Based on the foregoing, the Commission believes that OCC's proposed modifications to its rules governing the acceptance, valuation, and haircutting of Government securities is consistent with OCC's obligation to safeguard securities and funds.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and particularly with Section 17A(b)(3)(F) of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, [6] that the proposed rule change (File No. SR–OCC–96–09) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority. [7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–28184 Filed 11–1–96; 8:45 am]

BILLING CODE 8010–01–M

[5] 15 U.S.C. 78q–1(b)(3)(F) (1988).

[6] 15 U.S.C. 78s(b)(2) (1988).

[7] 17 CFR 200.30(a)(12) (1996).

[Release No. 34–37883; File No. SR–PHILADEP–96–11]

Self-Regulatory Organizations; Philadelphia Depository Trust Company; Order Granting Approval of a Proposed Rule Change Regarding the Destruction of Certain Expired Securities Certificates

October 28, 1996.

On June 28, 1996, the Philadelphia Depository Trust Company (''Philadep'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–PHILADEP–96–11) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] regarding the destruction of certain expired securities certificates. Notice of the proposal was published in the Federal Register on August 21, 1996.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The rule change will amend Philadep Rule 31 which governs the orderly destruction of securities certificates relating to expired warrants and rights to permit the destruction of such securities certificates to be carried out under the supervision of Philadep's internal audit department.[3] Section (c) of Rule 31 previously required that all securities to be destroyed pursuant to the rule had to be forwarded to Philadep's internal audit department for destruction.[4] Under the rule change, Philadep is permitted to destroy the certificates in a designated area of Philadep under the supervision of the internal audit department instead of being required to destroy such certificates in the internal audit department itself.

II. Discussion

Section 17A(b)(3)(F) [5] of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible. The Commission believes Philadep's proposed rule change is consistent with Philadep's obligations under Section 17A of the Act because the rule change does not significantly alter the procedures previously approved by the Commission by which expired rights and warrants certificates are to be destroyed and thereby should not negatively affect Philadep's ability to safeguard securities or funds.[6]

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–PHILADEP–96–11) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–28231 Filed 11–1–96; 8:45 am]

BILLING CODE 8010–01–M

[1] 15 U.S.C. § 78s(b)(1) (1988).

[2] Securities Exchange Act Release No. 37570 (August 14, 1996), 61 FR 43287.

[3] The procedures for the destruction of expired securities set forth in Rule 31 require Philadep to (i) contact the transfer agent or the issuer of the expired securities to verify that the respective warrants or rights have expired, (ii) obtain written confirmation from such transfer agent or issuer that the certificates representing such warrants or rights have expired (if there is no transfer agent, Philadep personnel must exercise all reasonable due diligence to confirm the expired nature of the respective certificates including consulting with the Philadep's legal department, internal audit department and senior management), (iii) notify its participants that in the judgment of the transfer agent, or other appropriate parties if a transfer agent does not exist, the securities certificates have expired, (iv) delete such securities positions from its participants' account on or after the thirtieth day following the date of such notice, and (v) appropriately mark the securities certificates and forward them to its internal audit department for destruction.

[4] Securities Exchange Act Release No. 35426 (February 28, 1995) [File No. SR–PHILADEP–94–05] (order approving proposed rule change authorizing Philadep to implement a program for the destruction of securities certificates relating to expired warrants and rights).

[5] 15 U.S.C. § 78q–1(b)(3)(F) (1988).

[6] The Commission previously stated upon establishment of Philadep's expired certificate destruction program for warrants and rights that such program is consistent with Section 17A of the Act because the program should reduce the administrative expenses associated with safekeeping and storage of worthless certificates and that Philadep's procedures were reasonably designed to prevent inadvertent destruction of warrants and rights certificates that have not expired. *Supra* note 4.

[7] 17 CFR 200.30–3(a)(12) (1996).

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2908]

Declaration of Disaster Loan Area; Florida

Manatee County and the contiguous counties of De Soto, Hardee, Hillsborough, Polk, and Sarasota in the State of Florida constitute a disaster area

as a result of damages caused by a fire at the Red Barn Flea Market in the City of Bradenton which occurred on October 21, 1996. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on December 27, 1996 and for economic injury until the close of business on July 28, 1997 at the address listed below: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308, or other locally announced locations.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.125
For Economic Injury	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 290805 and for economic injury the number is 924100.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: October 28, 1996.

Philip Lader,

Administrator.

[FR Doc. 96–28214 Filed 11–1–96; 8:45 am]

BILLING CODE 8025–01–P

[Declaration of Disaster Loan Area #2895] [Amendment #3]

Declaration of Disaster Loan Area; Virginia

In accordance with notices from the Federal Emergency Management Agency, dated September 23 and October 23, 1996, the above-numbered Declaration is hereby amended to include the Counties of Accomack, Charles City, Chesterfield, Essex, Gloucester, Henrico, Isle of Wight, James City, King & Queen, King George, King William, Lancaster, Mathews, Middlesex, New Kent, Northampton, Northumberland, Prince George, Prince William, Richmond, Surry and York, and the Independent Cities of Fredericksburg, Hopewell, Newport News, Poquoson, Suffolk and Williamsburg in the Commonwealth of Virginia as a disaster area due to damages caused by Hurricane Fran and associated severe storm conditions, including high winds, tornadoes, wind driven rain, and river and flash flooding from September 5 through September 23, 1996.

In addition, applications for economic injury loans from small businesses located in the contiguous County of Fairfax and the Independent City of Chesapeake in the Commonwealth of Virginia, and the contiguous County of Worcester in the State of Maryland may be filed until the specified date at the previously designated location.

Any counties contiguous to the above-named counties and not listed herein have been previously declared.

All other information remains the same, i.e., the termination date for filing applications for physical damage is November 6, 1996, and for loans for economic injury the deadline is June 9, 1997.

The economic injury number assigned to this is 924500 for Maryland.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: October 28, 1996.

James Rivera,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 96–28213 Filed 11–1–96; 8:45 am]

BILLING CODE 8025–01–P

[License No. 01/01–0300]

ESLO Capital Corporation; Notice of Surrender of License

Notice is hereby given that ESLO Capital Corporation, 212 Wright Street, Newark, New Jersey 07114 has surrendered its license to operate as a Small Business Investment Company under the Small Business Investment Act of 1958, as amended (''the Act''). ESLO was licensed by the Small Business Administration on May 31, 1979.

Under the authority vested by the Act and pursuant to the SBA Regulations promulgated thereunder, the surrender of the license was effective on October 17, 1996, and accordingly, all rights, privileges and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: October 18, 1996.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 96–28215 Filed 11–1–96; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended) this notice announces the Department of Transportation's (DOT) intention to request a revision of a currently approved collection. Comments are invited on: whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collections; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 26, 1996 [FR 61, page 43807–43808].

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

DATES: Comments on this notice must be received on or before December 4, 1996.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW, Washington, DC 20503, Attention DOT Desk Officer.

FOR FURTHER INFORMATION CONTACT: Ms. Judith Street, on (202) 267–9895.

SUPPLEMENTARY INFORMATION: The information collection activities associated with the Representatives of the Administrator, CFR part 183, including Aviation Medical Examiners, are currently cleared under OMB number 2120–0033. For administrative ease, the FAA proposes to separate the Aviation Medical Examiner clearance from the rest of the Representatives of the Administrator. There is no change in the CFR requirements. It is proposed that the Aviation Medical Examiner program be given a separate OMB clearance number. At this time of

request for clearance, the Aviation Medical Examiner Designation Application form, FAA form 8520–2 is being updated to include a few additional boxes to check off. The additional information does not constitute a significant increase in time to complete the form since it would only involve one data element and check marks in the appropriate boxes.

The additional data elements are as follows: A box to check off whether the doctor is male or female. (This will be done to provide that information to airmen and women who request a doctor of a specific gender.) A space for social security number. (This is a voluntary request.) An addition of more specialities in the medical specialty category from which the applicant can choose. In the General Information portion of the application, the addition of two questions to check off a yes or no.

Title: Aviation Medical Examiner Program.

OMB Control Number: 2120—new.

Type of Request: Revision of a currently approved information collection.

Affected Entities: An estimated 450 individuals applying to become aviation medical examiners.

Abstract: This information is collected for the purpose of obtaining essential information concerning the applicants' professional and personal qualifications. The FAA uses the information provided to screen and select the designees who serve as aviation medical examiners. The information is also used to make a list of designated aviation medical examiners readily available to the public.

Need: 14 CFR 183 implements the provisions of Title 49 U.S.C., section 44702.

Estimated Burden: The estimated burden is 225 hours annually.

Issued in Washington, DC., on October 29, 1996.

Phillip A. Leach,

Information Clearance Officer, U.S. Department of Transportation.

[FR Doc. 96–28220 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–62–P

[Summary Notice No. PE–96–52]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing and disposition of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before November 25, 1996.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, D.C. 20591.

Comments may also be sent electronically to the following internet address: nprmcmts@faa.dot.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Fred Haynes (202) 267–3939 or Angela Anderson (202) 267–9681 Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, D.C., on October 29, 1996.

Michael E. Chase,

Acting Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 28501.

Petitioner: Alaska Air Carriers Association.

Sections of the FAR Affected: 14 CFR 121.1.

Description of Relief Sought: To permit Alaska Air Carriers Association member companies to continue to operate 10- to 19-seat aircraft solely in Alaska in scheduled passenger service under 14 CFR part 135.

Docket No.: 28622.

Petitioner: Dodgen Aircraft Refinishing, Inc.

Sections of the FAR Affected; 65.91(c)(1).

Description of Relief Sought: To permit the petitioner to become eligible for an inspection authorization without holding a current mechanic certificate with airframe and powerplant ratings that have been in effect for a total of at least 3 years.

Docket No.: 28686.

Petitioner: Jerry L. Clifton.

Sections of the FAR Affected: 14 CFR 91.209.

Description of Relief Sought: To permit Scott C. Clifton or David L. Clifton to operate a hot air balloon in tethered flight at altitudes at or below 250 feet above ground level during the period from sunrise to sunset without meeting certain aircraft lighting requirements.

[FR Doc. 96–28281 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee Meeting on Emergency Evacuation Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) to discuss emergency evacuation issues.

DATES: The meeting will be held on November 21, 1996 at 9:00 a.m. Arrange for oral presentations by November 18, 1996.

ADDRESSES: The meeting will be held on the 20th Floor, MIC Room of the Boeing Company, 1700 North Moore Street, Arlington, VA 22202 (Rosslyn metro stop).

FOR FURTHER INFORMATION CONTACT: Jackie Smith, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue, SW., Washington, DC 20591, Telephone (202) 267–9682, FAX (202) 267–5075.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III), notice is given of an ARAC meeting to discuss emergency evacuation issues to be held on November 21, 1996 at Boeing Company, 20th Floor, MIC room, 1700 North Moore Street, Arlington, VA 22202 (Roslyn metro stop).

The agenda will include:

- Opening Remarks.
- Review of Action Items.
- Report on Performance Standards Working Group Activities including status of Performance Standards and TSO–69B Design Standard for escape slides.

Attendance is open to the public, but will be limited to space available. The public must make arrangements by November 18, 1996 to present oral statements at the meeting. Written statements may be presented to the committee at any time by providing 25 copies to the Assistant Executive Director for Emergency Evacuation Issues or by providing copies at the meeting. In addition, sign and oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC, on October 29, 1996.

Ava L. Robinson,

Assistant Executive Director for Emergency Evacuation Issues Aviation Rulemaking Advisory Committee.

[FR Doc. 96–28284 Filed 11–01–96; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc.; Technical Management Committee

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463, 5 U.S.C., Appendix 2), notice is hereby given for the RTCA Technical Management Committee meeting to be held November 15, 1996, starting at 9:00 a.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC 20036.

The agenda will be as follows: (1) Children's Remarks; (2) Review/ Approve Summary of Previous Meeting; (3) Consider/Approve: a. Proposed Final Draft, Minimum Performance and Installation Standards for Runway Guard Lights, RTCA Paper No. 276–96/ SC184–052; b. Proposed Final Draft, Change 2 to RTCA/DO–217, Minimum Aviation System Performance Standards DGNSS Instrument Approach System: Special Category I (SCAT I), RTCA Paper No. 381–96/TMC–241; (4) Discuss/Take Position on: a. FAA Request to Form New Special Committee to Address CNS/ATM Cockpit Controls and Multi-Function Display Issues, RTCA Paper No. 266–96/ TMC–229; b. FAA Request to Expand SC–169 Terms of Reference to Include Flight Information System (FIS) MOPS and MASPS, RTCA Paper No. 234–96/ TMC–225; c. FAA Request to Form New Special Committee to Develop MOPS and MASPS for Digital Terrain, Obstruction and Other Data Bases, RTCA Paper No. 240–96/TMC–227; d. FAA Request to Expand SC–182 Terms of Reference to Develop MOPS for a Computer-Based Avionics Suite that meets the needs of all segments of aviation, RTCA Paper No. 369–96/TMC–240; e. SC–159 Request to Revise Current Terms of Reference, RTCA Paper No. 298–96/TMC–243; (5) Other Business; (6) Date and Place of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC 20036; (202) 833–9339 (phone) or (202) 833–9434 (fax). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on October 29, 1996.

Janice L. Peters,

Designated Official.

[FR Doc. 96–28285 Filed 11–1–96; 8:45 am]

BILLING CODE 4810–13–M

Federal Railroad Administration

[FRA Docket No. RST–96–2]

Petition for Waiver of Compliance Cant Deficient Passenger Train Operation

In accordance with Title 49 Code of Federal Regulations (CFR) Sections 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) received from the National Railroad Passenger Corporation (Amtrak) a request for waiver of compliance with certain requirements of 49 CFR Part 213: TRACK SAFETY STANDARDS.

The purpose of Amtrak's petition is to secure approval from FRA to operate equipment know as RoadRailers in passenger trains that are now permitted to operate at four inches of cant deficiency. After Amtrak takes delivery, the RoadRailers will be used primarily in trains for time-sensitive first and second class mail.

For several years, Amtrak has operated passenger trains with a variety of equipment at four inches of cant deficiency (underbalance) on tracks either owned by Amtrak or other railroads such as Union Pacific, Burlington Northern, and Southern Pacific. This has allowed Amtrak to increase average train speeds and reduce the number of late arrivals. Without approval for the operation of RoadRailers at four inches of cant deficiency, Amtrak would have to revert to slower curving speeds on passenger trains that have RoadRailers in their consists.

Currently, Section 213.57(b) permits a maximum of three inches to be used as the underbalance term (cant deficiency) in the formulation of curve/speed tables by track maintenance engineers defining train speeds for curved track superelevations for any route between two points.

The waivers granted Amtrak and the other railroads permit the substitution of four inches in the Vmax formula in Section 213.57.

Interested parties are invited to participate in this proceeding by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning this proceeding should identify the appropriate docket number (e.g., Waiver Petition Docket No. RST–96–2) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, S.W., Washington, D.C. 20590. Communications received within 30 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at FRA's temporary docket room located at 1120 Vermont Avenue, N.W., Room 7051, Washington, D.C. 20005.

Issued in Washington, D.C. on October 23, 1996.

Phil Olekszyk,

Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. 96–28151 Filed 11–01–96; 8:45 am]

BILLING CODE 4910–06–P

National Highway Traffic Safety Administration

[Docket No. 96–082; Notice 2]

General Motors Corporation; Grant of Application for Decision of Inconsequential Noncompliance

This notice grants the application by General Motors Corporation (GM) of Warren, Michigan, to be exempted from the notification and remedy requirements of 49 U.S.C. 30118, and 30120 for a noncompliance with 49 CFR 571.108, Federal Motor Vehicle Safety Standard (FMVSS) No. 108, ''Lamps, Reflective Devices and Associated Equipment.'' The basis of the application is that the noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of receipt of the application was published on July 16, 1996, and an opportunity afforded for comment (61 FR 37109).

Standard No. 108 requires that turn signals be self-canceling by steering wheel rotation and capable of cancellation by a manually operated control. GM discovered that the self-canceling feature only works intermittently after left turns on slightly less than 2,000 1996 Model Buick Skylarks, because of a ''defective multi-function switch.'' GM believes that the failure is inconsequential because it occurs intermittently and in one direction only, and because the Skylarks are equipped with a reminder chime that activates if the turn signal is still on after ½ mile of driving.

GM supported its application for inconsequential noncompliance with the following:

''No more than 5.5 percent of the 1,969 vehicles, or 108 vehicles, are predicted to have a defective switch. This prediction is based on a sort of 400 switches, of which 22 were determined to possibly be suspect. This projection may overstate the field condition since the sort was very conservative; many of the suspect 22 switches may function properly in vehicles. In addition, the projection is based on a sort of the latest shipments of switches before the supplier corrected its manufacturing problem. Since the condition was caused by tooling dimensions drifting out of specification, the actual rate of defective switches for the entire production run may well be less than the projected rate.

''The self-cancel feature will operate properly for a majority of turn signal activations even on vehicles with a defective switch. The self-canceling feature works correctly when signaling for all right turns, as well as for some left turns. The switch is sensitive to the rate of turn signal lever actuation and position of the steering wheel, and will not cancel only intermittently, for some left hand turns. On one of the vehicles discovered with this condition, it took about 20 turn signal cycles to recreate the failure.

''All 1996 Skylarks have a turn signal reminder chime that will signal the driver if the turn signal indicator is still on after ½ mile of driving. Therefore, even in those instances when the self-cancel feature fails, the driver will get an additional cue that the turn signal is on and deactivate it.

''GM is not aware of any accidents, injuries, owner complaints or field reports associated with this condition.''

No comments were received on the application.

NHTSA accepts GM's analyses of the reported noncompliance and concur with their recommendation. The agency believes that the effects of this referenced noncompliance will not affect motor vehicle safety in a consequential position since the turn signal lamps meet all other requirements of Standard No. 108. Furthermore, GM has stated that the turn signals may be canceled through a manually-operated control and the 1996 Skylarks have a turn signal reminder chime that will signal the driver if the turn signal indicator is still on after ½ mile of driving. Although the agency is concerned by the ''defective multi-function switch'' reported by GM on the 1996 Model Buick Skylarks, the performance of the noncompliant equipment conforms to Standard No. 108 a substantial part of the time.

Accordingly, for the reasons expressed above, the petitioner has met its burden of persuasion that the noncompliance herein described is inconsequential to motor vehicle safety, and the agency grants GM'S application for exemption from notification of the noncompliance as required by 49 U.S.C. 30118 and from remedy as required by 49 U.S.C. 30120. (49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.50 and 501.8).

Issued on: October 29, 1996.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards

[FR Doc. 96–28227 Filed 11–1–96; 8:45 am]

BILLING CODE 4910–59–P

Surface Transportation Board

[STB Finance Docket No. 32760 (Sub-No. 20)]

The Atchison, Topeka and Santa Fe Railway Company—Trackage Rights Exemption—Southern Pacific Transportation Company

Southern Pacific Transportation Company (SPT) will assign overhead trackage rights to The Atchison, Topeka and Santa Fe Railway Company over a total of approximately 3,683 feet of track owned by Kansas City Southern Railway (KCS) from KCS milepost 766.70 to SPT milepost 30.50 near Beaumont, TX.[1] The transaction is expected to be consummated on or about December 16, 1996.

These trackage rights are related to conditions imposed as part of the recently approved merger in *Union Pacific Corporation, Union PacificRailroad Company, and Missouri Pacific Railroad Company—Control and Merger—Southern Pacific Rail Corporation, Southern Pacific Transportation Company, St. Louis Southwestern Railway Company, SPCSL Corp., and The Denver and Rio Grande Western Railroad Company;* Finance Docket No. 32760 (STB served Aug. 12, 1996) (Decision No. 44).

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 32760 (Sub-No. 20), must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423 and served on: (1) Richard E. Weicher, Vice President and General Counsel, The Atchison, Topeka and Santa Fe Railway Company, 6th Floor, 1700 East Golf Road, Schaumburg, IL 60173–5860; and (2) Gary A. Laakso, General Attorney, Southern Pacific Transportation Company, One Market Plaza, San Francisco, CA 94105.

As a condition to this exemption, any employees affected by the trackage

[1] SPT has overhead trackage rights on this trackage pursuant to its 1979 Agreement with KCS, which was approved by the Interstate Commerce Commission (ICC) in *Southern Pacific Transportation Company—Trackage Rights—Over Kansas City Southern Railway Company,* Finance Docket No. 29441 (ICC served Dec. 1, 1980). SPT states that the instant verified notice of exemption corrects the description of the total footage and SPT milepost number stated in that ICC decision.

rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: October 28, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–28232 Filed 11–1–96; 8:45 am]

BILLING CODE 4915–00–P

[STB Finance Docket No. 33160]

Falls Road Railroad Co., Inc.—Acquisition and Operation Exemption—Consolidated Rail Corporation

Falls Road Railroad Co., Inc. (FRRR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire and operate the line of railroad now owned and operated by Consolidated Rail Corporation (Conrail) known as the Falls Road Secondary Track, extending from milepost 58.29±, at Lockport, to milepost 16.60±, at Brockport, in Niagara, Orleans, and Monroe Counties, NY, a total of 41.69 route miles. In addition, FRRR will acquire operating easements only between mileposts 16.60± and 16.92± (owned by, or to be conveyed by Conrail to, Monroe County) and between mileposts 45.01± and 45.53± (owned by, or to be conveyed by Conrail to, the adjoining landowner).

Operations were expected to commence on or after October 24, 1996.

This transaction is related to STB Finance Docket No. 33161, *David Monte Verde, Michael Thomas, Charles Riedmiller, Jeffrey Baxter and John Herbrand and Genesee Valley Transportation Co. Inc.—Continuance in Control Exemption—Falls Road Railroad Co., Inc.*, wherein the named individuals and Genesee Valley Transportation Co., Inc., have concurrently filed a verified notice to continue in control of FRRR, upon its becoming a Class III rail carrier.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to reopen the proceeding to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33160, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423. In addition, a copy of each pleading must be served on Eric M. Hocky, Gollatz, Griffin & Ewing, P.C., 213 West Miner Street, P.O. Box 796, West Chester, PA 19381–0796.

Decided: October 25, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–28235 Filed 11–1–96; 8:45 am]

BILLING CODE 4915–00–P

[STB Finance Docket No. 33161]

David Monte Verde, Michael Thomas, Charles Riedmiller, Jeffrey Baxter and John Herbrand, and Genesee Valley Transportation Co. Inc.—Continuance in Control Exemption—Falls Road Railroad Co., Inc.

David Monte Verde, Michael Thomas, Charles Riedmiller, Jeffrey Baxter and John Herbrand (Individual Applicants), and Genesee Valley Transportation Co. Inc. (GVT), a noncarrier holding company,[1] have filed a notice of exemption to continue in control of the Falls Road Railroad Co., Inc. (FRRR), upon FRRR's becoming a Class III railroad.[2]

The transaction was expected to be consummated upon FRRR's commencement of operations on or after October 24, 1996.

This transaction is related to STB Finance Docket No. 33160, *Falls Road Railroad Co., Inc.—Acquisition and Operation Exemption—Consolidated Rail Corporation*, wherein FRRR seeks to acquire and operate certain rail lines from Consolidated Rail Corporation.

GVT controls 5 existing Class III railroad subsidiaries: Depew, Lancaster & Western Railroad Co., Inc., operating between Lancaster and Depew, NY; Lowville & Beaver River Railroad Co., operating between Lowville and Croghan, NY; Mohawk Adirondack & Northern Railroad Corp., operating (a) between Carthage and Lowville, (b) between Carthage and Newton Falls, and (c) between Utica and Lyons Falls, NY; Genesee & Mohawk Valley Railroad Co., operating (a) a portion of the Utica Yard, (b) a portion of the Rome Industrial trackage in Oneida County, NY, and (c) a portion of the Batavia-Lehigh and Lower Town Industrial trackage in Genesee County, NY; and Delaware-Lackawanna Railroad Co., Inc., operating (a) between Fell Township and Moosic (Scranton), (b) tracks within Scranton, and (c) between Scranton and Mt. Pocono, PA.[3]

GVT states that: (i) The rail lines to be operated by FRRR do not connect with any railroad in the corporate family; (ii) the transaction is not part of a series of anticipated transactions that would connect FRRR with any railroads in the corporate family; and (iii) the transaction does not involve a Class I carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33161, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423. In addition, a copy of each pleading must be served on Eric M. Hocky, Esq., Gollatz, Griffin & Ewing, P.C., 213 West Miner Street, P.O. Box 796, West Chester, PA 19381–0796.

Decided: October 25, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96–28236 Filed 11–1–96; 8:45 am]

BILLING CODE 4915–00–P

[1] The Individual Applicants collectively own 100% of the outstanding shares of GVT that in turn controls a number of Class III carriers.

[2] At commencement of operations by FRRR, the entire outstanding capital stock of FRRR will be owned by GVT. Individual Applicants will continue in indirect control of FRRR.

[3] GVT owns a controlling interest of the stock of Lowville & Beaver River Railroad and 100% of the stock of the other carriers under its control.

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Certification of Compliance With State and Local Law.

DATES: Written comments should be received on or before January 3, 1997 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Janice Fields, Firearms and Explosives Operations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8052.

SUPPLEMENTARY INFORMATION:

Title: Certification of Compliance With State and Local Law.

OMB Number: 1512–0523.

Form Number: ATF F 5300.37.

Abstract: Applicants for a Federal firearms license will certify that they are in compliance with State and local laws and that they have provided notification of their intent to conduct firearms business to the chief law enforcement officer in the locality of the business premises.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Individuals or households, business or other for-profit.

Estimated Number of Respondents: 70,000.

Estimated Time Per Respondent: 6 minutes.

Estimated Total Annual Burden Hours: 7,000.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 28, 1996.

John W. Magaw,

Director.

[FR Doc. 96–28143 Filed 11–1–96; 8:45 am]

BILLING CODE 4810–31–P

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Miscellaneous Requests and Notices for Distilled Spirits Plants.

DATES: Written comments should be received on or before January 3, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Wine, Beer and Spirits Regulations Branch, Steve Simon, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8183.

SUPPLEMENTARY INFORMATION:

Title: Miscellaneous Requests and Notices for Distilled Spirits Plants.

OMB Number: 1512–0206.

Form Number: ATF F 5110.41

Abstract: The information provided by applicants assists ATF in determining eligibility and providing for registration. These eligibility requirements are for persons who wish to establish distilled spirits plant operations. However, both statutes and regulations allow variances from regulations, and this information gives data to permit a variance.

Current Actions: This information collection is being submitted as an extension with changes. Upon approval of this collection, ATF F 5110.34 is being eliminated, and some of the burden formerly associated with that form is being taken up by letterhead notices under this submission. Also, some requirements are being shifted from the submission of a prescribed ATF form to the submission of letterhead applications or notices. The net effect will be an increase of 50 burden hours for 1512–0206.

Type of Review: Extension with changes.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 328.

Estimated Time Per Respondent: 5 hours.

Estimated Total Annual Burden Hours: 1,620.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: October 28, 1996.

John W. Magaw,

Director.

[FR Doc. 96–28144 Filed 11–1–96; 8:45 am]

BILLING CODE 4810–31–P

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Federal Firearms Licensee Theft/Loss Report.

DATES: Written comments should be received on or before January 3, 1997, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Janice Fields, Firearms and Explosives Operations Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202) 927–8052.

SUPPLEMENTARY INFORMATION:

Title: Federal Firearms Licensee Theft/Loss Report.

OMB Number: 1512–0524.

Form Number: ATF F 3310.11.

Abstract: Authorization of this form is requested within 7 days as the Violent Crime Control and Law Enforcement Act requires Federal firearms licensees to report to the Bureau of Alcohol, Tobacco and Firearms and to the appropriate local authorities any theft or loss of a firearm from the licensee's inventory or collection, within a specific timeframe after the theft or loss is discovered.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Individuals or households, business or other for-profit.

Estimated Number of Respondents: 4,000

Estimated Time Per Respondent: 24 minutes

Estimated Total Annual Burden Hours: 1600

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs of operation, maintenance, and purchase of services to provide information.

Dated: October 28, 1996.

John W. Magaw,

Director.

[FR Doc. 96–28145 Filed 11–1–96; 8:45 am]

BILLING CODE 4810–31–P

Office of the Comptroller of the Currency

Federal Reserve System

Federal Deposit Insurance Corporation

Proposed Collection; Comment Request

AGENCIES: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the OCC, the Board, and the FDIC (the ''agencies'') may not conduct or sponsor, and the respondent need not respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number. The Consolidated Reports of Condition and Income (Call Report) are currently approved collections of information for the agencies. Under the auspices of the Federal Financial Institutions Examination Council (FFIEC), of which the agencies are members, the agencies are proposing to no longer accept Call Reports that are filed directly with them in hard copy (paper) form. The only Call Reports that the agencies would accept would be those filed electronically or on computer diskette with the agencies' electronic collection agent. A bank could either file its reports directly with the agent or contract with a third party for the conversion of its reports from hard copy (paper) to automated form and the filing of the reports with the agent. The agencies would phase out their acceptance of paper Call Report forms as of the June 30, September 30, and December 31, 1997, report dates based on bank size. Comments are invited on the use of this automated collection technique from both users and nonusers of Call Report software and the electronic filing method. In particular, respondents are requested to comment on the automated collection process as a way to minimize the burden of this information collection on banks, on any initial implementation costs to banks, and on ongoing costs to banks after initial implementation. At the end of the comment period, the comments received will be evaluated to determine whether modifications should be made to the proposal before the FFIEC gives its final approval. The agencies will then submit the filing policy to OMB for review and approval.

DATES: Comments must be submitted on or before January 3, 1997.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the OMB control number(s), will be shared among the agencies.

OCC: Written comments should be submitted to the Communications Division, Ninth Floor, Office of the Comptroller of the Currency, 250 E Street, S.W., Washington, D.C. 20219, Attention: OMB Control No. 1557–0081 [FAX number (202) 874–5274; Internet address: regs.comments@occ.treas.gov]. Comments will be available for inspection and photocopying at that address.

Board: Written comments should be addressed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, N.W., Washington, D.C. 20551, Attention: OMB Control No. 7100–0036, or delivered to the Board's mail room between 8:45 a.m. and 5:15 p.m., and to the security control room outside of

those hours. Both the mail room and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, N.W. Comments received may be inspected in room M-P–500 between 9:00 a.m. and 5:00 p.m., except as provided in section 261.8 of the Board's Rules Regarding Availability of Information, 12 CFR 261.8(a).

FDIC: Written comments should be addressed to the Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, N.W., Washington, D.C. 20429, Attention: OMB Control No. 3064–0052. Comments may be hand-delivered to room F–402, 1776 F Street, N.W., Washington, D.C. 20429, on business days between 8:30 a.m. and 5:00 p.m. Comments may be sent through facsimile to: (202) 898–3838 or by the Internet to: comments@fdic.gov. Comments will be available for inspection at the FDIC Public Information Center, room 100, 801 17th Street, N.W., Washington, D.C., between 9:00 a.m. and 4:30 p.m. on business days.

A copy of the comments may also be submitted to the OMB desk officer for the agencies: Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed revisions to the collections of information may be requested from any of the agency clearance officers whose names appear below.

OCC: Jessie Gates, OCC Clearance Officer, (202) 874–5090, Office of the Comptroller of the Currency, OMB Control No. 1557–0081, 250 E Street, S.W., Washington, D.C. 20219.

Board: Mary M. McLaughlin, Board Clearance Officer, (202) 452–3829, Division of Research and Statistics, Board of Governors of the Federal Reserve System, OMB Control No. 7100–0036, 20th and C Streets, N.W., Washington, D.C. 20551. For the hearing impaired only, Telecommunications Device for the Deaf (TDD), Dorothea Thompson, (202) 452–3544, Board of Governors of the Federal Reserve System, 20th and C Streets, N.W., Washington, D.C. 20551.

FDIC: Steven F. Hanft, FDIC Clearance Officer, (202) 898–3907, Office of the Executive Secretary, Federal Deposit Insurance Corporation, OMB Control No. 3064–0052, 550 17th Street N.W., Washington, D.C. 20429.

SUPPLEMENTARY INFORMATION:

Proposal to Revise the Filing Method for the Following Currently Approved Collections of Information

Title: Consolidated Reports of Condition and Income (Call Report).

Form Number: FFIEC 031, 032, 033, 034.[1]

Frequency of Response: Quarterly.

Affected Public: Business and other for-profit (Insured commercial and FDIC-supervised savings banks).

For OCC:

OMB Number: 1557–0081.

Estimated Number of Respondents: 2,800 national banks.

Estimated Time per Response: 39.62 burden hours.

Estimated Total Annual Burden: 443,744 burden hours.

For Board:

OMB Number: 7100–0036.

Estimated Number of Respondents: 1,002 state member banks.

Estimated Time per Response: 45.70 burden hours.

Estimated Total Annual Burden: 183,166 burden hours.

For FDIC:

OMB Number: 3064–0052.

Estimated Number of Respondents: 6,668 insured state nonmember commercial and savings banks.

Estimated Time per Response: 28.72 burden hours.

Estimated Total Annual Burden: 765,900 burden hours.

Note Regarding Burden: The preceding burden estimates include the time for reviewing the Call Report instructions, gathering and maintaining data in the form required for the Call Report, and completing the Call Report information collection, but exclude the time for compiling and maintaining business records in the normal course of a bank's activities. The estimated time per response varies by agency because of differences in the composition of the banks under each agency's supervision (e.g., size distribution of banks, types of activities in which they are engaged, and number of banks with foreign offices).

General Description of Report: This information collection is mandatory: 12 U.S.C. 161 (for national banks), 12 U.S.C. 324 (for state member banks), and 12 U.S.C. 1817 (for insured state nonmember commercial and savings banks). Except for select sensitive items, this information collection is not given confidential treatment. Small businesses (i.e., small banks) are affected.

Abstract: Call Reports are filed quarterly with the agencies for their use in monitoring the condition and performance of reporting banks and the industry as a whole. The reports are also used to calculate banks' deposit insurance assessments and for monetary policy and other public policy purposes.

Current Actions: Under the auspices of the FFIEC, the agencies are proposing to no longer accept Call Reports filed directly with them in hard copy (paper) form. The only Call Reports that the agencies would accept would be those filed electronically or on computer diskette with the agencies' electronic collection agent. A bank could either file its reports directly with the agent or arrange for a third party to convert its reports from hard copy (paper) form to automated form and then file them with the agent. The agencies' acceptance of paper Call Report forms would be phased out as of the June 30, September 30, and December 31, 1997, report dates based on bank size.

Type of Review: Revision.

For the past eight years, a bank has been permitted to electronically submit its Call Report to the agencies' electronic collection agent over telephone lines using a computer and modem.[2] Alternatively, a bank could mail a computer diskette containing its Call Report to the agent. Electronic Data Systems Corporation (EDS) is the electronic collection agent for the agencies. A bank submitting its Call Report to EDS electronically or on diskette is not required to mail a hard copy of its Call Report directly to any of the agencies unless specifically requested to do so.[3] Nevertheless, the bank must maintain in its files a signed and attested printout of the data submitted to EDS showing at least the title of each Call Report item and the reported amount. To fulfill the Call Report's signature and attestation requirement, the cover page of the Call Report forms that the agencies mail to the bank each quarter must be signed by an officer and bank directors and

[1] The FFIEC 031 report form is filed by banks with domestic and foreign offices. The FFIEC 032 report form is filed by banks with domestic offices only and total assets of $300 million or more. The FFIEC 033 report form is filed by banks with domestic offices only and total assets of $100 million or more but less than $300 million. The FFIEC 034 report form is filed by banks with domestic offices only and total assets of less than $100 million.

[2] Since the June 30, 1989, report date, banks that have or have had more than one foreign office, other than a ''shell'' branch or an International Banking Facility, and that use any of the additional 15 days allowed for the completion of their reports, have been required to file their reports electronically with the agencies' electronic collection agent. This requirement applies to fewer than 200 banks.

[3] Such requests rarely have been made.

attached to the printout placed in the bank's files.

Electronic filing capability is available through the use of computer software that supports this submission method. Software that EDS has certified for electronic filing is available through certain vendors that have completed a certification process. Currently, Call Report preparation software products marketed by the American Bankers Association/DBI Financial Systems, Inc.; DPSC Software, Inc.; Information Technology, Inc.; and Sheshunoff Information Services, Inc., have been certified for electronic submission by EDS.[4] Information Technology's software operates on mainframe computers while the other three vendors' software products run on personal computers. The annual cost of Call Report software for personal computers starts at approximately $200 for small banks and the software runs effectively on any 286 or higher personal computer with a hard drive. No formal computer training is necessary to operate Call Report software. Banks generally have found that the instruction manuals for the Call Report software and the customer support help desks operated by the software vendors provide all the assistance necessary for their use of the software.

As an alternative to purchasing software, a bank could develop its own Call Report software and go through the certification process. However, banks normally find that purchasing certified computer software which is updated regularly by a vendor is more economical than developing and maintaining their own software.

The agencies have provided the aforementioned software companies with a significant number of edits that the agencies normally use for validating the Call Report information submitted to them each quarter. As a result, while each bank is responsible for the quality of its Call Report data, a bank using a commercial software package can correct errors identified by the software package prior to filing the Call Report, and provide better quality data to the agencies. This procedure saves a bank time by reducing agency inquiries for data correction after the Call Report has been filed. The commercial software also provides immediate confirmation to a bank that files electronically that EDS has received its Call Report. Thus, electronic submission promotes the accuracy of and speeds the receipt and processing of Call Report data. This means that electronic submission also translates into lower costs for the agencies and for the insurance funds administered by the FDIC.

Over the past five years, the percentage of banks submitting Call Reports to the electronic collection agent has climbed from 28 percent to 54 percent. The number of banks using certified computer software to file Call Reports in this manner has increased from 3,503 as of the June 30, 1991, report date to 5,570 as of the June 30, 1996, report date. This reflects the banking industry's growing recognition of the benefits of this powerful tool for completing and filing reports. Furthermore, some 2,400 additional banks, 23 percent of all institutions, used computer software to prepare their June 30, 1996, Call Report, but submitted a computer-generated hard copy (paper) facsimile report to the agencies. The agencies believe that these banks can change from their current paper-based filing method to the electronic or computer diskette filing method with little difficulty. Thus, about 77 percent of banks currently use computer software for preparing and filing their Call Reports. The distribution of banks by size and report preparation and filing method as of the June 30, 1996, report date is as follows:

Asset size	Banks using computer software to file with electronic collection agent		Banks using computer software to file computer-generated hard copy (paper) reports		Banks using computer software		Banks not using computer software		Total banks	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Less than $10 million	90	29	48	16	138	45	170	55	308	100
$10–$25 million	507	34	403	27	910	61	575	39	1,485	100
$25–$50 million	926	39	724	30	1,650	69	734	31	2,384	100
$50–$100 million	1,371	53	681	27	2,052	80	515	20	2,567	100
Over $100 million	2,676	74	542	15	3,218	89	376	11	3,594	100
All banks	5,570	54	2,398	23	7,968	77	2,370	23	10,338	100

The agencies are proposing to phase out their acceptance of hard copy (paper) Call Reports filed directly with them according to the following timetable:

- Beginning with the Call Reports for June 30, 1997, banks with assets of $50 million or more (as reported in the June 30, 1996, Call Report) must file their Call Reports electronically or on computer diskette with the agencies' electronic collection agent.
- Beginning with the Call Reports for September 30, 1997, banks with assets of $25 million or more (as reported in the June 30, 1996, Call Report) must file their Call Reports electronically or on computer diskette with the collection agent.
- Beginning with the Call Reports for December 31, 1997, all banks must file their Call Reports electronically or on computer diskette with the collection agent.

Once a bank's Call Reports must be filed electronically or on computer diskette with EDS, the agencies' electronic collection agent, the bank would have two ways to satisfy this filing requirement. The bank could prepare its reports in automated form and file them directly with EDS. Alternatively, it could complete its reports in hard copy (paper) form and contract with a third party, such as one of the Call Report software companies,

[4] For further information on available Call Report preparation software, contact:

American Bankers Assoc./DBI Financial Systems, Inc., P.O. Box 1249, Cannon Beach, Oregon 97110, Telephone: (800) 774–3279.

DPSC Software, Inc., 23501 Park, Sorrento, Suite 105, Calabasas, California 91302, Telephone: (800) 825–3772.

Information Technology, Inc., 1345 Old Cheney Road, Lincoln, Nebraska 68512, Telephone: (403) 423–2682. Sheshunoff Information Services, Inc., P.O. Box 13203 Capitol Station, Austin, Texas 78711–3203, Telephone: (800) 456–2340.

for the conversion of its paper reports to automated form and the filing of the reports with EDS.

Under the proposed timetable, each bank would receive the applicable set of Call Report forms at the end of each of the first three quarters of 1997 (i.e., through the September 30, 1997, report date) just as at present without regard to their eligibility to file paper Call Report forms. For the December 31, 1997, report date, each bank would receive a sample set of Call Report forms but could not file a hard copy (paper) report with the agencies. In 1998 and subsequent years, the agencies would send each bank a sample of the applicable set of that year's Call Report forms only once during the year, i.e., before the end of the first quarter, rather than quarterly. The agencies would monitor banks' need for annual sample forms and could modify this procedure if deemed appropriate.

Request for Comment

Comments submitted in response to this Notice will be shared among the agencies and will be summarized or included in the agencies' requests for OMB approval. All comments will become a matter of public record. Written comments are invited on the use of this automated collection technique from both users and nonusers of Call Report software and the electronic filing method. Respondents are requested to comment on the automated collection process as a way to minimize the burden of this information collection on banks. Commenters also are requested to provide estimates of any initial costs that banks not currently using Call Report preparation software will incur in implementing this electronic filing method as well as estimates of the ongoing costs to such banks from the use of this method after its initial implementation. Similarly, commenters are requested to provide estimates of any initial and ongoing costs that would not otherwise be incurred by banks that currently use Call Report software, but submit computer-generated hard copy (paper) reports to the agencies.

The agencies invite comment on the accuracy of their estimates of the overall burden of the Call Report information collections as the filing requirements are proposed to be revised. These burden estimates include the time for reviewing instructions, gathering and maintaining data in the required form for the Call Report, and completing the report. In addition, comment is requested on whether this proposed revision to the Call Report information collections is necessary for the proper performance of the agencies' functions, including whether the information has practical utility, and on ways to enhance the quality, utility, and clarity of the information collected in the Call Report.

The agencies also request comments on whether they should consider discontinuing their acceptance of other hard copy (paper) reports (such as the Annual Report of Trust Assets (form FFIEC 001), which is filed annually as of each December 31 by insured banks and savings associations with trust powers and nondeposit trust companies, and the Summary of Deposits, which is filed annually as of each June 30 by each bank with more than one office) and instead accept only reports that are filed electronically or on computer diskette.

Dated: October 28, 1996.

Karen Solomon,

Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, October 28, 1996.

William W. Wiles,

Secretary of the Board.

Dated at Washington, D.C., this 29th day of October, 1996.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 96–28238 Filed 11–1–96; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–P

Customs Service

Solicitation of Applications for TECRO/AIT Carnet Issuing and Guaranteeing Association

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: General notice.

SUMMARY: This notice advises the public of the signing of a bilateral carnet agreement between the Taipei Economic and Cultural Representative in the United States (TECRO) and the American Institute in Taiwan (AIT) for the temporary admission of goods, commercial samples and professional equipment. It further informs the public that Customs is soliciting applications from those associations in the United States which are willing and capable of issuing and guaranteeing any TECRO/AIT carnets pursuant to the Agreement.

DATES: Applications must be received by January 3, 1997.

ADDRESSES: Written applications should be addressed to Assistant Commissioner, Field Operations, U.S. Customs Service, 1031 Constitution Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: William Scopa, Office of Field Operations 202–927–3112, or Sharon Goodson, International Organizations and Agreements Division 202–927–0971.

SUPPLEMENTARY INFORMATION:

Background

This notice advises the public of the signing of a bilateral carnet agreement between the Taipei Economic and Cultural Representative in the United States (TECRO) and the American Institute in Taiwan (AIT) for the temporary admission of goods, commercial samples and professional equipment. In a Notice of Proposed Rulemaking, also published in this issue of the Federal Register, Customs is proposing to amend its regulations which apply to carnets to reflect this new agreement.

A carnet is an international customs document, backed by an internationally valid guarantee, which may be used for the temporary admission of merchandise. The carnet is used in place of the usual national customs documentation and guarantees the payment of duties (including taxes) which may become due if the requirements of the carnet are not satisfied.

Taiwan is currently ineligible to accede to the ATA Carnet Convention, under which carnets facilitate trade among more than fifty contracting parties. Thus, Taiwan has sought access to the carnet facility through the recently concluded TECRO/AIT Carnet Agreement. This agreement was negotiated pursuant to the authority contained in 22 U.S.C. 3305.

Solicitation for Applications

As a result of the signing of the TECRO/AIT Carnet agreement, it is necessary for Customs to solicit applications for an organization to issue and guarantee TECRO/AIT carnets.

Generally, a domestic association in participating countries that are members of the International Bureau of Chambers of Commerce issues carnets to residents for use abroad. The issuing association must be approved by the Commissioner of Customs.

A domestic association in participating countries that are members of the International Bureau of Chambers of Commerce also generally guarantees the payment of duties and other sums to its respective customs authorities in the event of noncompliance with the conditions or the procedures for which the carnet is used. The guaranteeing association is jointly and severally liable

with the carnet holder for the payment of the sums. The guaranteeing association also must be approved by the Commissioner of Customs.

Pursuant to § 114.11, Customs Regulations (19 CFR 114.11), an association, in order to be approved by Customs, must provide in writing that it will undertake to perform the functions and fulfill the obligations specified in the Agreement to which the United States accedes. For the convenience of parties interested in applying to become the issuing and/or guaranteeing association under the TECRO/AIT Carnet Agreement, the text of the agreement is filed with this document at the Office of the Federal Register. Copies of the Agreement may also be obtained by contacting an individual identified in the **FOR FURTHER INFORMATION CONTACT** provision of this document.

To be considered, applications must be received not later than January 3, 1997. Applications should be sent to the address listed under the heading **ADDRESSES**, which appears near the beginning of this document.

Approved: October 29, 1996.

George J. Weise,

Commissioner of Customs.

[FR Doc. 96–28171 Filed 11–1–96; 8:45 am]

BILLING CODE 4820–02–M

UNITED STATES SENTENCING COMMISSION

Revisions to the Sentencing Guidelines for the United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of final action regarding amendments to sentencing guidelines effective November 1, 1996.

SUMMARY: The Sentencing Commission hereby gives notice of the following actions: (1) pursuant to section 730 of the Antiterrorism and Effective Death Penalty Act of 1996 and 28 U.S.C. 994(a), the Commission has amended § 3A1.4 (International Terrorism) and its accompanying commentary so that the adjustment in § 3A1.4 (relating to international terrorism) applies more broadly to Federal crimes of terrorism, as defined in 18 U.S.C. 2332b(g); and (2) pursuant to 28 U.S.C. 994 (a) and (p), the Commission has made miscellaneous additions and corrections to the Statutory Index and has made clerical amendments to the commentary of two guidelines.

DATES: The Commission has specified an effective date of November 1, 1996, for these actions.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Information Specialist, Telephone: (202) 273–4590.

Authorities: Section 730 of the Antiterrorism and Effective Death Penalty Act, 28 U.S.C. 994(a).

Richard P. Conaboy,

Chairman.

Amendments to Guidelines and Commentary

1. Amendment: Section 3A1.4 is amended in the title by deleting ''International''.

Section 3A1.4(a) is amended by deleting ''international'' and inserting in lieu thereof ''a federal crime of''.

The Commentary to § 3A1.4 captioned ''Application Notes'' is amended in Note 1 in the first sentence by deleting ''international'' and inserting in lieu thereof ''a federal crime of''; and in the second sentence by deleting ''International'' and inserting in lieu thereof ''Federal crime of'', and by deleting ''2331'' and inserting in lieu thereof ''2332b(g)''.

Reason for Amendment: This amendment implements section 730 of the Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. 104–132, 110 Stat. 1214. That section requires the Commission to amend the sentencing guidelines so that the adjustment in § 3A1.4 (relating to international terrorism) applies more broadly to Federal crimes of terrorism, as defined in 18 U.S.C. § 2332b(g), and provides that the Commission shall have the authority to promulgate this amendment as an emergency amendment under procedures set forth in section 21(a) of the Sentencing Act of 1987.

2. Amendment: Appendix A (Statutory Index) is amended by inserting at the appropriate place by title and section:

''8 U.S.C. § 1255A(c)(6)	2L2.1, 2L2.2'',
''16 U.S.C. § 1372	2Q2.1'',
''16 U.S.C. § 1387	2Q2.1'',
''18 U.S.C. § 474A	2B5.1, 2F1.1'',
''18 U.S.C. § 842 (l)–(o)	2K1.3'',
''18 U.S.C. § 844(b)	2K1.1'',
''18 U.S.C. § 844(g)	2K1.3'',
''18 U.S.C. § 844(n)	2X1.1'',
''18 U.S.C. § 844(o)	2K2.4'',
''18 U.S.C. § 956	2A1.5, 2X1.1'',
''18 U.S.C. § 1073	2J1.5, 2J1.6'',
''18 U.S.C. § 2319A	2B5.3'',
''21 U.S.C. § 843(a)(4)(A)	2D1.13'',
''26 U.S.C. § 7212(b)	2B1.1, 2B2.1, 2B3.1'',
''41 U.S.C. § 423(e)	2C1.1, 2C1.7, 2F1.1'',
''49 U.S.C. § 11902	2B4.1'',
''49 U.S.C. § 11903	2F1.1'',
''49 U.S.C. § 14103(b)	2B1.1'',
''49 U.S.C. § 14904	2B4.1'',
''49 U.S.C. § 14905(b)	2B1.1'',
''49 U.S.C. § 14909	2J1.1'',
''49 U.S.C. § 14912	2F1.1'',
''49 U.S.C. § 16102	2F1.1'',
''49 U.S.C. § 16104	2J1.1''.

Appendix A (Statutory Index) is amended in the line referenced to 8 U.S.C. § 1328, by deleting '', 2G1.2'';

in the line referenced to 18 U.S.C. § 32(a), (b) by inserting '', 2X1.1'' immediately following ''2K1.4'';

in the line referenced to 18 U.S.C. § 37 by inserting '', 2X1.1'' immediately following ''2K1.4'';

in the line referenced to 18 U.S.C. § 115(a) by inserting '', 2X1.1'' immediately following ''2A6.1'';

in the line referenced to 18 U.S.C. § 115(b)(2) by inserting '', 2X1.1'' immediately following ''2A4.1'';

in the line referenced to 18 U.S.C. § 115(b)(3) by inserting '', 2X1.1'' immediately following ''2A2.1'';

in the line referenced to 18 U.S.C. § 491 by inserting ''2B5.1,'' immediately before ''2F1.1'';

in the line referenced to 18 U.S.C. § 752 by inserting '', 2X3.1'' immediately following ''2P1.1'';

in the line referenced to 18U.S.C. § 1203 by inserting '', 2X1.1'' immediately following ''2A4.1'';

in the line referenced to 18 U.S.C. § 2280 by inserting '', 2X1.1'' immediately following ''2K1.4'';

in the line referenced to 18 U.S.C. § 2281 by inserting '', 2X1.1'' immediately following ''2K1.4'';

in the line referenced to 18 U.S.C. § 2421, by deleting '', 2G1.2'';

in the line referenced to 18 U.S.C. § 2422, by deleting '', 2G1.2'';

in the line referenced to 18 U.S.C. § 2423(a), by deleting ''2G1.2'' and inserting in lieu thereof ''2G1.1'';

by deleting:

''42 U.S.C. § 7413	2Q1.2, 2Q1.3'',

and inserting in lieu thereof:

''42 U.S.C. § 7413(c) (1)–(4).	2Q1.2, 2Q1.3
42 U.S.C. § 7413(c)(5)	2Q1.1'';

in the line referenced to 49 U.S.C. § 11904 by deleting ''2B4.1'' and inserting in lieu thereof ''2F1.1 (2B4.1 for offenses committed prior to January 1, 1996)'';

in the line referenced to 49 U.S.C. § 11907(a) by inserting ''(for offenses committed prior to January 1, 1996)'' immediately following ''2B4.1'';

in the line referenced to 49 U.S.C. § 11907(b) inserting ''(for offenses committed prior to January 1, 1996)'' immediately following ''2B4.1''; and

in the line referenced to 49 U.S.C. § 46502(a), (b) by inserting, '', 2X1.1'' immediately following ''2A5.1''.

The Commentary to § 3B1.4 captioned ''Application Notes'' is amended in Note 1 by deleting ''processing'' and inserting in lieu thereof ''procuring''.

The Commentary to § 5C1.2 captioned ''Application Notes'' is amended in Note 6 in the second sentence by deleting 'a organizer,'' and inserting in lieu thereof 'an organizer,''.

Reason for Amendment: This amendment makes Appendix A (Statutory Index) more comprehensive. References are added for additional offenses, including offenses enacted by the Marine Mammal Protection Act Amendments of 1994, Pub. L. 103–238, 108 Stat. 532; the ICC Termination Act of 1995, Pub. L. 104–88, 109 Stat. 803; the National Defense Authorization Act for Fiscal Year 1996, Pub. L. 104–106, 110 Stat. 186; and the Antiterrorism and Effective Death Penalty Act of 1996, Pub. L. 104–132, 110 Stat. 1214. In addition, this amendment revises Appendix A to conform to the revision of existing statutes and reflect the consolidation of §§ 2G1.1 and 2G1.2. Finally, this amendment corrects clerical errors in §§ 3B1.4 and 5C1.2.

[FR Doc. 96–28206 Filed 11–1–96; 8:45 am]

BILLING CODE 2210–40–M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported For Exhibition; Determinations

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 F.R. 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 F.R. 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, ''Sepphoris in Galilee: Crosscurrents of Culture'' (See list [1]) imported from abroad for the temporary exhibition without profit within the United States, are of cultural significance. These objects are imported pursuant to a loan agreement with the foreign lenders. I also determine that the exhibition or display of the listed exhibit objects at North Carolina Museum of Art, in Raleigh, North Carolina, from on or about November 16, 1996, to on or about July 6, 1997, is in the national interest. Public Notice of these determinations is ordered to be published in the Federal Register.

Dated: October 30, 1996.

Les Jin,

General Counsel.

[FR Doc. 96–28328 Filed 11–1–96; 8:45 am]

BILLING CODE 8230–01–M

[1] A Copy of this list may be obtained by contacting Mrs. Jacqueline H. Caldwell, Assistant General Counsel, at 202/619–6982, and the address is Room 700, U.S. Information Agency, 301 Fourth Street, S.W., Washington, D.C. 20547–0001.

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Rehabilitation, Notice of Meeting

The Department of Veterans Affairs gives notice that a meeting of the Veterans' Advisory Committee on Rehabilitation, authorized by 38 U.S.C., Section 3121, will be held on November 12, 13, and 14, 1996, in Washington, D.C. The committee will meet in VA Central Office, Room 230, on November 12, from 9 a.m. to 4:30 p.m. and in VA Central Office, Room 342, on November 13, from 9 a.m. to 4:30 p.m., and November 14, from 9 a.m. to 12 noon. The purpose of the meeting will be to review the administration of veterans' rehabilitation programs and to provide recommendations to the Secretary.

On Tuesday, the Committee will discuss the status of the reengineering efforts of VA's Vocational Rehabilitation and Counseling Program. On Wednesday and Thursday, the Committee will discuss the recent GAO Report on VA's Vocational Rehabilitation and Counseling Program, VHA's new VISN System, and the Prosthetics Service.

The meeting will be open to the public. It will be necessary for those wishing to attend to contact Theresa Boyd at 202–273–7412 prior to November 7, 1996.

Interested persons may attend, appear before, or file statements with the Committee. Statements, if in written form, may be filed before or within 10 days after the meeting. Oral statements will be heard at 3:30 p.m. on November 13, 1996.

Dated: October 25, 1996.

By Direction of the Secretary.

Eugene A. Brickhouse,

Committee Management Officer.

[FR Doc. 96–28192 Filed 11–1–96; 8:45 am]

BILLING CODE 8320–01–M

Advisory Committee on Minority Veterans, Notice of Meeting

The Department of Veterans Affairs (VA), in accordance with Public Law 103–446, gives notice that a meeting of the Advisory Committee on Minority Veterans will be held November 18, 1996, to November 20, 1996, in VA Central Office, Room 230, 810 Vermont Avenue, NW, Washington, DC. The purpose of the Advisory Committee on Minority Veterans is to advise the Secretary of Veterans Affairs on the administration of VA benefits and services for minority veterans and to assess the needs of minority veterans and evaluate whether VA compensation, medical and rehabilitation services, outreach, and other programs are meeting those needs. The Committee will make recommendations to the Secretary regarding such activities.

The Committee will convene from 8:30 a.m. to 5:30 p.m. on Monday, November 18, 1996. The Committee will receive testimony from invited representatives from minority veterans groups, community-based organizations and veterans organizations. The Committee will conduct its meeting on Tuesday, November 19, 1996, from 9:00 a.m. to 5:00 p.m. In the morning, the Committee will receive a briefing from the Director, Center for Minority Veterans, on the Center's priorities, achievements, and issues being addressed. The afternoon session will focus on the Committee's goals and objectives, subcommittee structure, Committee budget, and other administrative matters. On Wednesday, November 20, 1996, the Committee will meet from 9:00 a.m. to 4:30 p.m. The morning session will be devoted to subcommittee working sessions held in designated break-out rooms (to be determined). Program officials will participate in subcommittee meetings. The full Committee will reform in the afternoon to hear subcommittee reports on their agendas for fiscal year 1997. The Committee will review the Secretary's comments on its' 1996 Annual Report. All sessions will be open to the public. It will be necessary for those wishing to attend to contact Mr. Anthony Hawkins, Department of Veterans Affairs, phone (202) 273–6708, prior to November 15, 1996. No time

will be allocated for the purpose of receiving oral presentations from the public, however, the Committee will accept appropriate written comments form interested parties on issues affecting minority veterans. Such comments should be referred to the Committee at the following address: Advisory Committee on Minority Veterans, Center for Minority Veterans (OOM), U.S. Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420.

Dated: October 25, 1996.

By Direction of the Secretary

Eugene A. Brickhouse,

Committee Management Officer.

[FR Doc. 96–28198 Filed 11–1–96; 8:45 am]

BILLING CODE 8320–01–M

Federal Register

Monday
November 4, 1996

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910, et al.

Occupational Exposure to 1,3-Butadiene; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915 and 1926

[Docket No. H–041]

RIN 1218–AA83

Occupational Exposure to 1,3-Butadiene

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: This final standard amends the Occupational Safety and Health Administration's (OSHA) occupational standard that regulates employee exposure to 1,3-Butadiene (BD). The basis for this action is a determination by the Assistant Secretary, based on animal and human data, that OSHA's current permissible exposure limit (PEL) which permits employees to be exposed to BD in concentrations up to 1,000 parts BD per million parts of air (1,000 ppm) as an eight-hour time-weighted average (TWA) does not adequately protect employee health. OSHA's new limits reduce the PEL for BD to an 8-hour TWA of 1 ppm and a short term exposure limit (STEL) of 5 ppm for 15 minutes. An ''action level'' of 0.5 ppm as an 8-hour TWA is included in the standard as a mechanism for exempting an employer from some administrative burdens, such as employee exposure monitoring and medical surveillance, in instances where the employer can demonstrate that the employee's exposures are consistently at very low levels. In order to reduce exposures and protect employees, OSHA's BD standard includes requirements such as engineering controls, work practices and personal protective equipment, measurement of employee exposures, training, medical surveillance, hazard communication, regulated areas, emergency procedures and recordkeeping.

DATES: The effective date of these amendments is February 3, 1997. Start-up date for engineering controls is November 4, 1998, and for the exposure goal program November 4, 1999. Affected parties do not have to comply with the information collection requirements in § 1910.1051(d) exposure monitoring, § 1910.1051(f) methods of compliance, § 1910.1051(g) exposure goal program, § 1910.1051(h) respiratory protection, § 1910.1051(j) emergency situations, § 1910.1051(k) medical screening and surveillance, § 1910.1051(l) communication of BD hazards to employees; and § 1910.1051(m) recordkeeping until the Department of Labor publishes a Federal Register notice informing the public that OMB has approved these information requirements under the Paperwork Reduction Act of 1995.

Other Dates: Written comments on the paperwork requirements of this final rule must be submitted on or before January 3, 1997.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates the following party to receive petitions for review of this regulation: Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210. These petitions must be filed no later than the 59th calendar day following promulgation of this regulation; see section 6(f) of the Occupational Safety and Health Act of 1970 (OSH Act), 29 CFR 1911.18(d), and *United Mine Workers of America* v. *Mine Safety and Health Administration,* 900 F.2d 384 (D.C. Circ. 1990).

Comments regarding the paperwork burden of this regulation, which are being solicited by the Agency as required by the Paperwork Reduction Act of 1995, are to be submitted to the Docket Office, Docket No. ICR 96–13, U.S. Department of Labor, Room N–2625, 200 Constitution Ave., NW., Washington, DC 20210, telephone (202) 219–7894. Written comments limited to 10 pages or less in length may also be transmitted by facsimile to (202) 219–5046.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Cyr, OSHA Office of Public Affairs, United States Department of Labor, Room N–3641, 200 Constitution Avenue, NW., Washington, DC. 20210, Telephone (202) 219–8151. Copies of the referenced information collection request are available for inspection and copying in the Docket Office and will be mailed to persons who request copies by telephoning Vivian Allen at (202) 219–8076. For electronic copies of the 1,3–Butadiene Information Collection Request, contact OSHA's WebPage on Internet at http://www.osh.gov/.

I. Collection of Information; Request for Comment

This final 1,3–Butadiene standard contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA95) 44 U.S.C. 3501 *et seq.* (see also 5 CFR part 1320). PRA95 defines collection of information to mean, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.'' (44 U.S.C. 3502(3)(A))

The title, the need for and proposed use of the information, a summary of the collections of information, description of the respondents, and frequency of response required to implement the required information collection is described below with an estimate of the annual cost and reporting burden (as required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2)). Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OSHA invites comments on whether the proposed collection of information:

- Ensures that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Estimates the projected burden accurately, including whether the methodology and assumptions used are valid;
- Enhances the quality, utility, and clarity of the information to be collected; and
- Minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Title: 1,3–Butadiene, 29 CFR 1910.1051.

Description: The final 1,3-Butadiene (BD) Standard is an occupational safety and health standard that will minimize occupational exposure to BD. The standard's information collection requirements are essential components that will protect employees from occupational exposure. The information will be used by employers and employees to implement the protection required by the standard. OSHA will use some of the information to determine compliance with the standard.

Summary of the Collection of Information: The collections of information contained in the standard include the provisions concerning objective data; exposure monitoring records and employee notification of exposure monitoring results; written plans for compliance, respiratory protection, exposure goal, emergency situations; information to the physician; employee medical exams and medical

records; respirator fit-testing records; record of training program; employee access to monitoring and medical records; and transfer of records to NIOSH.

Respondents: The respondents are employers whose employees may have occupational exposure to BD above the action level. The main industries affected are 1,3-Butadiene Polymer Production, Monomer purification of 1,3-Butadiene, Stand-Alone Butadiene Terminals, and Crude 1,3-Butadiene Producers.

Frequency of Response: The frequency of monitoring and notification of monitoring results will be dependent on the results of the initial and subsequent monitoring events and the number of different job classifications with BD exposure. The Compliance Plan is required to be established and updated as necessary and reviewed at least annually. The Exposure Goal Program, Respiratory Protection Program, and Emergency Plans are required to be established and updated as necessary. For those using respirators, respirator fit testing is required initially, and at least annually thereafter. The frequency of the medical examinations will be dependent on the number of employees who will be exposed at or above the action level, or in emergency situations. A record of the training program is required to be maintained. Those employers using objective data in lieu of monitoring must maintain records of the objective data relied upon. The employer must maintain exposure monitoring and medical records, which includes information provided to the physician or other licensed health care professional, in accordance with 29 CFR 1910.20. Fit-Test records must be maintained for respirator users until the next fit test is administered.

Total Estimated Cost: First Year $820,388; Second Year $658,949; and Third and Recurring Years $75,890.

Total Burden Hours: The total burden hours for the first year is estimated to be *8,077;* for the second year, the burden is estimated to be *5,342;* and for the third and recurring years, the burden is estimated to be *1,587.* The Agency has submitted a copy of the information collection request to OMB for its review and approval. Interested parties are requested to send comments regarding this information collection to the OSHA Docket Office, Docket No. ICR 96–13, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW, Washington, DC 20210. Written comments limited to 10 pages or fewer may also be transmitted by facsimile to (202) 219–5046.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the final information collection request; they will also become a matter of public record.

Copies of the referenced information collection request are available for inspection and copying in the OSHA Docket Office and will be mailed to persons who request copies by telephoning Vivian Allen at (202) 219–8076. Electronic copies of the 1,3-Butadiene information collection request are available on the OSHA WebPage on the Internet at http://www.osha.gov/.

Federalism

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act, a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such State Plan-States must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Where such standards are applicable to products distributed or used in interstate commerce, they may not unduly burden commerce and must be justified by compelling local conditions. (See section 18(c)(2).)

The final BD standard is drafted so that employees in every State will be protected by general, performance-oriented standards. States with occupational safety and health plans approved under section 18 of the OSH Act will be able to develop their own State standards to deal with any special problems which might be encountered in a particular state. Moreover, the performance nature of this standard, of and by itself, allows for flexibility by States and employers to provide as much leeway as possible using alternative compliance.

This final rule of BD addresses a health problem related to occupational exposure to BD which is national in scope.

Those States which have elected to participate under section 18 of the OSH Act would not be preempted by this regulation and will be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal Standard.

State Plans

The 23 States and 2 territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within 6 months of the publication of this final standard for occupational exposure to 1,3-butadiene or amend their existing standards if it is not ''at least as effective'' as the final Federal standard. The states and territories with occupational safety and health state plants are: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these states and territories.

SUPPLEMENTARY INFORMATION:

I. Table of Contents

The preamble to the final standard on occupational exposure to BD discusses events leading to the final rule, physical and chemical properties of BD, manufacture and use of BD, health effects of exposure, degree and significance of the risk presented, an analysis of the technological and economic feasibility, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions set forth in the proposed standard. The discussion follows this outline:

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (''the Act'') is to ''assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. U.S.C. 655(a) (authorizing summary adoption of existing consensus and federal standards within two year of Act's enactment), 655(b) (authorizing promulgation of standards pursuant to notice and comment), 654(b) (requiring employers to comply with OSHA standards.)

A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' 29 U.S.C. 652(8).

A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk, and is economically feasible, technologically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency actions, supported by substantial evidence, and is better able to effectuate the Act's purposes than any national consensus standard it supersedes. See 58 FR 16612–16616 (March 30, 1993).

The Supreme Court has noted that a reasonable person would consider a fatality risk of 1/1000 over a 45-year working lifetime to be a significant risk. Industrial Union *Dep't* v. *American Petroleum Institute, 448 U.S. 607,* 646 (1980) (benzene standard). OSHA agrees that a fatality risk of 1/1000 over a working lifetime *is well within the range of risk that* reasonable people would consider significant. See e.g., *International Union, UAW* v. *Pendergrass,* 878 F.2d 389 (D.C. Cir. 1989) (formaldehyde standard); *Building and Constr. Trades Dep't, AFL–CIO* v. *Brock,* 838 F.2d 1258, 1265 (D.C. Cir. 1988) (asbestos standard).

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. *American Textile Mfrs. Institute* v. *OSHA,* 452 U.S. 490, 513 (1981) (''ATMI''), *American Iron and Steel Institute* v. *OSHA,* 939 F.2d 975, 980 (D.C. cir. 1991) (''AISI'').

A standard is economically feasible if industry can absorb or pass on the cost of compliance without threatening its long term profitability or competitive structure. See *ATMI,* 452 U.S. at 530 n. 55; *AISI,* 939 F. 2d at 980.

A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. ATMI, 453 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA,* 37 F. 3d 665, 668 (D.C. Cir. 1994) (''LOTO III'').

All standards must be highly protective. See 58 FR 16614–16615; *LOTO III,* 37 F. 3d at 668. However, health standards must also meet the ''feasibility mandate'' of Section 6(b)(5) of the Act, 29 U.S.C. 655(b)(5). Section 6(b)(5) requires OSHA to select ''the most protective standard consistent with feasibility'' that is needed to reduce significant risk when regulating health hazards. *ATMI,* 452 U.S. at 509.

Section 6(b)(5) also directs OSHA to base health standards on ''the best available evidence,'' including research, demonstrations, and experiments. 29 U.S.C. 655(b)(5). OSHA shall consider ''in addition to the attainment of the highest degree of health and safety protection * * * the latest scientific data * * * feasibility and experience gained under this and other health and safety laws.'' *Id.*

Section 6(b)(7) of the Act authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing and other information gathering and transmittal provisions. 29 U.S.C. 655(b)(7).

Finally, whenever practical, standards shall ''be expressed in terms of objective criteria and of the performance desired.'' *Id.*

III. Events Leading to the Final Standard

The standard adopted for BD by OSHA in 1971 pursuant to Section 6(a) of the OSH Act, 29 U.S.C. 655 from an existing Walsh-Healey Federal Standard required employers to assure that employee exposure does not exceed 1,000 ppm determined as an 8-hour TWA (29 CFR 1910.1000, Table Z–1). The source of the Walsh-Healey Standard was the Threshold Limit Value (TLV) for BD developed in 1968 by the American Conference of Governmental Industrial Hygienists (ACGIH). This TLV was adopted by the ACGIH to prevent irritation and narcosis.

In 1983, the National Toxicology Program (NTP) released the results of an animal study indicating that BD causes cancer in rodents. (Ex. 20) Based on the strength of the results of this animal study, ACGIH in 1983 classified BD as an animal carcinogen and in 1984 recommended a new TLV of 10 ppm. (Ex. 2–4) Based on the same evidence, on February 9, 1984, the National Institute for Occupational Safety and Health (NIOSH) published a Current Intelligence Bulletin (CIB) recommending that BD be regarded as a potential occupational carcinogen, teratogen and a possible reproductive hazard. (Ex. 23–17) On January 5, 1984, OSHA published a Request for Information (RFI) jointly with the Environmental Protection Agency. (EPA) (49 FR 844) EPA also announced the initiation of a 180 day review under the authority of section 4(f) of the Toxic Substance Control Act (TSCA) (49 FR 845) to determine ''whether to initiate appropriate action to prevent or reduce the risk from the chemical or to find that the risk is not unreasonable.'' Comments were to be submitted to OSHA by March 5, 1984. On April 4, 1984, OSHA extended the comment period until further notice. (49 FR 13389)

Petitions for an Emergency Temporary Standard (ETS) of 1 ppm or less for workers' exposure to BD were submitted to OSHA on January 23, 1984, by the United Rubber, Cork, Linoleum and

Plastic Workers of America (URW), the Oil, Chemical and Atomic Workers (OCAW), the International Chemical Workers Union (ICWU), and the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO). (Ex. 6–4) On March 7, 1984, OSHA denied the petitions on the ground that the Agency was still evaluating the health data to determine whether regulatory action was appropriate.

Based on its 180-day review of BD, EPA published, on May 15, 1984, an Advance Notice of Proposed Rulemaking (ANPR) (49 FR 20524) to announce the initiation of a regulatory action by the EPA to determine and implement the most effective means of controlling exposures to the chemical BD under the TSCA. EPA was working with OSHA because available evidence indicated that exposure to BD occurs primarily within the workplace.

Information received in response to this ANPR was used by EPA to develop risk assessments. Subsequently, EPA identified BD as a probable human carcinogen (Group B2) according to EPA's classification of carcinogens, and concluded that current exposures during the manufacturing of BD and its processing into polymers presented an unreasonable risk of injury to human health. (Ex. 17–4) Additionally, EPA determined that the risks associated with exposure to BD may be reduced to a sufficient extent by action taken under the OSH Act. Following these findings, EPA, in accordance with section 9(a) of TSCA, on October 10, 1985 (50 FR 41393), referred BD to OSHA to give this Agency an opportunity to regulate the chemical under the OSH Act. EPA requested that OSHA determine whether the risks described in the EPA report may be prevented or reduced to a sufficient extent by action taken under the OSH Act and then if such a determination is made, OSHA issue an order declaring whether the manufacture and use of BD described in the EPA report present the risk therein described. EPA asked OSHA to respond within 180 days, by April 8, 1986. (50 FR 41393)

On December 27, 1985, OSHA published a notice soliciting public comments on EPA's referral report. (50 FR 52952) Based on all the available information, OSHA, on April 11, 1986, responded to the EPA referral report by making a preliminary determination (50 FR 12526) that a revised OSHA standard limiting occupational exposure to BD could prevent or reduce the risk of exposure to a sufficient extent and that such risks had been accurately described by EPA in the report. On October 1, 1986, OSHA published an ANPR (51 FR 35003) to initiate a rulemaking within the meaning of section 9(a) of TSCA. The Agency requested that comments be submitted by December 30, 1986. Twenty-four comments, some of them containing new information, were received in response to the ANPR. (Ex. 28–1 to 28–24) Six additional comments were received after the deadline. (Ex. 29–1 to 29–6)

OSHA reviewed the available data and conducted risk assessment, regulatory impact and flexibility analyses. These analyses demonstrate that the proposed standard was technologically and economically feasible and substantially reduced the significant risk of cancers and other adverse health effects.

On August 10, 1990, OSHA published its proposed rule to regulate occupational exposure to 1,3-butadiene. (55 FR 32736) Based on the Agency's review of studies of exposed animals and epidemiologic studies and taking into account technologic and economic feasibility considerations, OSHA proposed a permissible exposure limit (PEL) of 2 ppm as an 8-hour time-weighted average and a short term exposure limit (STEL) of 10 ppm for a 15 minute sampling period. Also included in the proposal was an ''action level'' of 1 ppm which triggered certain provisions of the standard such as medical surveillance and training.

OSHA convened public hearings in Washington, DC., on January 15–23, 1991, and in New Orleans, Louisiana, on February 20–21, 1991. The post-hearing period for the submission of briefs, arguments and summations was to end July 22, 1991, but was extended by the Administrative Law Judge to December 13, 1991, in order to give participants time to review new data on low-dose exposures submitted by NTP and a quantitative risk assessment done by NIOSH. The comment period closed February 10, 1992.

In the Fall of 1992, the International Agency for Research on Cancer (IARC) published the results of the Working Group on the Evaluation of Carcinogenic Risks to Humans, which reviewed the carcinogenic potential of BD and concluded that:

> There is limited evidence for the carcinogenicity in humans of 1,3-butadiene * * * There is sufficient evidence for the carcinogenicity in experimental animals * * * (Ex. 125)

IARC stated that its overall evaluation led it to conclude that ''1,3-butadiene is probably carcinogenic to humans (Group 2A).'' (Ex. 125)

To assist OSHA in issuing a final rule for BD, representatives of the major unions and industry groups involved in the production and use of BD submitted the outline of a voluntary agreement reached by the parties dated January 29, 1996, outlining provisions that they agreed upon and recommended be included in the final rule. The letter transmitting the agreement was signed by J.L. McGraw for the International Institute of Synthetic Rubber Producers (IISRP), Michael J. Wright for the United Steelworkers of America (USWA), and Michael Sprinker (CWU). The committee that worked on the issues also included Joseph Holtshouser of the Goodyear Tire and Rubber Company, Carolyn Phillips of the Shell Chemical Company, representing the Chemical Manufacturers Association, Robert Richmond of the Firestone Synthetic Rubber and Latex Company, and Louis Beliczky (formerly of the URW) and James L. Frederick of the SWA.

The agreement proposed a change in the permissible exposure limits, additional provisions for exposure monitoring, and an exposure goal program designed to reduce exposures below the action level. It also set forth other modifications to the scope, respiratory protection, communication of hazards, medical surveillance, and start-up dates sections of the final rule.

On March 8, 1996 OSHA published the labor/industry joint recommendations and re-opened the record for 30 days to allow the public to comment. (61 FR 9381) In response to requests from the parties to the agreement, the comment period was extended to April 26, 1996. (61 FR 15205)

At the beginning of the comment period, OSHA placed in the rulemaking record an epidemiologic study of BD exposed workers by Delzell, et al. sponsored by IISRP, along with IARC volume 127 ''Butadiene and Styrene Assessment of Health Hazards,'' a published paper by Santos-Burgoa, et al. entitled ''Lymphohematopoietic Cancer in Styrene-Butadiene Polymerization Workers,'' and abstracts from a symposium entitled ''Evaluation of Butadiene and Isoprene Health Risks.'' (Ex. 117–1; 117–2; 117–3; 117–4) The epidemiological study had also been submitted to the EPA in compliance with provisions of the Toxic Substances Control Act.

In response to the re-opening of the BD record, 18 sets of comments were received. The parties to the labor/industry agreement submitted a draft regulatory text which put their recommendations into specific requirements. The outline and the

subsequent draft regulatory text are solely the work product of the negotiating committee. OSHA was neither a party to nor present at the negotiations.

While the responses to the record re-opening helped clarify the intent of the negotiating parties, the rationales behind several of the changes were not fully explained.

On September 16, 1996, Judge John M. Vittone, for Judge George C. Pierce who presided over the BD hearings, closed the record of the public hearing on the proposed standard for 1,3-butadiene and certified it to the Assistant Secretary of Labor. (Ex. 135)

IV. Chemical Identification, Production and Use

A. Monomer

The chemical 1,3-butadiene (BD) (Chemical Abstracts Registry Number 106–99–0) is a colorless, noncorrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure. It has a chemical formula of C_4H_6, a molecular weight of 54.1, and a boiling point of −4.7 °C at 760 mm Hg, a lower explosive limit of 2%, and an upper explosive limit of 11.5%. Its vapor density is almost twice that of air. It is slightly soluble in water, somewhat soluble in methanol and ethanol, and readily soluble in less polar organic solvents such as hexane, benzene, and toluene. (Ex. 17–17) It is highly reactive, dimerizes to 4-vinylcyclohexene, and polymerizes easily. Because of its low odor threshold, high flammability and explosiveness, BD has been handled with extreme care in the industry.

In the United States BD has been produced commercially by three processes: Catalytic dehydrogenation of n-butane and n-butene, oxidative dehydrogenation of n-butene, and recovery as a by-product from the C_4 co-product stream from the steam cracking process used to manufacture ethylene, which is the major product of the petrochemical industry. For economic reasons, almost all BD currently made in the U.S. is produced by the ethylene co-product process.

In the steam cracking process for ethylene, a hydrocarbon feedstock is diluted with steam then heated rapidly to a high temperature by passing it through tubes in a furnace. The output stream, containing a broad mixture of hydrocarbons from the pyrolysis reactions in the cracking tubes plus unreacted components of feedstock, is cooled and then processed through a series of distillation and other separation operations in which the various products of the cracking operation are separated for disposal, recycling or recovery.

The cracking process produces between 0.02 to 0.3 pounds of BD per pound of ethylene, depending upon the composition of the feedstock. BD is recovered from the C_4 stream by the separation operations. The C_4 stream contains from 30 to 50% BD plus butane, butenes and small fractions of other hydrocarbons. This crude BD stream from the ethylene unit may be refined in a unit on site, or transferred to another location, a monomer plant, owned by the same or a different company, to produce purified BD.

Regardless of the source of the crude BD-ethylene co-product, (dehydrogenation, or blending of C_4 streams from other sources), the processes used by different companies to refine BD for subsequent use in polymer production are similar. Extractive distillation is used to effect the basic separation of BD from butanes and butenes and fractional distillation operations are used to accomplish other related separations. A typical monomer plant process is described below.

C_3 and C_4 acetylene derivatives, present in the C_4 co-product stream, are converted to olefins by passing the stream through a hydrogenation reactor. The stream is then fed to an extractive distillation column to separate the BD from butanes and butenes. Several different solvents have been employed for this operation, including n-methylpyrrolidone, dimethylformamide, furfural, acetonitrile, dimethylacetamide, and cuprous ammonium acetate solution. The BD, extracted by the solvent, is stripped from it in the solvent recovery column, then fed to another fractionation column, the methylacetylene column, to have residual acetylene stripped out. The bottom stream from the methylacetylene column, containing the BD, is fed to the BD rerun column, from which the purified BD product is taken off overhead. The solvent, recovered in the solvent recovery column, is recycled to the extractive distillation column with part of it distilled to keep down the level of polymer. (Ex. 17–17)

A stabilizer is added to the monomer to inhibit formation of polymer during storage. It is stored as a liquid under pressure, sometimes refrigerated to reduce the pressure, generally stored in a tank farm in diked spheres. It is shipped to polymer manufacturers and other users by pipeline, barge, tank car, or tank truck.

BD is a major commodity product of the petrochemical industry. Total U.S. production of BD in 1991 was 3.0 billion pounds. Although BD is a toxic flammable gas, its simple chemical structure with low molecular weight and high chemical reactivity make it a useful building block for synthesizing other products. In ''1,3-Butadiene Use and Substitutes Analysis,'' EPA identified 140 major, minor and potential uses of BD in the chemical industry. (Ex. 17–15)

Over 60% of the BD consumed in the United States is used in the manufacture of rubber, about 12% in making adiponitrile which in turn is used to make hexamethylenediamine (HMDA), a component of Nylon, approximately 8% in making styrene-butadiene copolymer latexes, approximately 7% in producing polychloroprene, and about 6% in producing acrylonitrile-butadiene-styrene (ABS) resins. Lesser amounts are consumed in the production of rocket propellants, specialty copolymer resins and latexes for paint, coatings and adhesive applications, and hydrogenated butadiene-styrene polymers used as lubricating oil additives. Some nonpolymer applications include the manufacture of the agricultural fungicides, Captan and Captofol, the industrial solvent sulfolane, and anthroquinone dyes.

B. Polymers

BD based synthetic elastomers are manufactured by polymerizing BD by itself, by polymerizing BD with other monomers to produce copolymers, and by producing mixtures of these polymers. The largest-volume product is the copolymer of styrene and BD, styrene-butadiene rubber, followed in volume by polybutadiene, polychloroprene, and nitrile rubber. Polybutadiene is the polymer of BD monomer by itself. Polychloroprene is made by polymerizing chloroprene, produced by chlorination of BD. Nitrile rubbers are copolymers of acrylonitrile and BD.

Four general types of processes are used in polymerizing BD and its copolymers: emulsion, suspension, solution and bulk polymerization. In emulsion and suspension polymerization, the monomers and the many chemicals used to control the reaction are finely dispersed or dissolved in water. In solution polymerization, the monomers are dissolved in an organic solvent such as hexane, pentane, toluene. In bulk polymerization, the monomer itself serves as solvent for the polymer. The polymer product, from which end-use products are manufactured, is produced in the form of polymer crumb (solid particles), latex (a milky suspension in water), or cement (a solution).

Emulsion polymerization is the principal process used to make synthetic rubber. A process for the manufacture of styrene-butadiene crumb is typical of emulsion processes. Styrene and BD are piped to the process area from the storage area. The BD is passed through a caustic soda scrubber to remove the inhibitors which were added to prevent premature polymerization. The fresh BD monomer streams are mixed with styrene, aqueous emulsifying agents, activator, catalyst, and modifier, and then fed to the first of a train of reactors. The reaction proceeds stepwise in the series of reactors to around 60% conversion of monomer to polymer. In the cold process, the reactants are chilled and the reactor temperature is maintained at 4°C to 7°C (40°F to 45°F) and pressure at 0 to 15 psig; in the hot rubber process, temperature and pressure are around 50°C (122°F) and 40 to 60 psig, respectively.

The latex from the reactor train is flashed to evaporate unreacted BD which is compressed, condensed and recycled. Uncondensed vapors are absorbed in a kerosene absorber before venting and the absorbed BD is steam stripped or recovered from the kerosene by some other operation. The latex stream is passed through a steam stripper, operated under vacuum, to remove and recover unreacted styrene. The styrene and water in the condensate are separated by decanting. The styrene phase is recycled to the process. Noncondensibles from the stripping column contain some BD and are directed through the BD recovery operations.

Stripped latex, to which an antioxidant has been added, is pumped to coagulation vessels where dilute sulfuric acid and sodium chloride solution are added. The acid and brine mixture breaks the emulsion, releasing the polymer in the form of crumb. Sometimes carbon black and oil are added during the coagulation step since better dispersion is obtained than by mixing later on.

The crumb and water slurry from the coagulation operation is screened to separate the crumb. The wet crumb is pressed in rotary presses to squeeze out most of the entrained water then dried with hot air on continuous dry belt dryers. The dried product is baled and weighed for shipment.

Production of styrene-butadiene latex by the emulsion polymerization process is similar to that for crumb but is usually carried out on a smaller scale with fewer reactors. For some but not all products, the reaction is run to near completion, monomer removal is simpler and recovery may not be practiced.

Polybutadiene rubber is usually produced by solution polymerization. Inhibitor is removed from the monomer by caustic scrubbing. Both monomer and solvent are dried by fractional distillation, mixed in the desired ratio and dried in a desiccant column. Polymerization is conducted in a series of reactors using initiators and catalysts and is terminated with a shortstop solution. The solution, called rubber cement, is pumped to storage tanks for blending. Crumb is precipitated by pumping the solution into hot water under violent agitation. Solvent and monomer are recovered by stripping and distillation similar to those previously described. The crumb is screened, dewatered, dried and baled.

Polychloroprene (neoprene) elastomers are manufactured by polymerizing chloroprene in an emulsion polymerization process similar to that used for making styrene-butadiene rubber. The monomer, chloroprene (2-chloro-BD), is made by chlorination of BD to make 3,4-dichlorobutene, and dehydrochlorination of the latter.

Nitrile rubbers, copolymers of acrylonitrile and BD, are produced by emulsion polymerization similar to that used to make styrene-butadiene rubber.

Substantial amounts of BD are used in the production of two other large volume polymers: Nylon resins and ABS resin. Dupont manufactures adiponitrile from BD and uses the product to make hexamethylenediamine which is polymerized in making Nylon resins and fibers, including Nylon 6,6. Acrylonitrile, BD and styrene are the monomers used to make ABS resin which is a major thermoplastic resin. Chemically complex emulsion, suspension and bulk polymerization processes are used by different producers to make ABS polymer.

V. Health Effects

A. Introduction

The toxicity of BD was long considered to be low and non-cumulative. Thus, the OSHA standard for BD was 1,000 ppm on the basis of its irritation of mucous membranes and narcosis at high levels of exposure. However, in the 1980s, carcinogenicity studies indicated BD is clearly a carcinogen in rodents. In 1986, the American Conference of Governmental Industrial Hygienists (ACGIH) was prompted by these studies to lower the workplace threshold limit value (TLV) from 1,000 to 10 ppm. (Ex. 2–5)

Rodent studies are now conclusive that BD is an animal carcinogen. Further, a consistent body of epidemiologic studies have also shown increased mortality from hematopoietic cancers associated with BD exposure among BD-exposed production and styrene/BD rubber polymer workers. Complementary studies of metabolic products and genotoxicity support these cancer findings. OSHA was also concerned about evidence that BD affects the germ cell as well as the somatic cell, and what potential reproductive toxicity might result from exposure to BD. Since BD itself does not appear to be carcinogenic, but must be metabolized to an active form, OSHA also reviewed studies on the metabolism of BD to determine wether they might help explain the observed differences in cancer incidence among species.

The following sections discuss the effects of BD exposure, both in human and animal systems.

B. Carcinogenicity

1. Animal Studies

In the proposed BD rule, OSHA discussed the results of two lifetime animal bioassays, one on the Sprague-Dawley rat and one in the $B6C3F_1$ mouse. (55 FR 32736 at 32740) Both studies found evidence of BD carcinogenicity, with the greater response in the mouse. The rat study involved exposure levels of 0, 1000, or 8000 ppm BD, starting at five weeks of age, to groups of 100 male and 100 female Sprague-Dawley rats for 6 hours per day, five days per week, for 105 weeks. Mortality was increased over controls in the 1,000 ppm exposed female rats and in both of the male rat exposure groups. Significant tumor response sites in the male rats included exocrine adenomas and carcinomas (combined) of the pancreas in the highest exposure group (3, 1, and 11 tumors in the 0, 1000, and 8000 ppm groups, respectively); and Leydig-cell tumors of the testis (0, 3, and 8 in the same groups, respectively). In the female rats, the significantly increased tumor response also occurred in the highest exposure group; cancers seen included follicular-cell adenomas and carcinomas (combined) of the thyroid gland (0,4, and 11 tumors in the three exposure groups, respectively), and benign and malignant (combined) mammary gland tumors (50, 79, and 81 in the same exposure groups). To a lesser degree there were also sarcomas of the uterus (1, 4, 5 tumors in the three exposure groups), and Zymbal gland (0, 0, 4 tumors in the same exposure groups, respectively). While only high

exposure group tumor response for some of these sites was statistically significant, trend tests were also significant.

In contrast to the generally less than 10% increase in tumor response seen in the Sprague-Dawley rat at levels far above BD metabolic saturation, the carcinogenic response to BD in the $B6C3F_1$ mouse in the National Toxicology Program study (NTP I) was extensive. (Ex. 23–1) In this study, groups of 50 male and 50 female mice were exposed via inhalation to 0, 625 or 1250 ppm BD for 6 hours per day, 5 days per week in a study originally designed to last 2 years. However, the high carcinogenic response included multiple primary cancers, with short latent periods, and led to early study termination (60–61 weeks) due to high cancer mortality in both the 625 ppm and 1250 ppm exposure groups of both sexes. This mortality was due mainly to lymphocytic lymphomas and hemangiosarcomas of the heart, both of which were typically early occurring and quickly fatal. This large and rapidly fatal carcinogenic response led to both the NTP and industry to undertake additional studies to better understand the mechanisms involved.

Some commenters have associated qualitative or quantitative differences in mouse and rat BD carcinogenicity with the differences in rat and mouse BD metabolism. Many studies published and submitted to the BD record since the proposed rule have sought to better characterize the metabolic, distributional, and elimination processes involved, and some have attributed species differences (at least in part) to the metabolic differences. These will be addressed separately in the metabolism section.

Another factor hypothesized to account for differences between mouse and rat BD carcinogenicity was the role of activation of ecotropic retrovirus in hematopoietic tissues on tumor response in the $B6C3F_1$ mouse. This virus is endogenous to the $B6C3F_1$ mouse and was hypothesized to potentiate the BD lymphoma response in this strain. To study this hypothesis Irons and co-workers exposed both (60) $B6C3F_1$ male (those with the endogenous virus) and (60) NIH Swiss male (those without the endogenous virus) mice to either 0 or 1250 ppm BD, for 6 hours./day, 5 days per week for 52 weeks. (Ex. 32–28D) A third group of 50 $B6C3F_1$ male mice received 1250 ppm for 12 weeks only and was observed until study termination at 52 weeks. The results of the study showed significantly increased thymic lymphomas in all exposed groups but significantly greater response in the $B6C3F_1$ mouse—1 tumor/60 (2%) in the control (zero exposure) group, 10/48 (21%) in the 12 week exposure group, and 34/60 (57%) in the 52 week exposure group—vs. the NIH Swiss mice, which developed 0 tumors/60 in the control group, and 8 tumors/57 (14%) in the BD exposed group. Hemangiosarcomas of the heart were also observed in both strains exposed to BD for 52 weeks—5/60 (8%) in the $B6C3F_1$ mice vs. 1/57 in the NIH Swiss mice. (Ex. 32–28D). The $B6C3F_1$ response was very similar to the NTP I high exposure group response, verifying that earlier study. The qualitatively similar lymphoma responses of the two strains also confirmed that the mouse hematopoietic system is highly susceptible to the carcinogenic effects of BD, although quantitatively the strains may differ. The 21% 1-year lymphoma response in the 12-week stop-exposure $B6C3F_1$ group also increased concerns about high concentration, short duration exposures.

NTP II Study

Concurrent with the industry studies, the NTP, in order to better characterize the dose-response and lifetime experience, conducted a second, much larger research effort over a much broader dose range. (Ex. 90; 96) These toxicology and carcinogenesis studies included a 100-fold lower (6.25 ppm) low exposure group than NTP I, several intermediate exposure groups, a study of dose-rate effects using several high-concentration partial lifetime (stop-) exposure groups, and planned interim sacrifice groups. Other parts of the study included clinical pathology studies (with the 9- and 15-month interim sacrifices, metabolism studies, and examination of tumor bearing animals for activated oncogenes).

For the lifetime carcinogenesis studies, groups of 70 $B6C3F_1$ mice of each sex were exposed via inhalation to BD at levels of 0, 6.25, 20, 62.5, 200, or 625 ppm (90 of each sex in this highest group) for 6 hours per day, 5 days per week for up to 2 years. Up to 10 randomly selected animals in each group were sacrificed after 9 and 15 months of exposure, and these animals were assessed for both carcinogenicity and hematologic effects.

For the stop-exposure study, different groups of 50 male mice were exposed 6 hours per day, 5 days per week to concentrations of either 200 ppm for 40 weeks, 625 ppm for 13 weeks, 312 ppm for 52 weeks, or 625 ppm for 26 weeks. Following the BD exposure period, the exposed animals were then observed for the remainder of the 2-year study. The first two stop-exposure groups received a total exposure (concentration times duration) of 8,000 ppm-weeks, while the latter two groups received approximately 16,000 ppm-weeks of exposure. For the analysis discussed below, groups are compared both with each other for dose-rate effects and with the lifetime (2 year) exposure groups for recovery effects.

Methodology

Male mice were 6–8 weeks old and female mice were 7–8 weeks old when the exposures began. Animals were exposed in individual wire mesh cage units in stainless steel Hazelton 2000 chambers (2.3 m^3). The exposure phase extended from January, 1986 to January, 1988. Animals were housed individually; water was available *ad libitum;* NIH–07 diet feed was also available *ad libitum* except during exposure periods. Animals were observed twice daily for moribundity and mortality; animals were weighed weekly for the first 13 weeks and monthly thereafter. Hematology included red blood cell count (RBC), and white blood cell count (WBC). The study was conducted in compliance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations with retrospective quality assurance audits.

The results of the study are presented below for the two-year and stop-exposure study. Between study group comparisons are made where it is deemed appropriate. Emphasis is placed on the neoplastic effects.

Results

Two-Year Study

While body weight gains in both exposed male and female mice were similar to those of the control groups, exposure related malignant neoplasms were responsible for decreased survival in all exposure groups of both sexes exposed to concentrations of 20 ppm or above. Excluding the interim sacrificed animals, the two-year survival decreased uniformly with increasing exposure for females (37/50, 33/50, 24/50, 11/50, 0/50, 0/70), and nearly uniformly for males (35/50, 39/50, 24/50, 22/50, 4/50, 0/70). As with the earlier NTP study, all animals in the 625 ppm group were dead by week 65, mostly as a result of lymphomas or hemangiosarcomas of the heart. The 200 ppm exposure groups of both sexes also had much higher mortality, but significantly less than that of the 625 ppm group. The survival of the lowest exposure group (6.25 ppm) was slightly better than controls for the male mice, slightly less for the female mice. Mean

survival for the males was an exposure-related 597, 611, 575, 558, 502, and 280 days; for the females it was similarly 608, 597, 573, 548, 441, and 320 days. This decreased survival with increasing exposure was almost totally due to tumor lethality.

Carcinogenicity

Nine different sites showed primary tumor types associated with butadiene exposures, seven in the male mice and eight in the female mice. These were lymphoma, hemangiosarcoma of the heart, combined alveolar-bronchiolar adenoma and carcinoma, combined forestomach papilloma and carcinoma, Harderian gland adenoma and adenocarcinoma, preputial gland adenoma and carcinoma (males only), hepatocellular adenoma and carcinoma, and mammary and ovarian tumors (females only). These are shown in Table V–1 adapted from Melnick et al. (Ex. 125) From this table it is seen that six of these tumor sites are statistically significantly increased in the highest exposed males and five were statistically significantly increased in the highest exposed females. Two additional sites which showed significant increases at lower exposures showed decline at the highest exposures because other tumors were more rapidly fatal. At 200 ppm preputial gland adenoma and carcinoma combined were significantly increased in males ($p<.05$; 0/70 (0%) control vs. 5/70 (7%) in the 200 ppm group) and hepatocellular adenoma and carcinoma were increased for both exposed males and females. At the lowest exposure concentration, 6.25 ppm, only female mouse lung tumors (combined adenoma and carcinoma) showed statistical significance ($p<.05$; 4/70 (6%) in controls vs. 15/70 (21%) in the 6.25 ppm group); these tumors in female mice showed a monotonic increase with increasing exposure up to 200 ppm. At 20 ppm female mouse lymphomas and liver tumors also reached statistical significance (lymphomas, $p<.05$; 10/70 (15%) in controls vs. 18/70 (26%) in the 20 ppm group; liver tumors, $p<.05$; 17/70 (24%) in controls vs. 23/70 (33%) in the 20 ppm group), and at 62.5 ppm, tumors at several other sites were also significantly increased. In general, while there were some differences in amount of tumor response between the male and female mice, there is fairly consistent pattern of tumor type in mice of both sexes for the six non-sexual organ sites.

TABLE V–1.—TUMOR INCIDENCES (I) AND PERCENTAGE MORTALITY-ADJUSTED TUMOR RATES (R) IN MICE EXPOSED TO 1,3-BUTADIENE FOR UP TO 2 YEARS.

[Adapted from Ex. 125]

Tumor	Sex	Exposure concentration (ppm)											
		0		6.25		20		62.5		200		625	
		I	R[c]	I	R	I	R	I	R	I	R	I	R
Lymphoma	M	4/70	8	3/70	6	8/70	19	11/70	[a]25	9/70	[a]27	69/90	[a]97
	F	10/70	20	14/70	30	[a]18/70	41	10/70	26	19/70	[a]58	43/90	[a]89
Heart—Hemangiosarcoma	M	0/70	0	0/70	0	1/70	2	5/70	[a]13	20/70	[a]57	6/90	[a]53
	F	0/70	0	0/70	0	0/70	0	1/70	3	20/70	[a]64	26/90	84
Lung—Alveolar-bronchiolar adenoma and carcinoma.	M	22/70	46	23/70	48	20/70	45	33/70	[a]72	42/70	[a]87	12/90	[a]73
Forestomach—Papilloma and carcinoma	F	4/70	8	15/70	[a]32	19/70	[a]44	27/70	[a]61	32/70	[a]81	25/90	[a]83
Harderian gland—Adenoma and adenocarcinoma	M	1/70	2	0/70	0	1/70	2	5/70	13	12/70	[a]36	13/90	[a]75
	F	2/70	4	2/70	4	3/70	8	4/70	12	7/70	[a]31	28/90	[a]85
Preputial gland—Adenoma and carcinoma	M	6/70	13	7/70	15	11/70	25	24/70	[a]53	33/70	[a]77	7/90	[a]58
	F	9/70	18	10/70	21	7/70	17	16/70	[a]40	22/70	[a]67	7/90	48
Liver—Hepatocellular adenoma and carcinoma	M	0/70	0	0/70	0	0/70	0	0/70	0	5/70	[a]17	0/90	0
Mammary gland—Adenocarcinoma	M	31/70	55	27/70	54	35/70	68	32/70	69	40/70	[a]87	12/90	75
Ovary—Benign and malignant granulosa-cell tumors.	F	17/70	35	20/70	41	23/70	[a]52	24/70	[a]60	20/70	[a]68	3/90	28
	F	0/70	0	2/70	4	2/70	5	6/70	[a]16	13/70	[a]47	13/90	[a]66
	F	1/70	2	0/70	0	0/70	0	9/70	[a]24	11/70	[a]44	6/90	44

[a] Increased compared with chamber controls (0 ppm), $p < 0.05$, based on logistic regression analysis.
[b] The Working Group noted that the incidence in control males and females was in the range of that in historical controls (Haseman et al., 1985).
[c] Mortality adjusted tumor rates are adjusted for competing causes of mortality, such as death due to other tumors, whose rates differ by exposure group.

Hemangiosarcoma of the heart, with metastases to other organs was first observed at 20 ppm in 1 male (the historical controls for this strain are 1/2373 in males and 1/2443 in females), in 5 males and 1 female at 62.5 ppm and in 20 males and 20 females at 200 ppm; at 625 ppm these tumor rates leveled off as other tumors, especially lymphomas became dominant. Lymphatic lymphomas increased to statistical significance first in females at 20 ppm and were usually rapidly fatal, the first tumor appearing at week 23, most likely preempting some of the later appearing tumors in the higher exposure groups. Because of the plethora of primary tumors and the different time patterns observed to onset of each type, several tumor dose-response trends do not appear as strong as they would otherwise be.

Non-Neoplastic Effects

Several non-cancer toxic effects were noted in the exposed groups, reflecting many of the same target sites for which the neoplastic effects were seen. (Ex. 90; 96; 125).

Although the reported numbers differ slightly in the different exhibits, generally dose-related increases in hyperplasia were observed in the heart, lung, forestomach, and Harderian gland, both in the two-year study (both sexes) and in the stop-exposure study (conducted in males only). In addition, testicular atrophy was observed in both the two-year and stop-exposure male mice, but remained in the 6%–10% range except for the 2-year, 625 ppm

group where it was 74%. Ovarian germinal hyperplasia (2/49 (control), 3/49 (6.25 ppm), 8/48 (20 ppm), 15/50 (62.5 ppm), 15/50 (200 ppm), 18/79 (625 ppm), ovarian atrophy (4/49, 19/49, 32/48, 42/50, 43/50, 69/79), and uterine atrophy (1/50, 0/49, 1/50, 1/49, 8/50, 41/78) were also dose related, with ovarian atrophy significantly increased at the lowest BD exposure of 6.25 ppm. These toxic effects to the reproductive organs are discussed in greater detail in the reproductive effects section of this preamble. Bone marrow atrophy was noted only in the highest exposure groups, occurring in 23/73 male mice and 11/79 female mice.

Stop-Exposure Study

As with the 2-year study, the body weights of the four treated groups in the stop-exposure study were similar to controls. All exposure groups exhibited markedly lower survival than controls, and only slightly better survival than that of the comparable full lifetime exposure groups. Mortality appeared to be more related to total dose than to exposure concentration. Most deaths were caused by tumors.

Neoplastic Effects

All of these stop-exposure groups exhibited a very similar tumor profile to that of the lifetime high exposure groups, with the lone exception of liver tumors, which were increased only in the lifetime exposure group; all the other multiple primary tumors were observed at significantly increased levels in both the stop- and lifetime-exposure groups, Table V–2. (Ex. 125) In addition, the 625 ppm, 26 week exposure group had higher rates for several of the tumor types compared to the lifetime 625 ppm group, possibly because of the shorter exposure group's slightly better survival. The most prevalent tumor type, lymphoma, also showed a dose-rate effect, as the tumor incidence was greater for exposure to short-term higher concentrations compared with a lower long-term exposure ($p=.01$; 24/50 at 625 ppm for 13 weeks vs. 12/50 at 200 ppm for 40 weeks: $p<.0001$; 37/50 at 625 ppm for 26 weeks vs. 15/50 at 312 ppm for 52 weeks). The same pattern was seen with forestomach tumors and preputial gland carcinomas. Conversely, the hemangiosarcomas of the heart and alveolar-bronchiolar tumors showed an opposite trend, as lower exposures for a longer time yielded a significantly higher incidence of these tumors than the same cumulative exposures over a shorter time (survival-adjusted, as opposed to the raw incidence lung tumor rates actually suggest no dose-response trends). These inconsistent trends with the different tumor sites may be the result of multiple mechanisms of carcinogenicity or partially due to the rapid fatality caused by lymphocytic lymphomas in the short-term high-exposure groups. As with the lifetime study, angiosarcomas of the heart and lymphomas presented competing risks in the highly exposed mice.

TABLE V–2.—TUMOR INCIDENCES (I) AND PERCENTAGE MORTALITY-ADJUSTED TUMOR RATES (R) IN MALE MICE EXPOSED TO 1,3-BUTADIENE IN STOP-EXPOSURE STUDIES. (AFTER EXPOSURES WERE TERMINATED, ANIMALS WERE PLACED IN CONTROL CHAMBERS UNTIL THE END OF THE STUDY AT 104 WEEKS.)

[Adapted from Ex. 125]

Tumor	Exposure									
	0		200 ppm, 40 wk		625 ppm, 13 wk		312 ppm, 52 wk		625 ppm, 26 wk	
	I	R[c]	I	R	I	R	I	R	I	R
Lymphoma	4/70	8	12/50	[a]35	24/50	[a]61	15/50	[a]55	37/50	[a]90
Heart—Hemang-iosarcoma	0/70	0	7/50	[a]47	7/50	[a]31	33/50	[a]87	13/50	[a]76
Lung—Alveolar-bronchiolar adenoma and carcinoma	22/70	46	35/50	[a]88	27/50	[a]87	32/50	[a]88	18/50	[a]89
Forestomach—Squamous-cell papilloma and carcinoma	1/70	2	6/50	[a]20	8/50	[a]33	13/50	[a]52	11/50	[a]63
Harderian gland—Adenoma and adenocarcinoma	6/70	13	27/50	[a]72	23/50	[a]82	28/50	[a]86	11/50	[a]70
Preputial gland—Carcinoma	0/70	0	1/50	3	5/50	[a]21	4/50	[a]21	3/50	[a]31
Kidney—Renal tubular adenoma	0/70	0	5/50	[a]16	1/50	5	3/50	[a]15	1/50	11

From Melnick et al (1990).

AA[a]Increased compared with chamber controls (0ppm), $p<0.05$, based on logistic regression analysis.

[c]Mortality adjusted tumor rates are adjusted for competing causes of mortality, such as death due to other tumors, whose rates differ by exposure group.

Activated Oncogenes

The presence of activated oncogenes in the exposed groups which differ from those seen in tumors in the control group can help in identifying a mechanistic link for BD carcinogenicity. Furthermore, certain activated oncogenes are seen in specific human tumors and K-*ras* is the most commonly detected oncogene in humans. In independent studies, tumors from this study were evaluated for the presence of activated protooncogenes. (Ex. 129) Activated K-*ras* oncogenes were found in 6 of 9 lung adenocarcinomas, 3 of 12 hepatocellular cancers and 2 of 11 lymphomas in BD exposed mice. Nine of these 11 K-*ras* mutations, including all six of those seen in lung tumors, were G to C conversions in codon 13. Activation of K-*ras* genes by codon 13 mutations has not been detected in lung or liver tumors or lymphomas in unexposed $B6C3F_1$ mice, but activation by codon 12 mutation was observed in 1 of 10 lung tumors in unexposed mice. (Ex. 129)

Conclusion

All of the four animal bioassays (one rat, three mouse) find a clear carcinogenic response; together they provide sufficient evidence to declare BD a known animal carcinogen and a probable human carcinogen. The three mouse studies, all with a positive lymphoma response, further support a finding that the mouse is a good model for BD related lymphatic/hematopoietic and other site tumorigenicity. The most recent NTP II study confirms and strengthens the previous NTP I and Irons et al. mouse studies, and presents clear evidence that BD is a potent multisite carcinogen in $B6C3F_1$ mice of both sexes. (Ex. 23–1;32–28D, Irons) The finding of lung tumors at exposures as low as 6.25 ppm, 100 fold lower than the lowest exposure of the NTP I study and a level that is in the occupational exposure range, increases concern for workers' health. Two other concerns

raised by both the second NTP and the Irons et al. studies are, (1) substantial carcinogenicity is found with less-than-lifetime exposures (as low as 12 or 13 weeks) for lymphomas and hemangiosarcomas, at least at higher concentrations, and, (2) for lymphomas and at least two other sites, there appears to be a dose-rate effect, where exposure to higher concentrations for a shorter time yields higher tumor response (by a factor of as much as 2–3) than a comparable total exposure spread over a longer time. These findings suggest that even short-term exposures should be as low as possible. Positive studies for genotoxicity and the detection of activated K-*ras* oncogenes in several of these tumors induced in mice, including lymphomas, liver, and lung, suggest a mutagenic mechanism for carcinogenicity, and support reliance on a linear low-dose extrapolation procedure (on the basis of the multistage mutagenesis theory of carcinogenicity), at least for these tumor sites. The finding of activated K-*ras* oncogenes in these mouse tumors may also be relevant to humans, because K-*ras* is the most commonly detected oncogene in humans.

The different dose-rate trends for different tumor sites suggest that different mechanisms are involved at different sites. The observation of a highly nonlinear exposure-response for lymphomas at exposure levels of 625 ppm and above suggests a secondary high-exposure mechanism as well, not merely a metabolic saturation, as is suspected with the high-exposure saturation seen in Sprague-Dawley rats. (Ex. 34–6, Owen and Glaister) The picture emerges of BD as a potent genotoxic multisite carcinogen in mice, far more potent in mice than in rats.

With respect to appropriate tumor sites for risk extrapolation from mouse to humans, Melnick and Huff have presented information comparing animal tumor response for five known or suspected human carcinogens—BD, benzene, ethylene oxide, vinyl chloride, and acrylonitrile. (Ex. 117–2) BD, benzene, and ethylene oxide all have strong occupational epidemiology evidence of increased lymphatic/hematopoietic cancer (LHC) mortality and all three cause both LHC, lung, Harderian gland, and mammary gland tumors in mice, plus several other primary tumors (see Table V–3). Only BD and vinyl chloride cause mouse hemangiosarcomas, BD in the heart and vinyl chloride in the liver. In rats, while all five carcinogens cause tumors at multiple sites, only brain and Zymbal gland tumors are associated with as many as four of the compounds. In general mice and rats are affected at different tumor sites by these carcinogens. LHC, lung, Harderian gland, mammary gland and, possibly hemangiosarcomas are sites in mice which correlate well with human LHC. This suggests that mice, rats and humans may have different target sites for the same carcinogen, but that compounds which are multisite carcinogens in the mouse and rat are likely to be human carcinogens as well. Based on BD's strong LHC association in humans, and its multisite carcinogenicity in the mouse, including occurrence at several of the same target sites seen with other carcinogens, OSHA concludes that the mouse is a good animal model for predicting BD carcinogenesis in humans.

TABLE V–3.—SITES AT WHICH NEOPLASMS ARE CAUSED BY 1,3-BUTADIENE IN MICE AND RATS: COMPARISON WITH RESULTS OF STUDIES WITH BENZENE, ETHYLENE OXIDE, VINYL CHLORIDE AND ACRYLONITRILE

[From Ex. 117–2]

Site	1,3–Butadiene		Benzene		Ethylene oxide		Vinyl chloride		Acrylonitrile	
	Mice	Rats	Mice	Rats	Mice	Rats	Mice	Rats	Mice	Rats
Lymphatic/hematopoietic	•		•		•	•			NS	
Lung	•		•		•		•			
Heart	[f]•									
Liver	•		•				[a]•	[a]•		
Forestomach	•		•	•				•		•
Harderian gland	•		•		•					
Ovary	•		•							
Mammary gland	•	•	•		•		•			•
Preputial gland	•		•							
Brain		•				•		•		•
Zymbal gland		•	•	•				•		•
Uterus		•		•	•					
Pancreas		•								
Testis		•								
Thyroid gland		•								

NS, not studied.
Hemangiosarcoma.

2. Epidemiologic Studies

(i) *Introduction.* OSHA has concluded that the epidemiologic studies contained in this record, as well as the related hearing testimony and record submissions, show that occupational exposure to BD is associated with an increased risk of death from cancers of the Lymphohematopoietic (LH) system. However, in contrast to the available toxicologic data, our understanding of BD epidemiology is based on observational studies, not experimental ones. In other words, the investigators who conducted these epidemiologic studies did not have control over the exposure status of the individual workers. They were, nonetheless, able to select the worker populations and the observational study design.

Cohort and case control studies are two types of observational study designs. Each of these designs has strengths and weaknesses that should be considered when the results are interpreted. Cohort studies, for example, have the advantages of decreasing the chance of selection bias regarding exposure status and providing a more complete description of all health outcomes subsequent to exposure. The disadvantages of cohort studies include the large number of subjects that are needed to study rare diseases and the potentially long duration required for follow-up. By comparison, case control studies are well suited for the study of rare diseases and they require fewer

subjects. The disadvantages of case control studies, however, include the difficulty of selecting an appropriate control group(s), and the reliance on recall or records for information on past exposures. Regardless of the selected observational study design, the greatest limitation of occupational epidemiologic studies is their ability to measure and classify exposure.

In spite of the inherent limitations of observational epidemiologic studies, guidelines have been developed for judging causal association between exposure and outcome. Criteria commonly used to distinguish causal from non-causal associations include: Strength of the association as measured by the relative risk ratio or the odds ratio; consistency of the association in different populations; specificity of the association between cause and effect; temporal relationship between exposure and disease which requires that cause precede effect; biologic plausibility of the association between exposure and disease; the presence of a dose-response relationship between exposure and disease; and coherence with present knowledge of the natural history and biology of the disease. These criteria have been considered by OSHA in the development of its conclusion regarding the association between BD and cancer of the LH system.

As stated previously, each type of epidemiologic study design has strengths and weaknesses. Since epidemiologic studies are observational and not experimental, each study will also have inherent strengths and weaknesses; there is no perfect epidemiologic study. The most convincing evidence of the validity and reliability of any epidemiologic study comes with replication of the study's results.

There are six major epidemiologic studies in the record that have examined the relationship between occupational exposure to BD and human cancer. These studies include: A North Carolina study of rubber workers (Ex. 23–41; 23–42; 23–4; 2–28; 23–27; 23–3); a Texaco study of workers at a BD production facility in Texas (Ex. 17–33; 34–4; 34–4); a NIOSH study of two plants in the styrene-butadiene rubber (SBR) industry (Ex. 2–26; 32–25); the Matanoski cohort study of workers in SBR manufacturing (Ex. 9; 34–4); the nested case-control study of workers in SBR manufacturing conducted by Matanoski and Santos-Burgoa (Ex. 23–109); and a follow-up study of synthetic rubber workers recently completed by Delzell et al. (Ex. 117–1). Several comments in the record have concluded that these studies demonstrate a positive association between occupational exposure to BD and LH cancers. However, OSHA has been criticized by the Chemical Manufacturers Association (CMA) and the International Institute of Synthetic Rubber Producers, Inc. (IISRP) for its interpretation of these studies as showing a positive association; the chief criticisms will be discussed below. (Ex. 112 and 113)

OSHA's final consideration of the BD epidemiologic studies is organized and presented according to what have been identified as key issues. These are the epidemiologic issues that were raised and considered throughout the rulemaking. They are also the issues most pertinent to OSHA's conclusions. These key issues surrounding BD exposure and LH cancer are: Evidence of an association; observation of a dose-response relationship; observation of short latency periods; the potential role of confounding exposures and the observed study results; the biological basis for grouping related LH cancers; relevance of subgroup analyses; and appropriateness of selected reference populations.

(ii) *Evidence of an Association Between BD and LH Cancer.* Each of the studies listed above contributes to the epidemiologic knowledge upon which OSHA's conclusion regarding the relationship of BD exposure and LH cancer has been developed.

(a) *North Carolina Studies.* This series of studies was undertaken to examine work-related health problems of a population of workers in a major tire manufacturing plant. They were not designed to look specifically at the health hazards of BD. (Tr. 1/15/91, p. 117) However, in a work area that involved the production of elastomers, including SBR, relative risks of 5.6 for lymphatic and hematopoietic malignancies and 3.7 for lymphatic leukemia were found among workers employed for more than five years. The International Agency for Research on Cancer (IARC) evaluation concluded that this study suggests an association between lymphatic and hematopoietic malignancy and work in SBR manufacturing. (Tr. 1/15/91, p. 117) However, the IISRP asserted that these studies do not provide ''meaningful evidence of an association between butadiene and cancer.'' (Ex. 113, p. A–23) OSHA recognizes that the researchers who conducted these studies acknowledged that the workers may have had exposures to organic solvents, including benzene, a known leukemogen, as pointed out by the IISRP. (Ex. 113, p. A–24)

(b) *Texaco Study.* The two Texaco studies examined mortality of a population of workers in a BD manufacturing facility in Texas. (Ex. 17–33; 34–4 Vol. III, H–2; Divine 34–4, Vol. III, H–1) A qualitative method of exposure classification, based on department codes and expert consensus judgement, was used in the Downs study. (Ex. 17–33; 34–4, Vol. III, H–2) From this methodology four exposure groups were defined: Low exposure, which included utility workers, welders, electricians, and office workers; routine exposure, which included process workers, laboratory personnel, and receiving, storage and transport workers; non-routine exposure, which included skilled maintenance workers; and unknown exposure, which included supervisors and engineers. It is OSHA's opinion that although this is a crude approach to exposure classification, there are important findings in this study that contribute to our understanding of BD epidemiology.

In the Downs study (Ex. 34–4, Vol. III, H–2) the standardized mortality ratio (SMR) for all causes of death in the entire study cohort was low (SMR 80; $p < .05$) when compared to national population rates. However, a statistically significant excess of deaths was observed for lymphosarcoma and reticulum cell sarcoma combined (SMR 235; 95% confidence interval (CI) = 101,463) when compared with national population rates. (The issue of reference population selection is discussed below in paragraph (viii).)

When analyzed by duration of employment, the SMR for the category of all LH neoplasms was higher in workers with less than five years employment (SMR = 167) than for those with more than five years employment (SMR = 127). (Ex. 34–4, Vol. III, H–2) However, neither of these findings was statistically significant. Alternatively, it has been suggested that perhaps the short-term workers were wartime workers, and that these workers were actually exposed to higher levels of BD, albeit for a shorter time. (Tr. 1/15/91, p. 119)

Analyses of the four exposure groups also showed elevated but not statistically significant SMRs. The routine exposure group had a SMR of 187 for all LH neoplasms, explained primarily by excesses in Hodgkin's disease (SMR = 197) and other lymphomas (SMR = 282). (Ex. 34–4, Vol. III, H–2) Those workers in the non-routine exposure group also had an elevated SMR for all LH neoplasms (SMR = 167), with excess mortality for Hodgkin's disease (SMR = 130), leukemias (SMR = 201), and other

lymphomas (SMR = 150) (Ex. 34–4, Vol. III, H–2).

These data were updated by Divine by extending the period of follow-up from 1979 through 1985. (Ex. 34–4, Vol. III, H–1) The SMR for all causes of mortality remained low (SMR = 84, 95% CI = 79,90), as it did for mortality from all cancers (SMR = 80, 95% CI = 69,94). (Ex. 34–4, Vol. III, H–1) However, the SMR for lymphosarcoma and reticulosarcoma combined was elevated and statistically significant (SMR = 229, 95% CI = 104,435). This finding was consistent with the previous analyses done by Downs. (Tr. 1/15/91, p. 120).

Exposure group analyses were also consistent with the previous findings by Downs. The highest levels of excess mortality from lymphatic and hematopoietic malignancy were again seen in the routine and non-routine exposure groups. The routine exposure group that was ''ever employed'' had a statistically significant excess of lymphosarcoma (SMR = 561, 95% CI = 181,1310), that accounted for most of the LH excess. (Ex. 34–4, Vol. III, H–1) The cohort of workers employed before 1946 (wartime workers) also demonstrated a statistically significant excess of mortality due to lymphosarcoma and reticulosarcoma combined (SMR = 269, 95% CI = 108,555). (Ex. 34–4, Vol. III, H–2)

In summary, the Texaco study provides several notable results. The first of these is the consistently elevated mortality for lymphosarcoma. This finding is consistent with excess lymphomas observed in experimental mice. (Ex. 23–92) Second, the excess risk of mortality was found in the routine and non-routine exposure groups. Based on the types of jobs held by workers in these two exposure groups, this finding suggests that the incidence of lymphatic malignancy is highest in the groups with the heaviest occupational exposure to BD. (Tr. 1/15/91, p. 121) The third notable result of this study was the significantly elevated rate of malignancy in workers employed for fewer than 10 years.

(c) *NIOSH Study.* The NIOSH study was undertaken in January 1976 in response to the report of deaths of two male workers from leukemia. (Ex. 2–26; 32–25) These workers had been employed in two adjacent SBR facilities (Plant A and Plant B) in Port Neches, Texas. The hypothesis tested by this study is that:

> Employment in the SBR production industry was associated, specifically, with an increased risk of leukemia and, more generally, with an increased risk of other malignancies of hematopoietic and lymphatic tissue. (Ex. 2–26)

This study did not specifically examine the association between BD and all LH cancers. Thus, OSHA agrees with the criticism that this study by itself did not demonstrate that occupational exposure to BD *causes* cancer. (Ex. 113, pp. A–13, A–19) However, the findings in this study are consistent with the patterns observed in the other epidemiologic studies discussed in this section. In Plant A, the overall mortality was significantly decreased (SMR=80, $p<0.05$). (Ex. 2–26) The SMR for all malignant neoplasms was also decreased (SMR=78), but this result was not statistically significant. (Ex. 2–26) The SMR for LH cancers was elevated (SMR=155), as it was for lymphosarcoma and reticulum cell sarcoma (SMR=181) and leukemia (SMR=203), but none of these results was statistically significant. (Ex. 2–26)

The pattern of mortality for a subgroup of wartime workers was also examined for the Plant A population. For this subgroup of white males, employed at least six months between the beginning of January 1943 and the end of December 1945, there was an elevated SMR for lymphatic and hematopoietic neoplasms (SMR = 212) that was statistically significant at the level of $0.05<p<0.1$. (Ex. 2–26) Likewise, the SMR for leukemia was increased (SMR=278), also with statistical significance at the level of $0.05<p<0.1$. (Ex. 2–26)

At Plant B, the overall mortality was low (SMR=66, $p<0.05$), as was death from all malignant neoplasms (SMR=53, $p<0.05$). (Ex. 2–26) The SMR for LH cancer was also low (SMR=78), but this finding was not statistically significant. (Ex. 2–26)

When this study was updated, the mortality patterns remained unchanged. (Ex. 32–25) The most remarkable findings of the NIOSH study are the excess mortality for malignancies of the LH system, and the excess of these cancers in workers employed during the wartime years.

(d) *Matanoski Cohort Study.* The cohort study conducted by Matanoski et al. is comprised of two follow-up periods: In the original study, completed in June 1982, the cohort was followed from 1943 to 1979; and in the update, completed in March 1988, the cohort follow-up period was extended to 1982. (Ex. 9; 23–39; 34–4, Vol. III, H–3 and H–6, respectively) The original study analyzed mortality data for 13,920 male workers employed for more than one year in eight SBR production plants in the United States and Canada. Although historical quantitative exposure data were not available, creation of a job dictionary made it possible to designate four general work activities as surrogates for exposure: Production; utilities; maintenance; and a combined category of all other jobs. The work activities with the highest BD exposures were production and maintenance. (Ex. 16–39) The total duration worked was measured by the dates of first and last employment.

The mortality experience for the original study cohort, as compared with death rates for males in the United States, was low for all causes (SMR=81) and all cancers (SMR=84). (Ex. 9; 23–39) The SMR for all LH cancers was also low (SMR=85). (Ex. 9; 23–39) The mortality rate for Hodgkin's disease was slightly elevated (SMR=120), but it was not statistically significant. (Ex. 9; 23–39) In fact, there were no statistically significant excesses in mortality from cancer at any site found in this original cohort study.

These initial data were also analyzed according to major work area. There were not any elevations of mortality rates for the category of all LH cancers. (Ex. 9; 23–39) For production workers, the SMR for other lymphatic cancers was elevated (SMR=202), but it was not statistically significant. (Ex. 9; 23–39) The SMR for leukemia in the utilities work group was also elevated (SMR=198), but it was based on only two deaths and was not statistically significant. (Ex. 9; 23–39) Slight excesses, none of which was statistically significant, were seen for Hodgkin's disease in each of the four work group categories. (Ex. 9; 23–39)

OSHA has been criticized for its opinion, expressed in the preamble of the BD proposed rule, that the original Matanoski cohort study did not have sufficient power to detect a difference in the cancer SMR if one actually existed. (Ex. 113, pp. A–10–11) Statistical power of at least 80% is the accepted rule-of-thumb for epidemiologic research study design. Calculations provided by Matanoski indicate that, for the outcomes of greatest concern to OSHA, statistical power was often below the 80% level. (Ex. 9) For leukemia, statistical power to detect 25% and 50% increases in mortality was only 27% and 62%, respectively. (Ex. 9) The power to detect a 25% increase in mortality for all lymphohematopoietic cancers was only 49%. (Ex. 9) However, the study did have a statistical power of 93% to detect a SMR of 150 for all LH cancers. (Ex. 9) Thus, for the cancers of most interest to OSHA, this study had limited statistical power to detect mortality excesses that were less than two-fold. OSHA does not consider this to be an ''unrealistically strict standard of acceptability,'' as alleged by the

IISRP, but rather part of a thorough critique of an epidemiologic study with purportedly ''negative results.'' (Ex. 113, p. A–11)

The update of Matanoski's original study extends the period of cohort follow-up from 1979 to 1982, providing a full 40 years of mortality experience for analysis. The update study cohort differed from the original cohort in two additional ways: Canadian workers with relatively short-term exposure were removed from the cohort; and the proportion of workers lost to follow-up was reduced. The extension of follow-up resulted in findings of excess mortality from lymphatic and hematopoietic cancers that had not been observed in the original analyses. (Ex. 34–4, Vol. III, H–6)

The SMR for all causes of mortality remained low (SMR=81, 95% CI=78,85), as it did for death from all cancers (SMR=85, 95% CI=78,93). (Ex. 34–4, Vol. III, H–6) For lymphatic and hematopoietic cancers, the overall SMR for white males was not increased (SMR=92, 95% CI=68,123). (Ex. 34–4, Vol. III, H–6) However, for black males, the SMR for all LH cancers was elevated (SMR=146, 95% CI=59,301). (Ex. 34–4, Vol. III, H–6) Specific increases were also found for lymphosarcoma (SMR=132), leukemia (SMR=218, 95% CI=59,560), and other lymphatic neoplasms (SMR=116, 95% CI=14,420). (Ex. 34–4, Vol. III, H–6) These increases were based on small numbers of observed deaths.

Analyses conducted on the four exposure groups also produced some evidence of excess mortality. For the total cohort of production workers, an elevated SMR was observed for all lymphopoietic cancers (SMR=146, 95% CI=88,227). (Ex. 34–4, Vol. III, H–6) For white production workers, the SMR for that category was 110, explained principally by excess mortality from other lymphatic neoplasms (SMR=230, 95% CI=92,473). (Ex. 34–4, Vol. III, H–6) Although based on small numbers, the results for black production workers were more pronounced and statistically significant: The SMR for all lymphatic and hematopoietic cancers was 507 (95% CI=187,1107). (Ex. 34–4, Vol. III, H–6) That overall increase in black workers reflected excess mortality from lymphosarcoma (SMR=532), leukemia (SMR=656, 95% CI=135,1906), and other lymphatic cancers (SMR=482, 95% CI=59,1762). (Ex. 34–4, Vol. III, H–6)

A pattern of excess mortality for all LH cancers was also seen in utility workers (SMR=203, 95% CI=66,474). (Ex. 34–4, Vol. III, H–6) That elevated SMR may be explained by elevated rates for leukemia (SMR=192, 95% CI=23,695) and other lymphatic cancers (SMR=313, 95% CI=62,695). (Ex. 34–4, Vol. III, H–6) No increases in LH malignancy were seen in the other exposure groups, i.e., maintenance or other workers.

From these study results Matanoski et al. concluded:

> Deaths from cancers of the hematopoietic and lymphopoietic system are higher than expected in production workers with significant excesses for leukemias in black workers and other lymphomas in all (production) workers. (Ex. 34–4, Vol. III, H–6, p. 116)

In response to criticism from the IISRP that OSHA placed too much emphasis on the findings in the group of black production workers, OSHA is aware of the statement offered by the researchers that because of the potential for bias from misclassification of race: ''* * * the total SMRs are probably the most correct representation of risk.'' (Ex. 34–4, Vol. III, H–6) However, OSHA also agrees with the authors that the risk of death from LH cancers seems to be higher in this SBR industry population than in the general population, and these causes of death seem to be associated with different work areas. These cohort study findings stimulated the design and implementation of the Santos-Burgoa and Matanoski nested case-control study.

(e) *Santos-Burgoa and Matanoski Nested Case-Control Study.* To further investigate the findings of the cohort study, Santos-Burgoa and Matanoski et al. designed and conducted a case-control study of LH cancers in workers in the styrene-butadiene polymer manufacturing industry. (Ex. 23–109; 34–4, Vol. III, H–4) The specific questions addressed by this research study are: ''Is there a risk of any lymphatic or hematopoietic cancer which is associated with exposure to (BD) or styrene or both?''; and ''is there a risk of these cancers related to exposure to jobs within the industry?'' (Ex. 34–4, Vol. III, H–4) This is the first study to specifically investigate the association between LH cancers and individual worker exposure to BD, which is why, contrary to the opinion of IISRP, OSHA places so much ''weight'' on these results. (Ex. 113, pp. A–25–34)

The subjects in this case-control study were ''nested,'' or contained, within the population of the original cohort study. ''Cases'' in this study were defined as males who worked one year or more at any of eight synthetic rubber polymer producing plants and who died of or with a lymphopoietic cancer. These cancers included: Lymphosarcoma and reticulum cell sarcoma, Hodgkin's lymphoma, non-Hodgkin's lymphoma, all leukemias, multiple myeloma, polycythemia vera, and myelofibrosis. Sixty-one cases were identified, but two cases were omitted from data analyses, resulting in a total of 59 cases. One case was omitted because he could not be matched to controls, and the other case lacked job records from which exposure could be identified.

Eligible ''controls'' included workers who were either alive or had died of any cause other than malignant neoplasms, who had been employed at one of the eight SBR plants, and who had not been lost to follow-up. These controls were individually matched to cases on the following criteria: Plant; age; hire year; employment as long or longer than the case; and survival to the death of the case. The study aim was to select four controls per case. Even though this was not always possible, there were, on average, just over three controls per case in each group of lymphopoietic cancer. The total number of controls was 193.

Unlike the previous studies, in this research study an exposure measurement value for BD (and also for styrene) was determined for each case and control. This value was determined by a multi-step process. First, the job records of each subject were reviewed and the number of months that each job was held was determined. Second, the level of BD (and styrene) associated with the job was estimated by a panel of five industrial experts, i.e., engineers with long term experience in SBR production. The exposure level for BD (and styrene) for each job was based on a scale of zero to ten, with ten being the rank given to the job with the highest exposure. The next step in the development of each individual job-exposure matrix was to add all of the exposures to the chemicals for all the months a specific job was held and then sum the exposures over a working lifetime. This procedure resulted in a cumulative BD exposure value for each case and control.

The distribution of the cumulative exposure estimates for the study population was not normally distributed, i.e., there were some extreme values. In order to approximate a normal distribution, a required assumption for many statistical analyses, a logarithmic transformation of these values was done. (Ex. 34–4, Vol. III, H–4) Exposure was analyzed as a dichotomous variable, i.e., ever/never exposed. ''Exposed'' workers were defined as those with a log rank cumulative exposure score above the mean of the scores for the entire population of cases and controls within

a cancer subtype; ''non-exposed'' workers were those with a score below the mean.

There were several important findings in this study. First, in the unmatched analysis of cases and controls, the leukemia subgroup had a significant excess risk of 6.8 fold for exposure to BD among cases compared to controls (Odds Ratio (OR)=6.82, 95% CI=1.10,42.23). (Ex. 34–4, Vol. III, H–4) The results were even stronger in the matched-pair analyses. In that analysis for exposure to BD, the OR was 9.36 (95% CI=2.05,22.94) in the leukemia subgroup. (Ex. 34–4, Vol. III, H–4) This result can be interpreted to mean that cases with leukemia were more than nine times as likely as their controls to be exposed to BD. Additionally, the data in this analysis indicate that BD exposure above the group mean is 2.3 times (OR=2.30, 95% CI=1.13,4.71) more common among cases with all lymphopoietic cancers when compared to a similar exposure in the controls. (Ex. 34–4, Vol. III, H–4)

This case-control study has been the subject of criticism that has centered on both validity and reliability. (Ex. 23–68; 113) For example, the data from this study have been criticized as being ''inconsistent'' with the results of the Matanoski cohort study. (Ex. 23–68; 113, p. A–25) Further, it has been suggested that ''the study results are not reliable and should not be relied upon by OSHA.'' (Ex. 113, p. A–25) OSHA rejects these criticisms for the reasons discussed below.

First, regarding the issue of inconsistency, a nested case control study does not test the same hypotheses or make the same comparisons as a cohort study. (Ex. 32–24; Tr. 1/15/91, p. 161; Tr. 1/16/91, p. 347) In fact, as presented in the above discussions of the studies, they ask and answer different research questions. For example, the cohort study asked whether all of the SBR workers have a different risk of leukemia from the general population, and the case control study asked whether workers with leukemia have different exposures within the industrial setting from workers without leukemia. (Ex. 32–24) Thus, the criticism that the results of these two studies are incompatible, and therefore invalid, is not relevant. (Ex. 32–24)

Second, the challenge directed at the reliability of the case-control study does not hold up under close scrutiny. This criticism is based on four issues: Log transformation of the exposure data; instability of the results; irregular dose-response pattern; and selection criteria for ''controls.'' (Ex. 113, A–29–34)

Regarding the log transformation of the exposure data, the IISRP asserts that there is not a sound rationale for this approach to data analyses. (Ex. 113, A–29–30) However, Santos-Burgoa offered the following explanation of this procedure in his testimony:

> For analysis, exposures were categorized in advance above and below the mean of the cumulative exposure for the study subjects. This cutpoint was defined from the very beginning of the analysis design as follows. The total cumulative exposures, as happens in most environmental exposures, showed a skewed distribution with many observations at the low levels and few at the high levels. Since the geometric mean is the best estimate of the central tendency point in log normal data, such as exposure data, the cumulative exposures were transformed by the logarithm, and then the mean was calculated. (Ex. 40, pp. 12–13)

It is OSHA's opinion that, given the log normal distribution of the exposure data, Santos-Burgoa chose the best approach for data analyses.

The case-control study has also been criticized for producing ''highly unstable and therefore unreliable'' results. (Ex. 113, A–30) For example, the leukemia subgroup (matched-pair analysis) OR of 9.36 with a 95% confidence interval of 2.05–22.94 has been used to illustrate statistical instability of the data. (Ex. 113, A–31) However, as previously discussed, the disease category of ''all lymphopoietic cancers'' (matched-pair analysis) had an OR of 2.30 with a confidence interval of 1.13–4.71. Thus, it is OSHA's opinion that, while some specific odds ratios may have wide confidence intervals, the study results as a whole are not ''unreliable.''

The IISRP has also criticized the case-control study for ''* * * fail(ing) to demonstrate a dose-response relationship * * *'' (Ex. 113, A–32) However, the test for linear trend, i.e., test for dose-response, shows a statistically significant, but irregular, trend in the odds of leukemia with increasing levels of exposure to BD. Specifically, as exposure levels increase the pattern of odds ratios is: 7.2; 4.9; 13.0; 2.5; and 10.3. (Ex. 23–109, Table 10) Although this is not a compelling linear dose-response, in OSHA's opinion, it is suggestive of a pattern of increasing disease risk at increasing exposure levels.

Inconsistent application of the control selection criteria is the final criticism directed at the case-control study by the IISRP. (Ex. 113, A–33) However, careful review of docket exhibits related to the case-control study reveals this criticism to be unfounded. In his dissertation, Santos-Burgoa clearly states the protocol for control selection:

> All cohort subjects were arranged into groups by plants, date of birth, date of hire, duration of work and duration of follow-up. A two and a half year period around each time variable was relaxed in a few instances when no more controls were available. One lymphosarcoma case was lost since no match was found for his date of birth, even allowing for three and a half years around the date. This was the only case lost to analysis because of lack of a matched control. (Ex. 32–25, p. 80)

With only 59 cases, Santos-Burgoa was correctly concerned about loss of valuable data should any additional cases need to be eliminated due to lack of a match. Also, regarding the potential for bias, abstractors were blinded to case or control status when employment data were being collected. (Ex. 34–4, Vol. III, App. H–5) Thus, it is most likely that any misclassification bias would be nondifferential, biasing the study results towards the null.

(f) *Delzell et al. Follow-up Study for the IISRP.* The most recent study of synthetic rubber workers was conducted by Delzell et al. (Ex. 117–1) This study updated and expanded the research on SBR workers conducted by NIOSH, Matanoski et al., and Santos-Burgoa. More specifically, the Delzell et al. study consists of workers at seven of eight plants previously studied by The Johns Hopkins University (JHU) investigators, and the two plants included in the NIOSH study.

This retrospective cohort study evaluated the associations between occupational exposure to BD, styrene, and benzene and mortality from cancer and other diseases among the SBR workers. There were five study objectives:

> (1) To evaluate the overall and cause-specific mortality experience of SBR workers relative to that of the USA and Canadian general populations;
>
> (2) To assess the cancer incidence experience of Canadian synthetic rubber workers relative to that of the general population of Ontario;
>
> (3) To determine if overall and cause-specific mortality patterns vary by subject characteristics such as age, calendar time, plant, period of hire, duration of employment, time since hire and payroll status (hourly or salaried);
>
> (4) To examine relationships between work areas within the SBR study plants and cause-specific mortality patterns;
>
> (5) To evaluate the relationship between exposure to BD and [styrene] and the occurrence of leukemia and other lymphopoietic cancers among SBR workers. (Ex. 117–1 p. 10)

The study population for this investigation included 17,964 male synthetic rubber workers employed in one of eight plants in either the USA or Canada. In order to be eligible for

inclusion, a worker had to be employed for a total of at least one year before the closing date of the study, January 1, 1992. Additional eligibility criteria were developed for selected plants due to limitations in availability of plant records and follow-up of subjects. The eligibility criteria in this study were considered by the investigators to be more restrictive than in either the JHU or NIOSH studies. (Ex. 117–1, p. 13) Most of the exclusions were based on less than one year of employment. During the study period of 1943 through 1991, there were 4,665 deaths in the study population.

The methods used in this study included development of work history information and retrospective quantitative exposure estimates for individual members of the study population. Complete work history information was available for approximately 97% of the study cohort. There was a total of 8,281 unique ''work area/job'' combinations for all of the plants combined, with a range of 199 to 4,850 in specific plants. Additionally, 308 work area groups were defined based on individual plant information regarding production, maintenance, and other operations, as well as jobs and tasks within each type of operation. Five ''process groups'' and seven ''process subgroups'' were derived from the work area groups. The process groups include: Production of SBR, solution polymerization (SP), liquid polymerization (LP), and latex production; maintenance; labor; laboratories; and other operations.

Six plants had sufficiently detailed individual work history information for use in development of retrospective quantitative exposure estimates for BD and styrene. The process used to produce these exposure estimates included: In-depth walk-through surveys of each plant; meetings with plant management; interviews with key plant experts, such as individuals with long-term employment. The interviews were used to collect information regarding the production process, specific job tasks, and exposure potential. Additionally, the results of industrial hygiene monitoring from these plants were obtained. The actual exposure estimation was based on:

Specification of the exposure model; the estimation of exposure intensities for specific tasks in different time periods; the estimation of exposure intensities for generic (nonspecific) job titles (e.g., ''laboratory worker'') in different time periods; validation of exposure intensity estimates; the computation of job- and time period specific summary indices; and the compilation of job-exposure matrices (JEMs) for BD, [styrene], and [benzene] and linkage with subjects' work histories. (Ex. 117–1, pp. 27–28)

A limited validation of the quantitative exposure estimations was conducted, which resulted in revision of the estimates used in analyses presented in the Delzell et al. study. (Ex. 117–1)

The major findings of this study have been reported by Delzell et al. in five categories: General mortality patterns; mortality among USA subjects compared to state populations; cancer incidence; mortality patterns by process group; and mortality patterns by estimated monomer exposure. Key results from each of these categories, especially as they relate to leukemia and other LH cancers, are briefly presented.

First, regarding general mortality patterns, there were deficits in both all causes (SMR=87, 95% CI=85,90) and all cancers (SMR=93, 95% CI=87,99) for the entire cohort. (Ex. 117–1, p. 53) Of the LH cancers, excess mortality was only observed for leukemia (SMR=131, 95% CI=97–174). (Ex. 117–1, p. 53) In a cohort subgroup having 10 or more years of employment and 20 or more years since hire, the excess of leukemia deaths was even greater (SMR=201, 95% CI=134,288). (Ex. 117–1, p. 54)

Analyses were also conducted to explore the possibility of racial differences in the general mortality patterns. Regarding mortality from leukemia, the SMRs were higher for blacks than for whites. In a subgroup of ''ever hourly'' workers with 10 or more years of work and 20 or more years since hire, the SMRs for leukemia were 192 (95% CI=119,294) for whites and 436 (95% CI=176,901) for blacks. (Ex. 117–1, p. 55)

Additionally, analyses were done by specific groups of LH cancers: Lymphosarcoma; leukemia; and other lymphopoietic cancer. For the overall cohort, there was an excess of mortality from lymphosarcoma in those members who died in 1985 and beyond (SMR=215, 95% CI=59,551). (Ex. 117–1, p. 116) This excess was observed in ''ever hourly'' white men; there were no lymphosarcoma deaths in blacks. (Ex. 117–1, p. 119)

In the ''other lymphopoietic cancer'' category, the overall cohort had a slight deficit of mortality (SMR=97, 95% CI=70,132). (Ex. 117–1, p. 116) When analyzed according to racial groups, whites were also observed to have a deficit of mortality from this group of cancers (SMR=91, 95% CI=63,127). (Ex. 117–1, p. 118) Blacks, however, had an increase in mortality from ''other lymphopoietic'' cancers (SMR=142, 95% CI=61,279). (Ex. 117–1, p. 120)

The analyses for leukemia mortality in the overall cohort showed a modest increase (SMR=131, 95% CI=97,174). (Ex. 117–1, p. 116) The increase in mortality was found primarily in the subgroups of workers who died in 1985 or later, those that worked for 10 or more years, and those with 20 or more years since hire. A dose-response type of pattern was observed among ''ever hourly'' subjects in the analysis of the relationship of leukemia and duration of employment: Less than 10 years worked, the SMR=95 (95% CI=53,157); 10–19 years worked, the SMR=170 (95% CI=85,304); and 20 or more years worked, the SMR=204 (95% CI=123,318). (Ex. 117–1, p. 117)

Leukemia mortality was also analyzed for racial difference among ''ever hourly'' men. Overall, the SMR was higher for black subjects (SMR=227, 95% CI=104,431) than for white (SMR=130, 95% CI=91,181). (Ex. 117–1, p. 122) In fact, there were statistically significant elevations in the leukemia SMR for black ''ever hourly'' men with 20 or more years worked (SMR=417, 95% CI=135,972), and 20 to 29 years since hire (SMR=446, 95% CI=145,1042). (Ex. 117–1, p. 122)

Second, Delzell et al. analyzed the mortality data of the USA cohort subgroup using both state general population rates and USA general population rates for comparison. The overall pattern of these analyses was that of ''slightly lower'' SMRs when the state general population rates were used. (Ex. 117–1, p. 60) For example, in the analysis for leukemia mortality, the SMR using the USA rates was 131 (95% CI not provided), and it decreased to 129 (95% CI=92,176) when state rates were applied. (Ex. 117–1, pp. 61, 136)

Third, the results of the Delzell et al. study include an analysis of the cancer incidence in the Canadian plant (plant 8). Regardless of whether the cancer experience of terminated workers was included or excluded, the overall cancer incidence was not elevated in this cohort subgroup (SIR=105, 95% CI=93,117; SIR=106, 95% CI=94,119, respectively). (Ex. 117–1, pp. 61–62) However, analysis of this cohort subgroup, with the terminated workers included, ''revealed an excess of leukemia cases before 1980 (overall cohort, 6 observed/3.0 expected; ever hourly, 6 observed/2.9 expected)'' (further data were not provided). (Ex. 117–1, p. 62)

Fourth, Delzell et al. examined mortality patterns by work process group. These analyses produced elevated SMRs for both lymphosarcoma and leukemia. There was excess lymphosarcoma mortality in field maintenance workers (SMR=219, 95% CI=88,451), production laborers

(SMR=263, 95% CI=32,951), and maintenance laborers (SMR=188, 95% CI=39,548). (Ex. 117–1, pp. 65–66) However, these results were not statistically significant, and may be due to chance. For leukemia, the results were more striking: Polymerization workers had a SMR of 251 (95% CI=140,414); workers in coagulation had a SMR of 248 (95% CI=100,511); maintenance labor workers had a SMR of 265 (95% CI=141,453); and workers in laboratories had a SMR of 431 (95% CI=207,793). (Ex. 117–1, pp. 66,151) It should be noted that excess mortality by work process group was also observed for other cancers, i.e., lung cancer and larynx cancer.

Fifth, the final set of analyses performed by Delzell et al. was designed to examine mortality patterns by estimated monomer exposure, i.e., BD, styrene, and benzene. Poisson regression analyses conducted to explore the association between ''BD ppm-years'' and leukemia indicated a positive dose-response relationship, after controlling for styrene ''ppm-years'', age, years since hire, calendar period, and race. Specifically, in the cohort group that included all person-years and leukemia coded as either underlying or contributing cause of death, the rate ratios (RRs) were: 1.0, 1.1 (95% CI=0.4,5.0), 1.8 (95% CI=0.6,5.4), 2.1 (95% CI=0.6,7.1), and 3.6 (95% CI=1.0,13.2) for BD ppm-year exposure groups of 0, >0–19, 20–99, 100–199, and 200+, respectively. (Ex. 117–1, pp. 68–69; 158) Poisson regression analyses were also conducted using varying exposure categories of BD ppm-years. These analyses demonstrated a stronger and more consistent relationship between BD and leukemia than between styrene and leukemia. (Ex. 117–1, p. 69, 159) Although a clearly positive relationship between BD ''peak-years'' and leukemia was observed from additional Poisson regression analyses, even after controlling for BD ppm-years, styrene ppm-years, and styrene peak-years, the dose-response relationship was less clear. (Ex. 117–1, pp. 71, 162)

In summary, one of the most important findings of the research of Delzell et al. was strong and consistent evidence that employment in the SBR industry produced an excess of leukemia. In the authors own words:

> This study found a positive association between employment in the SBR industry and leukemia. The internal consistency and precision of the result indicate that the association is due to occupational exposure. The most likely causal agent is BD or a combination of BD and [styrene]. Exposure to [benzene] did not explain the leukemia excess. (Ex. 117–1, p. 85)

(g) *Summary.* These studies provide a current body of scientific evidence regarding the association between BD and LH cancers. As previously discussed, two of the criteria commonly used to determine causal relationships are consistency of the association and strength of the association. The consistency criterion for causality refers to the repeated observation of an association in different populations under different circumstances. Consistency is perhaps the most striking observation to be made from this collection of studies: ''[E]very one of these studies to a greater or lesser extent finds excess rates of deaths from tumors of the lymphatic and hematopoietic system.'' (Tr. 1/15/91, p. 129)

Strength of the association is determined by the magnitude and precision of the estimate of risk. In general, the greater the risk estimate, e.g., SMR or odds ratio, and the narrower the confidence intervals around that estimate, the more probable the causal association. In the nested case-control study, although the confidence intervals were wide, the odds ratios provide evidence of a strong association between leukemia and occupational exposure to BD.

(iii) *Observation of a Dose-Response Relationship.* A dose-response relationship is present when an increase in the measure of effect (response), e.g., SMR or odds ratio, is positively correlated with an increase in the exposure, i.e., estimated dose. When such a relationship is observed, it is given serious consideration in the process of determining causality. However, the absence of a dose-response relationship does not necessarily indicate the absence of a causal relationship.

OSHA has been criticized for its conclusion that the epidemiologic data suggest a dose-response relationship. (Ex. 113) The IISRP offers a different interpretation of the data. In their opinion, the data provide a ''consistent finding of an inverse relationship between duration of employment and cancer mortality.'' (Ex. 113, A–34) This observation is further described by John F. Acquavella, Ph.D., Senior Epidemiology Consultant, Monsanto Company, as ''the paradox of butadiene epidemiology.'' (Ex. 34–4, Vol. I, Appendix A) This interpretation assumes that cumulative occupational exposure to BD will increase with duration of employment, and, thus, cancer mortality will increase with increasing duration of employment. (Ex. 113, A–35–39)

In OSHA's opinion, this is an erroneous assumption; the epidemiologic data for BD tell a different story. For the workers in these epidemiologic studies, it is unlikely that occupational exposure to BD was constant over the duration of employment. According to Landrigan, BD exposures were most likely higher during the war years than they were in subsequent years. (Tr. 1/15/91, p.146) It is logical that exposures would be especially intense during this time period because of wartime production pressures, the process of production start-up in a new industry, and the general lack of industrial hygiene controls during that phase of industrial history. Unfortunately, without quantitative industrial hygiene monitoring data, the true levels of BD exposure for wartime workers cannot be ascertained. In the absence of such data, however, OSHA believes it is reasonable to consider wartime workers as a highly exposed occupational subgroup. (Tr. 1/15/91, p. 121; Tr. 1/16/91, pp. 225–227) Thus, the excess mortality seen among these workers provides another piece of the evidence to support a dose-response relationship between occupational exposure to BD and LH cancers.

Additional support that excess mortality, among workers exposed to BD, is dose-related can be found in the analyses of the work area exposure groups. The studies by Divine, Matanoski, and Matanoski and Santos-Burgoa all provide evidence that excess mortality is greatest among production workers. (Ex. 34–4, Vol. III, H–1; 34–4, Vol. III, H–6; 23–109, respectively) Production workers are typically the most heavily exposed workers to potentially toxic substances. (Ex. 34–4)

The most compelling data that support the existence of a dose-response relationship for occupational exposure to BD and LH cancers are those in the study by Delzell et al. (Ex. 117–1) Analysis of the cumulative time-weighted BD exposure in ppm-years indicates a relative risk for all leukemias that increases positively with increasing exposure. This relationship is present even with statistical adjustment for age, years since hire, calendar period, race, and exposure to styrene. It is OSHA's opinion that identification of a positive dose-response in an epidemiologic study is a very powerful observation in terms of causality.

(iv) *Observation of Short Latency Periods.* Short latency periods, i.e., time from initial BD exposure to death, were seen in two epidemiologic studies. In the NIOSH study, three of the six leukemia cases had a latency period from three to four years. (Ex. 2–26) Additionally, five of these six workers were employed prior to 1945. (Ex. 2–26)

In the Texaco study update, a latency of less than 10 years was seen in four of the nine non-Hodgkin's lymphoma (lymphosarcoma) cases, and seven of these workers were also employed during the wartime years. (Ex. 34–4, Vol. III, H–1)

According to OSHA's expert witness, Dr. Dennis D. Weisenburger,

> these findings are contrary to the accepted belief that, if a carcinogen is active in an environment, one should expect the * * * SMRs to be higher for long-term workers than for short-term workers (i.e., larger cumulative dose). (Ex. 39, p. 9)

Thus, it has been argued that these findings appear to lack coherence with what is known of the natural history and biology of LH cancers. (Ex. 113, A–40–42) Furthermore, these findings have been interpreted as evidence against a causal association between BD and these LH cancers. (Ex. 113, A–42)

In OSHA's opinion, there are other possible explanations for these observations. First, as proffered by Dr. Weisenburger, a median latency period of about seven years has been found for leukemia in studies of atomic bomb victims, radiotherapy patients, and chemotherapy patients who have received high-dose, short-term exposures. (Ex. 39) In contrast, Dr. Weisenburger points out that low-dose exposure to an environmental carcinogen, such as benzene, has a median latency period for leukemia of about 15–20 years. (Ex. 39) He concludes that short-term, high-dose exposures may be associated with a short latency period, whereas long-term, low-dose exposures may be associated with a long latency period.

Second, the occurrence of short latency periods for LH cancer mortality in these two studies was concentrated in workers first employed during the wartime years. As previously discussed, it is possible that exposure to BD during the wartime years was greater than in subsequent years. (Ex. 39; Tr. 1/15/91, p. 121) Dr. Weisenburger suggests that the ''short latency periods for LH cancer in these studies may be explained by intense exposures to BD over a relatively short time period.'' (Ex. 39, p. 10)

In his testimony, Dr. Landrigan, another OSHA expert witness, makes the point that ''duration of employment is really only a crude surrogate for total cumulative exposures, not itself a measure of exposure.'' (Tr. 1/15/91, p. 121) In other words, it is possible that short-term workers employed during the wartime years may have actually had heavier exposures to BD than long-term workers. (Tr. 1/15/91, pp. 115–205) On cross-examination, Dr. Landrigan cautioned against ''assuming that duration of exposure directly relates to total cumulative exposure.'' (Tr. 1/15/91, p. 180) He also emphatically stated that an increased cancer risk in short-term workers would not be inconsistent with a causal association. (Tr. 1/15/91, p. 204)

(v) *The Potential Role of Confounding Exposures and Observed Results.* In epidemiologic studies ''confounding'' may lead to invalid results. Confounding occurs when there is a mixing of effects. More specifically, confounding may produce a situation where a measure of the effect of an exposure on risk, e.g., SMR, RR, is distorted because of the association of the exposure with other factors that influence the outcome under study.

For example, the IISRP has suggested that confounding exposures from other employment were responsible for the LH cancers observed in the studies of BD epidemiology. (Ex. 113, A–43) This argument is based on the past practice of using petrochemical industry workers, who may have also been exposed to benzene, to start up the SBR and BD production plants. The IISRP finds support for this position in the observation of elevated SMRs in short-term workers employed during the wartime years, precisely those most likely to be cross-employed. (Ex. 113, A–43)

However, there are a number of research methods in occupational epidemiology that are available to control potential confounding factors. Research methods that eliminate the effect of confounding variables include: Matching of cases and controls; adjustment of data; and regression analyses. In the nested case-control study, for example, cases and controls were matched on variables that otherwise might have confounded the study results. In the testimony provided by Santos-Burgoa, he states that the ''matching scheme allowed us to control for potential confounders and concentrate only on exposure variations.'' (Ex. 40, p. 12)

On cross-examination, Landrigan also addressed the potential role of confounding exposures and the observed study results. First, he observed that Dr. Philip Cole, Professor, Department of Epidemiology, School of Public Health, University of Alabama at Birmingham, one of the outspoken critics of OSHA's proposed rule, found no evidence for confounding in his review of the Matanoski study. (Tr. 1/15/91, p. 178) Second, Dr. Landrigan dismissed the notion of previous exposure to benzene as the causative agent for the observed results in the short-term workers. (Tr. 1/15/91, p. 178–179)

In their analyses of mortality patterns by estimated monomer exposure, Delzell et al. used Poisson regression to control for potential confounding factors. (Ex. 117–1) As previously stated, the analyses conducted to determine the association between BD ppm-years and leukemia indicated a positive dose-response relationship, even after controlling for styrene ppm-years, age, years since hire, calendar period, and race. In the opinion of the investigators, benzene exposure did not explain the excess of leukemia risk, and BD is the most likely causal agent. (Ex. 117–1, p. 85)

(vi) *The Biological Basis for Grouping Related LH Cancers.* The epidemiologic studies that have examined the association between occupational exposure to BD and excess mortality have grouped related LH cancers in their analyses. This approach has been criticized as evidence of a lack of ''consistency with respect to cell type'' which ''argues against a common etiologic agent.'' (Ex. 113, A–45) In other words, these critics suggest that the relationship between BD and excess mortality does not meet the specificity of association requirement for a causal relationship. This requirement states that the likelihood of a causal relationship is strengthened when an exposure leads to a single effect, not multiple effects, and this finding also occurs in other studies.

More specifically, OSHA has been criticized for its position that ''broad categories such as 'leukemia' or 'all LHC' should be used to evaluate the epidemiologic data.'' (Ex. 113, A–46) Dr. Cole, for example, commented that:

> It is a principle of epidemiology—and of disease investigation in general—that entities should be divided as finely as possible in order to maximize the prospect that one has delineated a homogeneous etiologic entity. Entities may be grouped for investigative purposes only when there is substantial evidence that they share a common etiology. (Ex. 63, p. 11)

It is Dr. Cole's opinion that LH cancers are ''distinct diseases'' with ''heterogeneous and multifactorial'' etiologies. (Ex. 63, p. 47)

Dr. Weisenburger, OSHA's expert in hematopathology, provided testimony to the contrary. (Ex. 39, pp. 7–8) According to Dr. Weisenburger, ''LH (cancer) cannot be readily grouped into 'etiologic' categories, since the precise etiologies and pathogenesis of LH (cancer) are not well understood.'' (Ex. 39, p. 7) In his opinion, because LH cancers are ''closely related to one

another and arise from common stem cells and/or progenitor cells, it is valid to group the various types of LH (cancer) into closely-related categories for epidemiologic study.'' (Ex. 39, p.7)

The issue of grouping related LH cancers to observe a single effect was also addressed by Dr. Landrigan in his testimony. (Tr. 1/15/91, pp. 131–133) The first point raised by Dr. Landrigan is that the ''diagnostic categories [for LH cancers] are imprecise and * * * overlapping.'' (Tr. 1/15/91, p. 131) For example, he explained that in clinical practice transitions of lymphomas and myelomas into leukemias may be observed. In such a case, one physician may record the death as due to lymphoma and another may list leukemia as the cause of death. (Tr. 1/15/91, p. 131–132) Additionally, Dr. Landrigan testified that ''some patients with lymphomas or multiple myeloma may subsequently develop leukemia as a result of their treatments with radiation or cytotoxic drugs.'' (Tr. 1/15/91, p. 132)

These recordings of disease transition are further complicated by the historical changes that have occurred in nomenclature and The International Classification of Diseases (ICD) coding. According to Dr. Landrigan,

> certain lymphomas and * * * leukemias, such as chronic lymphatic leukemia are now considered by some investigators * * * to represent different clinical expressions of the same neoplastic process. There have been recent immunologic and cytogenetic studies which indicate that there are stem cells which appear to have the capacity to develop variously into all the various sorts of hematopoietic cells including T-lymphocytes, plasma cells, granulocytes, erythrocytes, and monocytes. (Tr. 1/15/91, p. 132)

Dr. Landrigan summarized his testimony on this issue by stating that ''these different types of cells share a common ancestry * * * there is good biologic reason to think that they would have etiologic factors in common.'' (Tr. 1/15/91, pp. 132–133)

OSHA maintains the opinion, which is well supported by the record, that there is a biological basis and a methodologic rationale for grouping related LH cancers. Furthermore, OSHA rejects the criticism that the observation of different subtypes of LH cancers argues against the consistency and specificity of the epidemiologic findings.

(vii) *Relevance of Worker Subgroup Analyses.* OSHA has been criticized for focusing on and emphasizing the ''few positive results'' seen in the results of worker subgroup analyses. (Ex. 113, A–48) It has been pointed out, for example, that in the update of the Matanoski cohort study ''there were hundreds of SMRs computed in that study and it's not surprising that one or two or even more would be found to be statistically significant even when there is in fact nothing going on.'' (Tr. 1/22/91, p. 1444) Additionally, it has been suggested that OSHA has ignored the ''clearly overall negative results'' of the epidemiologic studies. (Ex. 113, A–48)

OSHA agrees with the observation that when many statistical analyses are done on a database, it is possible that some positive results may be due to chance. However, OSHA rejects criticism that the Agency has inappropriately concentrated on the positive results and disregarded the negative results. It is OSHA's opinion that there is a compelling pattern of results in the epidemiologic studies.

Furthermore, a reasonable explanation for the elevated SMR for black production workers in the update of the Matanoski cohort study is that this subset of the population actually had heavy exposure to BD. Support for this explanation can be found in the industrial hygiene survey results of Fajen et al. (Ex. 34–4) In this case, then, the risk for excess mortality would be concentrated in a small subset of otherwise very healthy and unexposed workers that would be diluted when analyses are based on the entire group being studied. The only way to observe the risk in the most highly exposed subset would be to analyze the data by subgroups of the population.

(viii) *Appropriateness of Selected Reference Populations.* OSHA also has been criticized for ''ignor[ing] the fact that most of the epidemiologic studies of butadiene-exposed workers only used U.S. cancer mortality rates for comparison to worker mortality.'' (Ex. 113, A–49) The significance of this criticism is based on the observation by Downs that ''use of local (mortality) rates (for comparison) tended to bring the SMRs closer to 100.'' (Ex. 17–33, p.14) This finding results from cancer rates along the Texas Gulf coast that are higher than national rates. (Ex. 17–33) In other words, it has been argued that national comparison rates artificially inflate the SMRs, while local rates provide a more accurate picture of the mortality experience of workers with occupational exposure to BD. (Ex. 113, A–50)

Dr. Landrigan captured the essence of this issue in his testimony on cross-examination,

> This is a perennial debate in epidemiology of whether to use local comparison rates or regional or national, and there's [sic] arguments [to] go both ways. (Tr. 1/15/91, p. 154)

He presented several arguments for using national rates. First, U.S. mortality rates are based on the entire population, so they are more stable. Second, national rates are more commonly used, so it is easier to compare results from different studies.

On the other hand, the argument in favor of using local rates centers on the fact that people in a local area may truly be different from the total population or a regional population(s). Thus, comparing a local subpopulation with the entire local population may provide more accurate results. However, the weakness in this argument was highlighted by Dr. Landrigan when he said that,

> * * * if there are factors acting in the local population, such as environmental pollution that may elevate rates in the local area so that they are closer to the rates in the occupationally exposed population, then theoretically at least one could argue that the local population is overmatched, too similar to the employee population and that the use of the national comparison group actually give [sic] a better reflection of reality. (Tr. 1/15/91, p. 155)

In fact, he went on to point out that the BD plants have been identified by the Environmental Protection Agency (EPA) as ''major'' polluters of the local environment with BD. (Tr. 1/15/91, p. 155)

OSHA acknowledges that there are pros and cons to both approaches of reference population selection. However, in the study by Delzell et al. mortality data of the USA cohort subgroup were analyzed using both state, i.e., local, general population rates and USA general population rates. (Ex. 117–1) As previously stated, there was little difference in the overall pattern of these analyses. (Ex. 117–1, p. 60) Additionally, the Santos-Burgoa and Matanoski nested case control study used the most appropriate comparison group of all: Those employed at the same facilities. (Ex. 23–109 and 34–4, Vol. III, H–4) Thus, given the available data in the record, OSHA is of the opinion that it cannot ignore the findings of excess mortality that are based on national comparison rates.

(ix) *Summary and Conclusions.* (a) *Summary.* Table V–4 lists the criteria that can be used to judge the presence of a causal association between occupational exposure to BD and cancer of the lymphohematopoietic system. When the available epidemiologic study results are examined in this way, there is strong evidence for causality. The data fulfill all of the listed criteria: Temporal relationship; consistency;

strength of association; dose-response relationship; specificity of association; biological plausibility; and coherence.

In his testimony, OSHA's epidemiologist expert witness agreed that there is ''definite evidence for the fact that occupational exposure to 1,3–Butadiene can cause human cancer of the hematopoietic and lymphatic organs.'' (Tr. 1/15/91, p. 133) Dr. Weisenburger, OSHA's expert witness in hematopathology, also concluded that ''it would be prudent to treat BD as though it were a human carcinogen.'' (Ex. 39, p. 11)

TABLE V–4.—EVIDENCE THAT 1,3-BUTADIENE IS A HUMAN CARCINOGEN

Criterion for causality	Met by BD
Temporal relationship	Yes.
Consistency	Yes.
Strength of association	Yes.
Dose-response relationship	Yes.
Specificity of association	Yes.
Biological plausibility	Yes.
Coherence	Yes.

(b) *Conclusion.* On the basis of the foregoing analysis, OSHA concludes that there is strong evidence that workplace exposure to BD poses an increased risk of death from cancers of the lymphohematopoietic system. The epidemiologic findings supplement the findings from the animal studies that demonstrate a dose-response for multiple tumors and particularly for lymphomas in mice exposed to BD.

C. Reproductive Effects

In addition to the established carcinogenic effects of BD exposure, various reports have led to concern about the potential reproductive and developmental effects of exposure to BD. The term reproductive effects refers to those on the male and female reproductive systems and the term developmental refers to effects on the developing fetus.

Male reproductive toxicity is generally defined as the occurrence of adverse effects on the male reproductive system that may result from exposure to chemical, biological, or physical agents. Toxicity may be expressed as alterations to the male reproductive organs and/or related endocrine system. For example, toxic exposures may interfere with spermatogenesis (the production of sperm), resulting in adverse effects on number, morphology, or function of sperm. These may adversely affect fertility. Human males produce sperm from puberty throughout life and thus the risk of disrupted spermatogenesis is of concern for the entire adult life of a man.

Female reproductive toxicity is generally defined as the occurrence of adverse effects on the female reproductive system that may result from exposure to chemical, biological, or physical agents. This includes adverse effects in sexual behavior, onset of puberty, ovulation, menstrual cycling, fertility, gestation, parturition (delivery of the fetus), lactation or premature reproductive senescence (aging).

Developmental toxicity is defined as adverse effects on the developing organism that may result from exposure prior to conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Developmental effects induced by exposures prior to conception may occur, for example, when mutations are chemically induced in sperm. If the mutated sperm fertilizes an egg, adverse developmental effects may be manifested in developing fetuses. Mutations may also be induced in the eggs. The major manifestations of developmental toxicity include death of the developing fetus, structural abnormality, altered growth and function deficiency.

To determine whether an exposure condition presents a developmental or reproductive hazard, there are two categories of research studies on which to rely: Epidemiologic, or studies of humans, and toxicologic, or experimental studies of exposed animals or other biologic systems.

Many outcomes such as early embryonic loss or spontaneous abortion are not easily detectable in human populations. Further, some adverse effects may be quite rare and require very large study populations in order to have adequate statistical power to detect an effect, if in fact one is present. Often, these populations are not available for study. In addition, there are fewer endpoints which may be feasibly measured in humans as compared to laboratory animals. For example, early embryonic loss is difficult to measure in the study of humans, but can be measured easily in experimental animals. There are no human studies available to address reproductive and developmental effects of BD exposure to workers. Thus, evidence on the reproductive and developmental toxicity of BD comes from toxicologic studies performed using primarily mice.

Animal studies have proved useful for studying reproductive/developmental outcomes to predict human risk. A very important advantage to the toxicological approach is the ability of the experimenter to fully quantitate the exposure concentration and conditions of exposure. Although extrapolation of risk to humans on a qualitative basis is accepted, quantitative extrapolation of study results is more complex.

In his testimony, OSHA's witness, Dr. Marvin Legator, an internationally recognized genetic toxicologist from the University of Texas Medical Branch in Galveston, cautioned that in assessing risk ''humans in general have proven to be far more sensitive than animals * * * to agents characterized as developmental toxicants.'' (Ex. 72) He also noted that ''of the 21 agents considered to be direct human developmental toxins, in 19 * * * the human has been shown to be more sensitive than the animal * * *'' He also pointed to the possibility that sub-groups of the human population may be even more highly sensitive than the population average.

OSHA believes that the animal inhalation studies designed to determine the effect of BD on the reproduction and development of these animals indicate that BD causes adverse effects in both the male and female reproductive systems and produces adverse developmental effects. These studies are briefly summarized and discussed below.

Toxicity to Reproductive Organs

In the first NTP bioassay, an increased incidence of testicular atrophy was observed in male mice exposed to BD atmospheric concentrations of 625 ppm. (Ex. 23–1) In female mice, an increased incidence of ovarian atrophy was observed at 625 and 1,250 ppm. These adverse effects were confirmed in reports of the second NTP study, which used lower exposure concentrations. The latter lifetime bioassay exposed male and female B3C6F1 mice to 0, 6.25, 20, 62.5, 200, and 625 ppm BD. (Ex. 114, p 115) See Table V–5. Testicular atrophy in males was significantly increased at the highest dose tested, 625 ppm, and reduced testicular weight was observed from BD exposures of 200 ppm. (Ex. 96) These latter data are not shown in the Table. In female mice at terminal sacrifice, 103 weeks, ovarian atrophy was significantly increased at all exposure levels including the lowest dose tested, 6.25 ppm, compared with controls. Evidence of ovarian toxicity was also seen during interim sacrifices, but in these cases was the result of higher exposure levels. After 65 weeks of exposure, 90% of the mice exposed to 62.5 ppm experienced ovarian atrophy.

TABLE V–5.—OVARIAN AND TESTICULAR ATROPHY IN MICE EXPOSED TO BD

Lesion	Weeks of exposure	Exposure concentration (ppm)					
		0	6.25	20	62.5	200	625
		Incidence (%)					
Testicular atrophy	40	0/10(0)	NE	NE	NE	0/10(0)	6/10(60)
	65	0/10(0)	NE	NE	NE	0/10(0)	4/7(57)
	103	1/50(2)	3/50(6)	4/50(8)	2/48(4)	6/49(12)	53/72(74)
Ovarian atrophy	40	0/10(0)	NE	NE	0/10(0)	9/10(90)	8/8(100)
	65	0/10(0)	0/10(0)	1/10(10)	9/10(90)	7/10(70)	2/2(100)
	103	4/49(8)	19/49(39)	32/48(67)	42/50(84)	43/50(86)	69/79(87)

NE, not examined microscopically.
Source: Ex. 114.

Extensive comments on the BD induced ovarian atrophy were received from Dr. Mildred Christian, a toxicologist who offered testimony on behalf of the Chemical Manufacturers Association. She questioned the relevance of using the data from studies of mice to extrapolate risk of ovarian atrophy to humans because most of the evidence was observed among the animals who were sacrificed after the completion of the species reproductive life and only after prolonged exposure to 6.25 ppm and 20 ppm (Ex. 118–13, Att 3, p. 4) On the other hand, Drs. Melnick and Huff, toxicologists from the National Institute of Environmental Health Sciences stated that: ''Even though ovarian atrophy in the 6.25 ppm group was not observed until late in the study when reproductive senescence likely pertains, the dose-response data clearly establish the ovary as a target organ of 1,3-butadiene toxicity at concentrations as low as 6.25 ppm, the lowest concentration studied.'' (Ex. 114, p. 116) In addition, it should be noted that an elevated incidence of ovarian atrophy was observed at periods of interim sacrifice of female mice exposed to 20 ppm that took place at the 65 week exposure period, a time prior to the ages when senescence would be expected to have occurred. NIOSH also accepted Dr. Melnick's view that mice exposed to 6.25 ppm BD demonstrated ovarian atrophy. (Ex. 32–35) OSHA remains concerned about the ovarian atrophy demonstrated at low exposure levels in the NTP study. Thus, OSHA concludes that exposure to relatively low levels of BD resulted in the induction of ovarian atrophy in mice.

Sperm-Head Morphology Study

NTP/Battelle investigators also described sperm head morphology findings using $B6C3F_1$ mice exposed as described in the dominant lethal study mentioned below, e.g., exposures to 200, 1000 and 5000 ppm BD. The mice were sacrificed in the fifth week post-exposure and examined for gross lesions of the reproductive system. (Ex. 23–75) The study authors chose this interval as having the highest probability for detecting sperm abnormalities. Epididymal sperm suspensions were examined for morphology. The percentage of morphologically abnormal sperm heads was significantly increased in the mice exposed at 1,000 ppm and 5,000 ppm, but not for those exposed to 200 ppm. The study authors concluded that ''these significant differences in the percentage of abnormalities between control mice and males exposed to 1000 and 5000 ppm [BD] indicated that their late spermatogonia or early spermatocytes were sensitive to this chemical.'' (Ex. 23–75, p. 16)

In reviewing this study, Dr. Mildred Christian stated that these results are not necessarily correlated with developmental abnormalities or reduced fertility and are ''reversible in nature'' and that the observed differences are ''biologically insignificant.'' (Ex. 76, p. 14) In its submission, the Department of Health Services of California said: ''A conclusion as to the reproductive consequences of these abnormalities cannot be made from this study.'' (Ex. 32–168) In reviewing Dr. Christian's comments, OSHA is in agreement that the observation of a significant excess of sperm head abnormalities as a result of BD exposure is not necessarily correlated with the development of abnormal fetuses or of reduced fertility; however, the Anderson study, which did evaluate fetal abnormality and reduced fertility, demonstrated a significant excess of both fetal abnormality plus early and late fetal mortality as a result of male mice exposure to BD. (Ex. 117–1, P. 171) These observations of fetal mortality could only occur as a result of an adverse effect on the sperm. In response to Dr. Christian's comment that the sperm head abnormality observed in the study is reversible, the reversibility would be dependent upon cessation of exposure. Since workers may be exposed to BD on a daily basis, the significance of reversibility may be moot.

Developmental Toxicity

Dominant Lethal Studies

A dominant lethal study was conducted by Battelle/NTP to assess the effects of a 5-day exposure of male CD–1 mice to BD atmospheric concentrations of 0, 200, 1,000 and 5,000 ppm BD for 6 hours per day on the reproductive capacity of the exposed males during an 8-week post-exposure period. (Ex 23–74) If present, dominant lethal effects are expressed as either a decrease in the number of implantations or as an increase in the incidence of intrauterine death, or both, in females mated to exposed males. Dominant lethality is thought to arise from lethal mutations in the germ cell line that are dominantly expressed through mortality to the offspring. In this study, the only evidence of toxicity to the adult male mouse was transient and occurred over a 20 to 30 minute period following exposure at 5,000 ppm. Males were then mated to a different female weekly for 8 weeks. After 12 days, females were killed and examined for reproductive status. Uteri were examined for number, position and status of implantation. Females mated to the BD-exposed males during the first 2 weeks post-exposure were described as more likely than control animals to have increased numbers of dead implantations per pregnancy.

For week one, the percentage of dead implantations in litters sired by males exposed to 1,000 ppm was significantly higher than controls. There were smaller increases at 200 ppm and 1000 ppm that were not statistically significant. The percentage of females with two or more dead implantations was significantly higher than the control value for all three exposure groups. For week two, the numbers of dead implantations per

pregnancy in litters sired by males exposed to 200 ppm and 1000 ppm were also significantly increased, but not for those exposed to 5000 ppm. No significant increases in the end points evaluated were observed in weeks three to eight. These results suggested to the authors that the more mature cells (spermatozoa and spermatids) may be adversely altered by exposure to BD. (Ex. 23–74)

The State of California Department of Health Services concluded that the above mentioned study showed no adverse effect from exposure to BD, with the possible exception of the increase in intrauterine death seen as a result of male exposures to 1000 ppm BD at the end of one week post exposure. (Ex. 32–16) Since values for the 5000 ppm exposure group were not significantly elevated for this same period of follow up, the California Department of Health thought the biological significance of the results of the 1000 ppm exposure was questionable. (Ex. 32–16) On the other hand, Dr. Marvin Legator stressed the low sensitivity of the dominant lethal assay which, he felt was due to the endpoint-lethality. He expressed the opinion that the studies were ''consistent with an effect on mature germ cells.'' (Ex. 72) He felt that since an effect was observable in this relatively insensitive assay that only the ''tip of the iceberg'' was observed, and that ''[t]ransmissible genetic damage, displaying a spectrum of abnormal outcomes can be anticipated at concentrations (of BD) below those identified in the dominant lethal assay procedure.'' (Ex. 72, p. 17)

The dominant lethal effect of BD exposure was more recently confirmed by Anderson et al. in 1993. (Ex. 117–1, p. 171) They studied CD–1 mice using a somewhat modified study design. Two exposure regimens were used. In the first, ''acute study,'' male mice were exposed to 0 (n=25), 1250 (n=25), or 6250 (n=50) ppm BD for 6 hours only. Five days later they were caged with 2 untreated females. One female was allowed to deliver her litter and the other was killed on day 17 of gestation and examined for the number of live fetuses, number of early and late post-implantation deaths and the number and type of any gross malformation. The authors stated that sacrifice on day 17 (rather than the standard days 12 through 15) allowed examination of near-term embryos for survival and abnormalities. The mean number of implants per female was reduced compared with controls at both concentrations of BD, but was statistically significant only at 1250 ppm. Neither post-implantation loss nor fetal abnormalities were significantly increased at either concentration. The authors concluded that ''a single 6-hour acute exposure to butadiene was insufficient to elicit a dominant lethal effect.'' (Ex. 117–1, p. 171)

In the second phase of the study, the ''subchronic study,'' CD–1 mice were exposed to 0 (n=25), 12.5 (n=25), or 1250 (n=50) ppm BD for 6 hours per day, 5 days per week, for 10 weeks. They were then mated. The higher 1250 ppm BD exposure resulted in significantly reduced numbers of implantations and in significantly increased numbers of dominant lethal mutations expressed as both early and late deaths. See Table V–6. Non-lethal mutations expressed as birth abnormalities were also observed in live fetuses (3/312; 1 hydrocephaly and 2 runts).

The lower exposure (12.5 ppm) did not result in decreases in the total number of implants, nor in early deaths; however, the frequencies of late deaths and fetal abnormalities (7/282; 3 exencephalies in 1 litter and one in another, two runts and one with blood in the amniotic sac) were significantly increased.

The authors felt that their finding of increased late deaths and fetal abnormalities at a subchronic, low exposure of 12.5 ppm was the main new finding of the study. They noted that these adverse health effects were increased 2–3 fold over historical controls. In evaluating these latter two studies OSHA notes that while there was no demonstrable effect on dominant lethality as a result of a single exposure to 1250 ppm BD, subchronic exposure to 12.5 ppm, the lowest dose tested, resulted in the induction of dominant lethal mutations and perhaps non-lethal mutations. (Ex 117–1, p 171) OSHA has some reservations about whether or not the fetal abnormalities observed in the Anderson et al. ''subchronic'' study were actually caused by non-lethal mutations or by some other mechanism because they were observed in only a few of the litters produced by the mice. (Ex. 117–1, p. 171)

TABLE V–6.—EFFECT OF BD ON REPRODUCTIVE OUTCOMES IN CD–1 MICE

	Implantations		Early deaths		Late deaths		Late deaths including dead fetuses		Abnormal fetuses	
	No.	Mean	No.	Mean [a]	No.	Mean [a]	No.	Mean [a]	No.	Mean [a]
Control	278	12.09±1.276	13	0.050±0.0597	0		2	0.007±0.0222	0	
12.5	306	12.75±2.507	16	0.053±0.0581	7	0.23**±0.038	8	0.026±0.0424	[b]7	0.024*±0.062
1250 ppm ...	406	10.68**±3.103	87	0.204***±0161	6	0.014***±0.0324	7	0.016±0.339	[c]3	0.011**±0.043≤

* Significantly different from control at: *p≤0.05; **p≤0.01; ***p≤0.001 (by analysis of variance and least significance test on arc-sine transform data).

[a] Per implantation.

[b] Four exencephalies (three in one litter), two runts (≤70% and 60% of mean body weight of others in litter; total litter sizes 7 and 9, respectively one fetus with blood in amniotic sac but no obvious gross malformation (significance of difference not altered if this fetus is excluded).

[c] One hydrocephaly, two runts (71% and 75% of mean body weight of others in litter; total litter sizes; 2 and 11, respectively).

A dominant lethal test was also performed by Adler et al. (Ex. 126) Male(102/E1XC3H/E1)F_1 male mice were exposed to 0 and 1300 ppm BD. They were mated 4 hours after the end of exposure with untreated virgin females. Females were inspected for the presence of a vaginal plug every morning. Plugged females were replaced by new females. The mating continued for four consecutive weeks. At pregnancy day 14–16 the females were killed and uterus contents were evaluated for live and dead implants. Exposure of male mice to 1300 ppm BD caused an increase of dead implants during the first to the third mating week after 5 days of exposure. The dead implantation rate was significantly different from the concurrent controls only during the second mating week. Adler et al. concluded that dominant lethal mutations were induced by BD in spermatozoa and late stage spermatids and that these findings confirmed the results of the Battelle/NTP study which showed effects on the same stages of

sperm development. (Ex. 23–74) The authors were of the opinion that BD may induce heritable translocations in these germ cell stages.

The earliest reproductive study reported on BD was conducted by Carpenter et al. in 1944. (Ex. 23–64) In this study, male and female rats were exposed by inhalation to 600, 2,300 or 6,700 ppm BD, 7.5 hours per day, six days per week for an 8-month period. Although this study was not specifically designed as a reproductive study, the fertility and the number of progeny were recorded. No significant effects due to BD exposure were noted for either the number of litters per female animal or for the number of pups per litter.

In the Hazelton study, Sprague-Dawley (SD) rats were exposed by inhalation to 0, 200, 1,000 or 8,000 ppm BD on days 6 though 15 of gestation. (Ex. 2–32) There were dose-related effects on maternal body weight gain, fetal mean weight and crown-to-rump length. Post-implantation loss was slightly higher in all BD-exposed groups. In addition, there were significant increases in hematoma in pups in the 200 and 1,000 ppm exposure groups. In the 8,000 ppm exposure group, a significantly increased number of pups had lens opacities and there was an increased number of opacities per animal. According to the authors, the highest exposure groups also had a significantly increased number of fetuses with skeletal variants, a higher incidence of bipartite thoracic centra, elevated incidence of incomplete ossification of the sternum, higher incidence of irregular ossification of the ribs, and ''other abnormalities of the skull, spine, long bones, and ribs.'' The authors concluded that the fetal response was not indicative of a teratogenic effect, but was the result of maternal toxicity.

In the Battelle/NTP study, pregnant Sprague-Dawley (SD) rats and pregnant Swiss mice were exposed to 0, 40, 200, or 1,000 ppm BD for 6 hours per day from day 6 through day 15 of gestation. (Ex. 23–72) Animals were sacrificed and examined one day before expected delivery. In the rat, very little effect was noted; in the 1,000 ppm exposure group only there was evidence of maternal toxicity, i.e., depressed body weight gains during the first 5 days of exposure. No evidence of developmental toxicity was observed in the SD rats evaluated in the study, e.g., the number of live fetuses per litter and the number of intrauterine deaths were within normal limits.

In the mouse, exposure to the above mentioned concentrations did not result in significant maternal toxicity, with the exception of a reduction in extra-gestational weight gain for the 200 ppm and 1000 ppm BD exposed dams. In the female mice, there was a significant depression of fetal body weight only at the 200 and 1,000 ppm exposure levels. Fetal body weight for male pups was reduced at all exposure concentrations, including the 40 ppm exposure level, even though evidence of maternal toxicity was not observed at this exposure concentration. No significant differences were noted in incidence of malformations among the groups. However, the incidence of supernumerary ribs and reduced ossification of sternebrae was significantly increased in litters of mice exposed to 200 and 1,000 ppm BD.

In reviewing these data, Drs. Melnick and Huff noted that since maternal body weight gain was reduced at the 200 and 1000 ppm exposure levels and body weights of male fetuses were reduced at the 40, 200, and 1000 exposure levels ''[t]he male fetus is more susceptible than the dam to inhaled 1,3-butadiene.'' (Ex. 114, p. 116) They further stated that ''the results of the study in mice reveal that a toxic effect of 1,3-butadiene was manifested in the developing organism in the absence of maternal toxicity.'' On the basis of this study, the authors concluded that ''1,3-butadiene does not appear to be teratogenic in either the rat or the mouse, but there is some indication of fetotoxicity in the mouse.'' (Ex. 23–72)

On the other hand, Dr. Mildred Christian was of the opinion that the significant decrease in male mouse fetal weight gain in the 40 ppm exposure group was not a selective effect of BD on the conceptus, but rather was a result of the statistical analysis used which she considered inappropriate. (Ex. 118–13, Att. 3, p. 6) She was also of the opinion that the larger litter sizes in the 40 ppm exposure group as compared with the control group contributed to the statistical finding. Dr. Christian, however, did not present any specific information on the type of analysis used for statistical testing that she thought made the results inappropriate. In general, one would expect that the evaluation of data from larger litter sizes would give one more confidence in the statistical findings.

In reviewing the same study, the State of California, Department of Health Services was more cautious. It stated that ''The increased incidence of reduced ossifications and the fetal weight reductions in the absence of apparent maternal toxicity in the 40- and 200-ppm groups is evidence of fetotoxicity * * * in the Swiss (CD–1) mouse.'' After reviewing the study results and arguments about the study, OSHA concluded that the NTP study provides evidence of fetotoxicity in the mouse. (Ex. 23–72)

Mouse spot test

Adler et al. (1994) conducted a spot test in mice. (Ex. 126) The spot test is an *in vivo* method for detecting somatic cell mutations. A mutation in a melanoblast is detected as a coat color spot on the otherwise black fur of the offspring. Pregnant females were exposed to 0 or 500 ppm BD for 6 hours per day on pregnancy days 8, 9, 10, 11 and 12. They were allowed to come to term and to wean their litters. Offspring were inspected for coat color spots at ages 2 and 3 weeks. Gross abnormalities were also recorded. Exposure to a concentration of 500 ppm did not cause any embryotoxicity, nor were gross abnormalities observed. The BD exposure, however, significantly increased the frequency of coat color spots in the offspring. This study demonstrates that BD exposure is capable of causing transplacentally induced somatic cell mutations that can result in a teratogenic effect in mice.

Summary of Reproductive and Developmental Effect

OSHA has limited its discussion on reproductive and developmental hazards to a qualitative evaluation of the data. This approach was chosen because no generally accepted mathematical model for estimating reproductive/developmental risk on a quantitative basis was presented during the rulemaking. For example, the CMA Butadiene panel disagreed with OSHA's findings in the proposal regarding the potential reproductive and developmental risks presented by BD exposure using an uncertainty factor approach. (See Ex. 112) They cited Dr. Christian's conclusion that the mouse possessed a ''special sensitivity'' to BD and should not be used as a model on which to base risk estimates.

The agency has determined, however, that animal studies, taken as a whole, offer persuasive qualitative evidence that BD exposure can adversely effect reproduction in both male and female rodents. The Agency also notes that BD is mutagenic in both somatic and germ cells. (Ex. 23–71; Ex. 114; Ex. 126)

Some evidence of maternal and developmental toxicity was seen in rats exposed to BD, but the concentrations used were much higher than those that elicited a response in mice. (Ex. 118–13, Att. 3, p. 2) In mice, evidence of fetotoxicity was observed in either the presence or absence of maternal toxicity, the latter evidence being

provided by decreased fetal body weight in male mice whose dams were exposed to 40 ppm BD, the lowest dose tested in the study. In addition, a teratogenic effect was observed in mice (coat color spot test) as a result of transplacentally induced somatic cell mutation.

OSHA is also concerned about the observation of a significant excess of sperm head abnormalities as a result of BD exposure, even though this expression of toxicity is not necessarily correlated with the development of abnormal fetuses or of reduced fertility. The Anderson study, which did evaluate reduced fertility and fetal abnormality, demonstrated a significant excess of both early and late fetal mortality and perhaps fetal abnormality as a result of male mice exposure to BD. (Ex. 117–1, P. 171) This observation could only occur as a result of an adverse effect on the sperm. Two additional studies also provide evidence of dominant lethality as a result of male exposure to BD. (Ex. 23–74; Ex. 126) The observation of germ cell effects is supported by additional evidence of genotoxicity in somatic cells, as demonstrated by positive results in the micronucleus test and in the mouse spot test. (Ex. 126)

Some of the adverse effects related to reproductive and developmental toxicity in the mouse, e.g., ovarian atrophy, testicular atrophy, reduced testicular weight, abnormal sperm heads, dominant lethal effects, were acknowledged by Dr. Christian, but she urged the Agency not to rely on these findings because of negative study results in other species, or because positive findings in other species required much higher exposure levels. (Ex. 118–13, Att. 3, p. 1)

For example, a CMA witness has argued that the diepoxide is responsible for the ovarian atrophy observed in relation to low level BD exposure (6.25 ppm). (Ex. 118–13, Att. 3) However, the monoepoxide could also play a role in the ovarian atrophy and evidence indicates that humans can form the monoepoxide of BD and that humans have the enzymes present that could cause conversion to the diepoxide. Therefore on a qualitative basis, the observation of ovarian atrophy in the mouse is meaningful in OSHA's view. In addition, the metabolic factors related to testicular atrophy, malformed sperm and dominant lethal mutations in the mouse are not known. (See section on *in vitro* metabolic studies.) These observations further support the findings in mice as being meaningful for humans on a qualitative basis. The mouse spot test which demonstrates a somatic cell mutation leading to a teratogenic effect inconsistent with data showing the ability of BD to cause adverse effects on chromosomes and *hprt* mutations in humans exposed to BD.

OSHA also notes that studies of workers exposed to low concentrations of BD demonstrated a significant excess of chromosomal breakage and an inability to repair DNA damage. Thus, BD exposure seems capable of inducing genetic damage in humans as a result of low level exposure. Therefore, the mouse studies which demonstrate genetic damage (mutations) in both somatic and germinal cells seem to be a better model on a qualitative basis than the rat for predicting these adverse effects in humans.

D. Other Relevant Studies

1. Acute Hazards

At very high concentrations, BD produces narcosis with central nervous system depression and respiratory paralysis. (Ex. 2–11) LC_{50} values (the concentration that produces death in 50 percent of the animals exposed) were reported to be 122,170 ppm (12.2% v/v) in mice exposed for 2 hours and 129,000 ppm (12.9% v/v) in rats exposed for 4 hours. (Ex. 2–11, 23–91) These concentrations would present an explosion hazard, thus limiting the likelihood that humans would risk any such exposure except in extreme emergency situations. Oral LD_{50} values (oral dose that results in death of 50 percent of the animals) of 5.5 g/kg body weight for rats and 3.2 g/kg body weight for mice have been reported. (Ex. 23–31) These lethal effects occur at such high doses that BD would not be considered ''toxic'' for purposes of Appendix A of OSHA's Hazard Communication Standard (29 CFR 1910.1200), which describes a classification scheme for acute toxicity based on lethality data.

At concentrations somewhat above the previous permissible exposure level of 1,000 ppm, BD is a sensory irritant. Concentrations of several thousand ppm were reported to cause irritation to the skin, eyes, nose, and throat. (Ex. 23–64, 23–94) Two human subjects exposed to BD for 8 hours at 8000 ppm reported eye irritation, blurred vision, coughing, and drowsiness. (Ex. 23–64)

2. Systemic Effects

In the preamble to the proposal, OSHA reviewed the literature to discern the systemic effects of BD exposure. (55 FR 32736 at 32755) OSHA discussed an IARC review which briefly examined several studies from the former Soviet Union. In these, various adverse effects, such as hematologic disorders, liver enlargement and liver and bile-duct diseases, kidney malfunctions, laryngotracheitis, upper respiratory tract irritation, conjunctivitis, gastritis, various skin disorders and a variety of neurasthenic symptoms, were ascribed to occupational exposure to BD. (Ex. 23–31) OSHA and IARC have found these studies to be of limited use primarily due to their lack of exposure information. Except for sensory irritant effects and hematologic changes, evidence from studies of other exposed groups have failed to confirm these observations.

Melnick and Huff summarized the observed non-neoplastic effects of BD exposure in the NTP I and NTP II mouse bioassays. They listed the following effects associated with exposure of B6C3F [1] mice to BD for 6 hours per day 5 days per week for up to 65 weeks:

* * * epithelial hyperplasia of the forestomach, endothelial hyperplasia of the heart, alveolar epithelial hyperplasia, hepatocellular necrosis, testicular atrophy, ovarian atrophy and toxic lesions in nasal tissues (chronic inflammation, fibrosis, osseous and cartilaginous metaplasia, and atrophy of the olfactory epithelium.) (Ex. 114, p. 114)

They noted that the nasal lesions were seen only in the group of male mice exposed to 1250 ppm BD and that no tumors were observed at this site. Further, Melnick and Huff suggested that some of the proliferative lesions observed in the bioassay might represent pre-neoplastic changes.

The findings of testicular and ovarian atrophy are discussed more fully in the Reproductive Effects section of this preamble,.

Nephropathy, or degeneration of the kidneys, was the most common non-carcinogenic effect reported for male rats in the Hazelton Laboratory Europe (HLE) study in which rats were exposed to 1000 or 8000 ppm BD for 6 hours per day, 5 days per week for up to 2 years. Nephropathy was one of the main causes of death for the high dose males. (Ex. 2–31, 23–84) The combined incidence of marked or severe nephropathy was significantly elevated in the high dose group over incidence in the low dose group and over incidence in the controls ($p<.001$). HLE's analysis of ''certainly fatal'' nephropathy shows a significant dose-related trend ($p<.05$), but when ''uncertainly fatal'' cases were included, the trend disappeared.

The HLE study authors concluded that the interpretation of the nephropathy incidence data was equivocal. They stated that ''an increase in the prevalence of the more severe grades of nephropathy, a common age-

related change in the kidney, was considered more likely to be a secondary effect associated with other unknown factors and not to represent a direct cytotoxic effect of the test article on the kidney.''

Upon reviewing the HLE rat study for the proposed rule, OSHA expressed concern that only 75% of the low-dose male rats in the HLE study exhibited nephropathy, while 87% of the control rats had some degree of nephropathy, suggesting low-dose male rats were less susceptible to kidney degeneration than control rats, thereby decreasing the comparability between rats in the low-dose and control groups. (55 FR 32736 at 32744) Dr. Robert K. Hinderer, in testifying for the CMA BD Panel, countered that the NTP I mouse study also had ''selected instances where the response in the test group (was) lower than that in the controls'' and that ''* * * (o)ne cannot look at single or a few individual site responses to evaluate the health status or overall effect of the chemical.'' (Ex. 51) OSHA agrees that there may be some variability in background response rates for specific outcomes. However, the Agency believes that it is important to assess the impact of the variability in background response rates when drawing conclusions about dose-related trends in the data. This was not done in the HLE study nephropathy analysis.

Other non-carcinogenic effects observed in the HLE rat study were elevated incidence of metaplasia in the lung of high dose male rats at terminal sacrifice as compared with incidence in male controls at terminal sacrifice, and a significant increase in high dose male rat kidney, heart, lung, and spleen weights over the organ weights in control male rats.

3. Bone Marrow Effects

There was a single study of BD-exposed humans discussed in the proposal—a study by Checkoway and Williams that examined 163 hourly production workers who were employed at the SBR facility studied by McMichael et al.. (described more fully in the Epidemiology Section of this Preamble.) (Ex. 23–4, 2–28).

Exposure to BD, styrene, benzene, and toluene was measured in all areas of the plant. BD and styrene concentrations, 20 (0.5–65) ppm and 13.7 (0.14–53) ppm, respectively, were considerably higher in the Tank Farm than in other departments. In contrast, benzene exposures, averaging 0.03 ppm, and toluene concentrations, averaging 0.53 ppm, were low in the Tank Farm. The authors compared the hematologic profiles of Tank Farm workers (n=8) with those of the other workers examined.

The investigation focused on two potential effects, bone marrow depression and cellular immaturity. Bone marrow depression was suspected if there were lower levels of erythrocytes, hemoglobin, neutrophils, and platelets. Cellular immaturity was suggested by increases in reticulocyte and neutrophil band form values.

Although the differences were small, adjusted for age and medical status, hematologic parameters in the Tank Farm workers differed from those of the other workers. Except for total leukocyte count, the hematologic profiles of the Tank Farm workers were consistent with an indication of bone marrow depression. The Tank Farm workers also had increases in band neutrophils, a possible sign of cellular immaturity, but no evidence that increased destruction of reticulocytes was the cause.

While acknowledging the limitations of the cross-sectional design of the study, the authors felt, nevertheless, that their results were ''suggestive of possible biological effects, the ultimate clinical consequences of which are not readily apparent.'' OSHA finds any evidence of hematological changes in workers exposed at BD levels well below the existing permissible limit (1000 ppm) to be of concern since such information suggests the inadequacy of the present exposure limit. However, this cross-sectional study involved only 8 workers with relatively high levels of exposure to BD and low levels of exposure to benzene, so it is quite insensitive to minor changes in hematologic parameters.

In a review of BD-related studies, published in 1986, an IARC Working Group felt the study of Checkoway and Williams could not be considered indicative of an effect of BD on the bone marrow (Ex. 2–28). In 1992, IARC concluded that the ''changes cannot be interpreted as an effect of 1,3-butadiene on the bone marrow particularly as alcohol intake was not evaluated.'' (Ex. 125, p. 262)

In light of the more recent animal studies that were not available to IARC, however, OSHA believes that the bone marrow is a target of BD toxicity. Furthermore, the fact that changes in hematologic parameters could be distinguished in workers exposed to BD at 20 ppm indicates that such measurements may prove a sensitive indicator of excessive exposure to BD.

In testimony for the CMA BD Panel, Dr. Michael Bird stated his conclusion that the hematological differences between the 8 tank farm workers and the lesser exposed group of workers was not ''statistically significant by the usual conventional statistics.'' (Tr. 1/18/1991, p. 1078) He believed that although the raw data were not available, the reported means were within the historical and expected range for these parameters. (Tr. 1/18/1991, p., 1078) In contrast, OSHA concludes from this study that the hematologic differences observed in BD-exposed workers, although small, are suggestive of an effect of BD on human bone marrow under occupational exposure conditions.

Thus OSHA considers the Checkoway and Williams study to be suggestive of hematologic effects in humans, but does not regard it as definitive. No other potential systemic effects of BD exposure on this population were addressed in the Checkoway and Williams study.

In 1992, Melnick and Huff reviewed the toxicologic studies of BD exposure in laboratory animals. (Ex. 114) Only slight to no systemic effects were observed in an early study of rats, guinea pigs, rabbits and a dog exposed to BD up to 6,700 ppm daily for 8 months. (Ex. 23–64) The study of Sprague Dawley rats exposed to doses of BD up to 8,000 ppm daily for 13 weeks also did not result in hematologic, biochemical, neuromuscular, nor urinary effects. However, there were marked effects seen in exposed mice.

Epidemiologic studies of the styrene-butadiene rubber (SBR) industry suggest that workers exposed to BD are at increased risk of developing leukemia or lymphoma, two forms of hematologic malignancy (see preamble section on epidemiology). Consequently, investigators have looked for evidence of hematopoietic toxicity resulting from BD exposure in animals and in workers. For example, Irons and co-workers at CIIT found that exposure of male $B6C3F_1$ mice to 1,250 ppm of BD for 6–24 weeks resulted in macrocytic-megaloblastic anemia, an increase in erythrocyte micronuclei and leukopenia, principally due to neutropenia. Bone marrow cell types overall were not altered, but there was an increase in the number of cells in the bone marrow of exposed mice due to an increase in DNA synthesis. (Ex. 23–12)

Melnick and Huff also reviewed the available information on bone marrow toxicity. (Ex. 114, p. 114) Table V–7 represents the reported findings of a study of 10 $B6C3F_1$ mice sacrificed after 6.25–625 ppm exposure to BD for 40 weeks. The authors concluded that these data demonstrated a concentration-dependent decrease in red blood cell number, hemoglobin concentration, and packed red cell

volume at BD exposure levels from 62.5 to 625 ppm. The effects were not observed at 6.25 and 20 ppm exposure levels. Melnick and Kohn also noted the increase in mean corpuscular volume in mice exposed at 625 ppm, and suggested that this and other observations (such as those of Tice (Ex. 32–38D)) who observed a decrease in the number of dividing cells in mice and decreased rate of their division), suggested that BD exposure led to a suppression of hematopoiesis in bone marrow. Melnick and Huff concluded that this, in turn, led to release of large immature cells from sites such as the spleen, which was considered indicative of macrocytic megaloblastic anemia by Irons. They concluded that these findings ''(establish) the bone marrow as a target of 1,3-butadiene toxicity in mice.'' (Ex. 114, p. 115)

TABLE I.—HEMATOLOGIC CHANGES IN MALE B6C3F$_1$ MICE EXPOSED FOR 6 HOURS/DAY, 5 DAYS/WEEK FOR 40 WEEKS

BD exposure (ppm)	Red blood cell count (×10^6/ul)	Hemoglobin conc. (g/dl)	Volume packed RBC (ml/dl)	Mean corpuscular vol
0	10.4±0.3	16.5±0.4	48.1±1.5	46.3±0.8
6.25	10.3±0.3	16.4±0.5	47.8±1.7	46.4±1.0
20	10.4±0.4	16.7±0.7	48.2±2.2	46.3±0.8
62.5	[a] 9.9±0.4	[a] 15.9±0.6	[a] 45.9±2.1	46.7±1.2
200	[a] 9.6±0.5	[a] 15.6±0.9	[a] 45.4±2.7	47.2±1.0
625	[a] 7.6±1.2	[a] 13.5±1.8	[a] 39.9±5.3	[a] 53.2±2.9

Adapted from Melnick and Huff, Exhibit 114.
[a] Different from chamber control (0 ppm), P<0.05. Results of treated groups were compared to those of control groups using Dunnett's t-test.

4. Mutagenicity and Other Genotoxic Effects

OSHA discussed the genotoxic effects of BD exposure in some detail in the proposal. (55 FR 32736 at 32760) Briefly, BD is mutagenic to *Salmonella typhimurium* strains TA 1530 and TA 1535 when activated with S9 liver fraction of Wistar rats treated with phenobarbital or Arochlor 1254. These bacterial strains are sensitive to base-pair substitution mutagens. Since the liver fraction is required to elicit the positive mutagenic response, BD is not a direct-acting mutagen and likely must be metabolized to an active form before becoming mutagenic in this test system. IARC published an extensive list of ''genetic and related effects of 1,3-butadiene.'' (Ex. 125) They noted in summarizing the data that BD was negative in tests for somatic mutation and recombination in *Drosophila*, and that neither mouse nor rat liver from animals exposed to 10,000 ppm BD showed evidence of unscheduled DNA synthesis.

As OSHA described in the proposed rule, and Tice et al. reported in 1987, BD is a potent *in vivo* genotoxic agent in mouse bone marrow cells that induced chromosomal aberrations and sister chromatid exchange in marrow cells and micronuclei in peripheral red blood cells. (55 FR 52736 at 52760) Some of these effects were evident at exposures as low as 6.25 ppm (6 hours/day, 10 days). However, similar effects were not observed in rat cells exposed to higher levels of BD (10,000 ppm for 2 days).

Sister chromatid exchange is a recombinational event in which nucleic acid is exchanged between the two sister chromatids in each chromosome. It is thought to result from breaks or nicks in the DNA. Irons et al. described micronuclei as ''* * * chromosome fragments or chromosomes remaining as the result of non-dysjunctional event. Their presence in the circulation is frequently associated with megaloblastic anemia.'' (Ex. 23–12).

In a subsequent study, Filser and Bolt exposed B6C3F$_1$ mice to the same 3 concentrations of BD, 6.25, 62.5 or 625 for 6 hours/day, 5 days/week, for 13 weeks. (Ex. 23–10) Peripheral blood samples were taken from 10 animals per group and scored for polychromatic erythrocytes (PCE) and micronucleated normochromatic erythrocytes (MN–NCE). The MN–NCE response, which reflects an accumulated response, was significantly increased in both sexes at all concentrations of BD, including 6.25 ppm.

Certain metabolites of BD also produce genotoxic effects. These are detailed in a number of reviews (see for example, Ex. 114, 125). Briefly, epoxybutene (the monoepoxide) is mutagenic in bacterial systems in the absence of exogenous metabolic activation. Epoxybutene also reacts with DNA, producing two structurally identical adducts and has been shown to induce sister chromatid exchanges in Chinese hamster ovary cells and in mouse bone marrow *in vivo*.

IARC in its review concluded that the diepoxide, 1,2,:3,4-diepoxybutane, induced DNA crosslinks in mouse hepatocytes and, like epoxybutene, is mutagenic without metabolic activation. As discussed below, BD diepoxide also induced SCE and chromosomal aberrations in cultured cells.

A human cross-sectional study involving a limited number of workers in a Texas BD plant indicated genotoxic effects. (Ex. 118–2D) Peripheral lymphocytes were cultured from 10 non-smoking workers and from age- and gender-matched controls who worked in an area of very low BD exposure (0.03 ppm). Production areas in the plant had a mean exposure of 3.5 ppm BD, with most exposed workers in this sample experiencing exposure of approximately 1 ppm BD.

Standard assays for chromosomal aberrations and a gamma irradiation challenge assay that was designed to detect DNA repair deficiencies were performed. The results of the standard assay indicated that the exposed group had a higher frequency of cells with chromosome aberrations and higher chromatid breaks compared with the control group. This difference was not statistically significant. In the challenge assay, the exposed group had a statistically significant increased frequency of aberrant cells, chromatid breaks, dicentrics (chromosomes having 2 centromeres) and a marginally significant higher frequency of chromosomal deletions than controls. Au and co-workers concluded that cells exposed to BD are likely to have more difficulty in repairing radiation induced damage. (Ex. 118–2D)

To determine the mutagenic potential of both BD and its three metabolite epoxides, Cochrane and Skopek studied effects in human lymphoblastoid cells (TK6) and in splenic T cells from exposed B6C3F$_1$ mice. (Ex. 117–2, p. 195) TK6 cells were exposed for 24 hours to epoxybutene (0–400 uM), 3,4-epoxy-1,2-butanediol (0–800 uM), or diepoxybutane (0–6 uM). All

metabolites were mutagenic at both the *hprt* (hypoxanthine-guanine phosphoribosyl transferase) and tk (thymidine kinase) loci, with diepoxybutane being active at concentrations 100 times lower than epoxybutane or epoxybutanediol.

They also studied mice exposed to 625 ppm BD for 2 weeks and found a 3-fold increase in *hprt* mutation frequency in splenic T cells compared with controls. They also intended to give daily IP doses of epoxybutene (60, 80 or 100 mg/kg) or diepoxybutane (7, 14, or 21 mg/kg) every other day for three days. However, only animals given the lowest dose of the diepoxide received three doses because of lethality. After two weeks of expression time, cells were isolated for determination of mutation frequency. Both exposure regimens resulted in increased mutation frequency. For example, at the highest exposure to epoxybutene, the average mutation frequency was 8.6×10^{6}, while the diepoxide exposed group had a frequency of 13×10^{6}, compared to a control mutation frequency of 1.2×10^{6}.

Cochrane and Skopek used denaturing gradient gel electrophoresis to study the nature of the splenic T cell *hprt* mutants in the DNA. They found about half were frameshift mutations. A potential ''hotspot'' was also described in which a plus one (+1) frameshift mutation in a run of six guanine bases was observed in four BD-exposed mice, in four expoxybutene-exposed mice and in two mice exposed to the diepoxide. They observed both G:C and A:T base pair substitutions in the epoxide treated group; however, similar to the findings of Recio, et al. (described below), A:T substitutions were observed only in the BD-treated group. The authors offered no hypothesis for this observation. These researchers also noted a significant correlation of dicentrics with the presence of a BD metabolite, (1,2-dihydroxy-4-(N-acetyl-cysteinyl-S)butane) in the urine of exposed workers. They further concluded that:

> This study indicates that the workers had exposure-induced mutagenic effects. Together with the observation of gene mutation in a subset of the population, this study indicates that the current occupational exposure to butadiene may not be safe to workers. (Ex. 118–2D)

An abstract by Hallberg submitted to the Environmental Mutagenesis Society describes a host-cell reaction assay in which lymphocytes transfected with a plasmid with an inactive chloramphenicol acetyl transferase (CAT) reporter gene were challenged to repair the damaged plasmid and reactivate the CAT gene. No effect was noted among cells of workers exposed to 0.3 ppm benzene; however, BD-exposed workers (mean exposure 3 ppm) had significantly reduced DNA repair capacity ($p=0.001$). The authors believed that this finding confirmed the DNA repair defect due to BD exposure observed in the Au et al. study's challenge assay. (Ex. 118–2D)

Ward and co-workers reported the results of a preliminary study to determine whether a biomarker for BD exposure and a biomarker for the genetic effect of BD exposure could be detected in BD-exposed workers. (Ex. 118–12A) The biomarker for exposure was excretion of a urinary metabolite of BD, (1,2-dihydroxy-4-(n-acetylcysteinyl-S)butane. The genetic biomarker was the frequency of lymphocytes containing mutations at the hypoxanthine-guanine phosphoribosyl transferase (*hprt*) locus. Study subjects included 20 subjects from a BD production plant and 9 from the authors' university; all were verified non-smokers. Seven workers were in areas or at jobs that were ''considered likely to expose them to higher levels of butadiene than in other parts of the plant.'' Ten worked in areas where the likelihood of BD exposure was low. Three ''variable'' employees worked in both types of jobs or areas. *hprt* assays of 6 of the 7 high exposure group and 5 of the 6 non-exposed groups were completed at the time of the report. Air sampling was used to estimate exposure. In the production area, the mean was approximately 3.5 ppm, with most samples below 1 ppm. In the central control area (lower exposure) the mean was 0.03 ppm. The frequency of mutant lymphocytes in the high-exposure group compared with either the low- or no-exposure group was significantly increased. The low- and non-exposed groups were not significantly different from each other in mutant frequencies.

Similarly, the concentration of the BD metabolite in urine was significantly greater in the high exposure group than in the lower- or non-exposed groups. There was a strong correlation among exposed subjects between the level of metabolite in urine and the frequency of the *hprt* mutants ($r=0.85$). (Ex. 118–2A)

Another study of humans for potential cytogenetic effects of BD exposure was reported recently by Sorsa et al. in which peripheral blood was drawn from 40 BD production facility workers and from 30 controls chosen from other departments of the same plants, roughly matched for age and smoking habits. (Ex. 124) Chromosome aberrations, micronuclei and sister-chromatid exchanges were analyzed. No exposure related effects were seen in any of the cytogenetic endpoints. The typical exposure was reported as less than 3 ppm. (Ex. 124)

Among the limited number of human studies involving BD exposed workers is that of Osterman-Golker who evaluated post-exposure adduct formation in the hemoglobin of mice, rats, and a small number of workers. (Ex. 117–2, p. 127) Mice and rats were exposed at 0, 2, 10, or 100 ppm for 6 hours per day, 5 days per week for 4 weeks and their blood tested for the presence and quantity of the BD metabolite, 1,2-epoxybutene, forming an adduct with the N-terminal valine of hemoglobin. The result was a linear response for mice at 2, 10 and 100 ppm; and, for rats at 2 and 10 ppm, with the 100 ppm dose group deviating from linearity. In addition, while the adduct level per gram of globin in the 100 ppm rats was about 4 times lower than the level observed in mice exposed to 100 ppm BD, at lower exposures, the adduct levels were similar.

In the portion of the study dealing with effects on humans, blood was taken from four workers in two areas of a chemical production plant with known BD exposure, and five workers from two non-production areas where BD concentrations were low. In the higher exposure area, the mean BD exposure was about 3.5 ppm, as determined by environmental sampling. The lower exposure areas had a mean BD level of about 0.03 ppm. On a mole of adduct per gram of hemoglobin level, the adduct levels in the higher BD exposed workers were 70 to 100 times lower than those of either the rat or mice exposed at the 2 ppm level discussed above. Production workers had adduct levels ranging from 1.1 to 2.6 pmol/g globin. Most controls in the study were below the level of detection of the assay (0.5 pmol adduct/ g globin). (Two heavy smokers reported from a previous study had higher adduct levels than non-smokers; their levels approached those observed in BD exposed workers and were consistent with the amount of BD in mainstream smoke.)

Similar results for mice and rats exposed to BD were reported by Albrecht et al. (Ex. 117–2, p. 135) In this study which exposed the rodents to 0, 50, 200, 500 or 1300 ppm for 6 hours/ day, for 5 consecutive days, BD monoepoxide adduct levels in the hemoglobin of mice were about five times that of the rat at most BD exposure concentrations. Humans were not studied in this report.

Another observation pertaining to human cytogenetics with potentially important implications for BD-induced

human disease is contained in a report by Wiencke and Kelsey. (Ex. 117–2, p. 265) These researchers studied the impact of the BD metabolite, diepoxybutane, exposure on sister chromatid exchange (SCE) frequencies in several groups of human blood cell cultures (n=173 healthy workers). They discovered that the study populations were bimodally distributed according to their sensitivity to induction of SCEs when cell cultures were exposed to 6 uM diepoxybutane. Wiencke and Kelsey reported that they had observed in earlier studies that ''genetic deficiency of glutathione S-transferase type u leads to bimodal induction of SCEs by epoxide substrates of the isozyme'' and that cells from individuals with the deficiency had SCE induction scores that were significantly higher than those observed in the general population. (Ex. 117–2, p. 271) Approximately 20% of the tested groups were sensitive to induction of SCE and the remaining 80% were relatively insensitive.[1] Subsequent testing indicated that the sensitive population was also sensitive to induction of chromosomal aberrations by diepoxybutane with significant increases in the frequencies of chromatid deletions, isochromatid deletions, chromatid exchanges and total aberrations. The relevance of these findings in not yet clear; however, they may indicate that certain subsets of the population are more highly susceptible to the effects of this mutagenic metabolite of BD.

Recio et al. used transgenic mice containing a shuttle vector with a recoverable lac 1 gene to study *in vivo* mutagenicity of BD and the spectrum of mutations produced in various tissues. (Ex. 118–7D) Mice were exposed to 62.5, 625 or 1250 ppm BD for 4 weeks (5 days/week, 6 hours/day). The investigators extracted DNA from bone marrow and determined mutagenicity at the lac 1 transgene.

The mutant DNA was sequenced. Dose-dependent mutagenicity—up to a 3-fold increase over air controls—was observed among mice exposed at 625 or 1250 ppm. Although a number of differences in patterns were noted, the most striking was that sequence analysis indicated an increased frequency of *in vivo* point mutations induced by BD exposure at adenine and thymine (A:T) base pairs following inhalation.

In further studies of BD-exposed transgenic mice, Sisk and co-workers exposed male $B6C3F_1$ mice to 0, 62.5, 625, or 1250 ppm, BD for 4 weeks (6 hour/day, 6 days/week). (Ex. 118–7Q) Bone marrow cells were isolated and mutation frequency and spectrum evaluated. Lac 1 mutation frequencies were significantly increased at all 3 exposure levels and were dose-responsive in the 62.5 and 625 ppm BD-exposed mice, compared to controls. A plateau in mutation frequencies was observed at 1250 ppm BD-exposed mice, perhaps indicating saturation or mutant loss due to the effects of high level exposure.

When the mutants were sequenced, several from the same animal were found to have identical mutations. Although they might have arisen independently, Sisk et al. felt that this was likely due to clonal expansion of a bone marrow cell with a mutated lac 1 gene.

As had Recio et al., Sisk et al. observed a higher frequency of mutations at A:T sites in the exposed mice DNA, compared with controls. A:T to G:C transitions comprised only 2% of the background mutations, but made up 15% of those in the exposed mice.

Sisk et al. concluded that their observation coupled with *in vitro* studies ''* * * suggest that BD may mutate hematopoietic stem cells.'' (Ex. 118–7Q, p. 476)

As discussed in the animal carcinogenicity section in this preamble, BD-induced mouse tumors have been found to have activated proto-oncogenes. Specifically, the K-ras oncogene is activated and is the most commonly detected oncogene in humans. (Ex. 129)

OSHA concludes that BD is mutagenic in a host of tests which show point and frameshift mutations, *hprt* mutations, chromosome breakage, and SCEs in both animals and humans. The data suggest that mice are more susceptible than rats to these alterations. In addition, certain subsets of the human population may be more susceptible to the effects of BD exposure than others (based on the Wiencke and Kelsey study of human blood cell cultures, Ex. 117–2, p. 265). OSHA further notes with concern the fact that the data suggest that BD exposure at relatively low levels adversely affects DNA repair mechanisms in humans and is associated with mutational effects.

5. Metabolism

In vitro genotoxicity studies have shown that BD is mutagenic only after it is metabolically activated. Biotransformation is probably also important to the carcinogenicity of this gas. It is thought that the formation of epoxides, specifically epoxybutene, also termed the ''monoepoxide'' and 1,2:3,4-diepoxybutane, termed the ''diepoxide,'' is required for activity and that the reaction is cytochrome P450 mediated[2]. Both the mono- and diepoxide are mutagenic in the Salmonella assay, with the diepoxide being more active. The reactive epoxides can bind to DNA, and formation of DNA adducts is hypothesized to initiate a series of events leading to malignancy.

As described earlier, for most cancer sites, mice are more sensitive than rats to the carcinogenic effects of BD exposure. Studies of the metabolism of BD have been undertaken in an attempt to elucidate the contributions of dose-metric factors for the observed differences in carcinogenicity between the species.

Much of the research in this area has been performed at the Chemical Industry Institute of Toxicology and in German laboratories. Work on metabolism of BD was described by OSHA in the 1990 proposal. (55 FR 32736 at 32756) OSHA reviewed the current literature in the record and concluded:

1. The rate of metabolism of BD in mice is approximately twice that in rats;

2. Mice accumulate more radiolabelled BD equivalents in a 6 hour exposure than do rats at the same concentration;

3. Mice have about twice the concentration of the metabolite (1,2-epoxy-3-butene) (BMO) in blood as rats exposed at similar concentrations;

4. Over a wide range of exposures, mice received a larger amount of inhaled BD per unit body weight than rats, and had a higher concentration of BMO in the blood than rats (As expected, because of body size differences and breathing rates, and some enzymology);

5. BD is readily absorbed and widely distributed in tissues of both mice and rats, with tissue concentrations per umole BD inhaled higher in mice than in rats, by factors of 15-fold or more;

6. While there are species differences in the amount of BD metabolism at various sites, both mice and rats metabolize BD to the same reactive metabolites suspected of being ultimate carcinogens.

In comments on OSHA's proposal, Dr. Michael Bird of Exxon testified on behalf of the CMA BD Task Group that the mouse ''will attain a significantly higher amount of the epoxides over a longer period of time than the rat. . . or primate when exposed to butadiene.''

[1] For example, in the 58 newspaper workers tested, 24% had greater than 95 SCE/cell, while the remaining 76% had fewer than 80 SCE/cell.

[2] Cytochrome is defined as any of a class of hemoproteins whose principal biologic function is electron transport by virtue of a reversible valency change of its heme iron. Cytochromes are widely distributed in animal and plant tissues.

(Ex. 52, p. 27) Dr. Bird concluded that the differences in metabolism of BD in the species help ''explain the greater sensitivity of the mouse to BD carcinogenic activity.'' He further concluded that the differences in rates of enzyme mediated processes indicate non-human primates have lower internal concentrations of BD or BMO, and ''man is more similar to the primate with respect to 1,2-epoxy-3-butene formation than the rat or mouse.'' (Ex. 52, p. 22) He argued that the mouse may be ''uniquely sensitive '' to BD carcinogenicity due to its greater uptake, faster BD metabolism and ''elimination of the epoxide 1,2-epoxy-3-butene is saturable in mice but not in rats.'' (Ex. 52, p. 21) He felt this observation correlated well with the observed cytogenetic and bone marrow response (seen in mouse, but not rats.)

Others hold an opposing view, e.g., Melnick and Kohn argued that ''[b]ecause the rat appears to be exceptionally insensitive to leukemia/lymphoma induction, the mouse must be considered as the more appropriate model for assessing human risk for lymphatic and hematopoietic cancers.'' (Ex. 130, p. 160)

Dr. Bird urged OSHA to use the monkey data of Dahl, et al. which indicated that the retention rate for BD in primates is over 6 times lower than that for the mouse, in ''drawing any firm conclusions about the cancer risk to humans.'' (Ex. 52, p. 36) During the public hearing, the work of Dahl was presented as a preliminary report. (Ex. 44) Dahl exposed 3 cynomolgus monkeys to BD and measured uptake and metabolism. Each animal was exposed to three concentrations of C^{14}-labeled BD, progressing from 10,300 to 8000 ppm with at least 3 months separating the re-exposure of each monkey. Post-exposure blood was taken. Each animal's breathing frequency and tidal volume was measured.

Dahl and co-workers found BD uptake to be lower in monkeys than in rats. The reported blood levels of the epoxides were also lower in the monkey than the levels reported by Bond et al. in rats and mice.

Dahl et al. attempted to quantitate total BD metabolites through collection of feces, urine and exhaled material though use of cryogenic traps. Measurement of residual labeled material retained in the animals at the end of the 96 hour post exposure period was not determined. HPLC (high-performance liquid chromatography) identification of the trapped material (at 95 C) indicated that only 5 to 15% of the radioactivity was present as monoepoxide.

Melnick and Huff, in reviewing this study, found its significance ''clouded'' because only three animals of unknown age were studied and there was uncertainty about the ability of vacuum line cryogenic distillation alone to identify and quantitate BD metabolites. (Ex. 114, p. 133) In testimony at the public hearing, Dr. James Bond of CIIT acknowledged the limitations of the use of vacuum-line cryogenic distillation as follows:

> * * * there will be some material no matter what kind of vacuum you apply to it * * * simply will not move into the traps. That's referred to as non-volatile material.
>
> We don't know what that material is and I think that's an important component of this study, because, in fact, in many cases it can represent 70 to 80 percent of the material that actually distills out. (Tr. 1/22/91, p. 1553)

Melnick and Huff were also concerned that only the monkeys, not the mice or rats, were anesthetized during exposure and question what impact that might have had on respiratory rates and cardiac output and what the influence might be on inhalation pharmacokinetics of BD. (Ex. 114, p. 133) In their 1992 review, Melnick and Huff concluded that studies to date have not revealed species pharmacokinetic differences of sufficient magnitude ''to account for the reported different toxic or carcinogenic responses in one strain of rats compared to two strains of mice.'' (Ex. 114, p. 134) In post hearing comments Dr. David A. Dankovic of NIOSH reviewed this topic and concluded ''* * * the most prudent course is to base 1,3-butadiene risk assessments on the external exposure concentration, unless substantial improvements are made in the methodology used for obtaining 'internal' dose estimates.'' (Ex. 101, Att. 2, p. 5)

Recent Studies

Recent studies have focused on the metabolism of BD to the epoxides, epoxybutene and diepoxybutane, and their detoxification by epoxide hydrolase and glutathione. Bond et al. recently reviewed BD toxicologic data. (Ex. 118–7G) Epoxybutene and diepoxybutane were reported to be carcinogenic to mice and rats via skin application and/or subcutaneous injection, with the diepoxide having more carcinogenic potency. Bond et al. also concluded that the diepoxide is more mutagenic than the monoepoxide by a factor of nearly 100 on a molar basis. The diepoxide also induces genetic damage *in vitro* mammalian cells (Chinese hamster ovary cells and human peripheral blood lymphocytes). These studies are summarized in this preamble discussion of reproductive effects.

In vitro metabolic studies

In 1992 Csanady et al. reported use of microsomal and cytosolic preparations from livers and lungs of Sprague-Dawley rats, $B6C3F_1$ mice and humans to examine cytochrome P450-dependent metabolism of BD. (Ex. 118–7AA) The preparations were placed in sealed vials and BD was injected by use of a gas-tight syringe. Air samples were taken from the head space at 5 minute intervals and analyzed by gas chromatography for epoxybutene.

Cytochrome P450-dependent metabolism of the monoepoxide to the diepoxide was examined. Enzyme mediated hydrolysis of BMO by epoxide hydrolase was measured. (Non-enzyme mediated hydrolysis was determined using heat-inactivated tissue and none was observed.) Second order rate constants were determined using 100 mM monoepoxide and 10 mM GSH. The human samples were quite variable, with rates ranging from 14 to 98 nmol/min/mg protein.

The maximum rates for BD oxidation to monoepoxide (Vmax) were determined to be highest for mouse liver microsomes[3] (2.6 nmol/mg protein/min); the Vmax values for humans were intermediate, at 1.2 nmol/mg protein/min; the Vmax values for rats was 0.6 nmol/mg protein/min. For lung microsomes, the Vmax in the mouse was found to be similar to the mouse liver rate, but over 10-fold greater than that of either humans or rats.

From these data Csanady et al. calculated a ratio of activation to detoxification for each species tested. These values, expressed as mg cytosolic protein/gm liver [glutathione-S-transferase is a cytosolic enzyme], resulted in the determination of an overall activation:detoxification ratio of 12.3 for the mouse, 1.3 for the rat, and 4.4 for the human samples.

If these *in vitro* liver microsomal studies can be extrapolated to the whole animal *in vivo,* then this implies, as pointed out by Kohn and Melnick, that the mouse produces 2.8 times as much BMO per mol of BD as the human and that the human activation:detoxification ratio is 3.4 times that of the rat. However, the Csanady et al. study demonstrated a wide variability in BD metabolic activity among the 3 human liver microsomes, and a 60-fold variation was found in 10 human liver

[3] A microsome is defined as one of the finely granular elements of protoplasm, resulting from fragmentation (homogenization) of the endoplasmic reticulum.

samples by Seaton et al. (Ex. 118–7N) Kohn and Melnick noted that this human variability in CYP2E1, the P450 enzyme primarily responsible for the activity, suggests that a ''* * * fraction of the human population may be as sensitive to butadiene as mice are.'' (Ex. 131, p. 620).

A study similar to that of Csanady et al., reported by Duescher and Elfarra in 1994, determined that the Vmax/Km ratios for BD metabolism in human and mouse liver microsome were similar and were nearly 3 to 3.5 fold higher than the ratio obtained with rat liver microsomes. (Ex. 128) Duescher and Elfarra suggest that differences between their results and those of Csanady et al. may have been due in part to experimental methodology differences, such as incubation and assay methods. Duescher and Elfarra found that two P450 isozymes, 2A6 and 2EI, were most active in forming BMO of the 7 isozymes tested. They concluded that since human liver microsomes oxidized BD at least as efficiently as mouse liver microsomes (and much more so than rat liver microsomes), this ''suggests that if [BMO] formation rate is the primary factor which leads to toxicity, humans may be at higher risk of expressing BD toxicity than mice or rats, and that the mouse may be the more appropriate animal model for assessing toxicity.'' Duescher and Elfarra felt that since P450/2A6 appears to play a major role in BD oxidation in human liver microsomes, and that it is more similar to that of mouse P450/2A5 than to rat P450/2A1, the mouse may be a better model to use in assessing human risk.

In 1994 Himmelstein et al. hypothesized that ''[S]pecies differences in metabolic activation and detoxification most likely contribute to the difference in carcinogenic potency of BD by modulating the circulating blood levels of the epoxides.'' (Ex. 118–13, Att 3) To address this, Himmelstein and colleagues looked at the levels of BD, BMO, and BDE in blood of rats and mice exposed at 62.5, 625, or 1250 ppm BD. Samples were collected at 2, 3, 4, and 6 hours of exposure for BD and BMO and at 3 and 6 h for the BDE. Blood was collected from mice by cardiac puncture and from rats through an in-dwelling jugular cannula. Melnick and Huff criticized earlier studies which failed to use in-dwelling cannulae.

> Because steady state levels of [monoepoxide] are lower in rats than in mice and because the metabolic elimination rate for this compound is 5 times faster in rats than in mice, any delay in obtaining immediate blood samples would have a much greater effect on analyses in blood samples obtained from rats than those obtained from mice. (Ex. 114, p. 133)

Himmelstein et al. found that the concentration of BD in blood was not directly proportional to the inhaled concentration of BD, suggesting that the uptake of BD was saturable at the highest inhaled concentration. In both rats and mice BD and the BMO blood levels were at steady state at 2, 3, 4 and 6 hours of exposure and declined rapidly when exposure ceased. This is consistent with exhalation being the primary route of elimination of BD. (Ex. 118–7B)

Genter and Recio used Western blot and immunohistochemical analyses to detect P450/2E1 in bone marrow of $B6C3F_1$ mice. (Ex. 118–7T) Although both methods detected the presence of the protein in livers of both male and female mice, non was seen in the bone marrow. The limits of detection were not stated in the report. The author hypothesized the BD might be converted to the monoepoxide in the liver prior to uptake by the bone marrow or that another pathway (e.g., myeloperoxidase) is responsible for BD oxidation in the marrow. Recio and Genter suggest that the greater sensitivity of mice to BD-induced carcinogenicity can be explained in part by the higher levels of both epoxides in the blood of mice compared with that of rats.

Himmelstein et al. furthered this work in 1995 in a report in which they determined levels of the epoxides in livers and lungs of mice and rats exposed to BD. (Ex. 118–7/O) Animals were exposed at 625 or 1250 ppm of BD for 3 or 6 hours. Himmelstein et al. found that in mice exposed to this regimen, the monoepoxide levels were higher in lungs than in livers. Rats at 625 and 1250 ppm had lower concentrations of BMO in lungs and livers than mice. When rats were exposed to 8000 ppm BD, the maximum concentration of BMO in the lung and liver was nearly the same. The diepoxide levels in lungs of mice exposed at 625 and 1250 ppm were 0.71 and 1.5 nmol/g respectively. The diepoxide was not detected in livers or lungs of rats exposed at any tested level.

Himmelstein et al. also observed depletion of glutathione in liver and lung samples from both rodent species. Following 6 hours of exposure, the lungs of mice exhibited greater depletion of GSH than mouse liver, rat liver or rat lung at all concentrations of BD tested. The conclusion reached by the study authors was that their data indicate that GSH depletion is associated with tissue burden of the epoxides and that this target organ dosimetry might help explain some of the non-concordance of cancer sites observed between the species. OSHA notes, however, that while % GSH depletion was highest in the mouse lung, the major increase in depletion was at 1250 ppm BD, while lung tumor incidence was increased in the female mice at 6.25 ppm and in male mice at 62.5 ppm. Depletion of glutathione was dependent on concentration and duration of BD exposure.

Himmelstein et al. stressed the importance of the fact that the diepoxide was detected in the mouse lung but was not quantifiable in the mouse liver, and stated that if the diepoxide was formed in the liver, it is rapidly detoxified or otherwise moved out of the liver. They also found that depletion of glutathione was greater in mouse than rat tissues for similar inhaled concentrations of BD and concluded that conjugation of the monoepoxide with glutathione by glutathione S-transferase is an important detoxification step.

In contrast to rats and mice, lungs and livers from humans had much faster rates of microsomal monoepoxide hydrolysis by epoxide hydrolase compared to cytosolic conjugation with glutathione by the transferase. (Ex. 118–7AA)

Thornton-Manning et al. in 1995 examined the production and disposition of monoepoxide and diepoxide in tissues of rats and mice exposed at 62.5 ppm BD. (Ex. 118–13, Att. 3) They found monoepoxide was above background in blood, bone marrow, heart, lung, fat, spleen and thymus tissues of mice after 2 or 4 hours of exposures to BD. In rats, levels of monoepoxide were increased in blood, fat, spleen and thymus tissues. No increase in monoepoxide in rat lung was observed. The more mutagenic diepoxide was detected in all tissues of the mice examined immediately following 4 hours of exposure. It was detected in heart, lung, fat, spleen and thymus of rats, but at levels 40- to 160-fold lower than those seen in mice.

In mice, the level of diepoxide exceeded the monoepoxide levels immediately after exposure in such target organs as the heart and lungs. Thornton-Manning et al. concluded that the high concentrations of diepoxide in heart and lungs they observed suggested to them that this compound may be particularly important in BD-induced carcinogenesis.

The study authors noted that neither epoxide was detected in rats' liver and was present only in quite low concentrations in the livers of mice. Thornton-Manning et al. found this

surprising since epoxides present in blood in the liver should have yielded values greater than those observed in the liver samples. They hypothesized that it might be due to prior metabolism of the epoxides before reaching the liver or it might be an artifact due to post-exposure metabolism of the epoxides in the liver.

Thornton-Manning et al. did not detect the monoepoxide in rat lungs, and found the diepoxide level to be quite low. In contrast, in the mice they found both epoxides present in lung tissue, with the monoepoxide level present at a concentration less than expected using blood volume values, and the diepoxide level agreeing with that expected as a function of blood volume. Thornton-Manning et al. concluded that these results ''* * * suggest that the lung is capable of metabolizing BDO, but perhaps is less active in metabolizing BDO_2. (Ex. 118–13, Att. 3) Moreover, Thornton-Manning et al. believed that although BD is oxidatively metabolized by similar metabolic pathways in the rats and mice, the quantitative differences in tissue levels between species may be responsible for the increased carcinogenicity of BD in mice.

TABLE V–8.—TISSUE LEVELS [PMOL/GM TISSUE, MEAN±S.E.] OF EPOXYBUTENE AND DIEPOXYBUTANE IN RATS AND MICE FOLLOWING A 4-HOUR EXPOSURE TO 62.5 PPM BD BY INHALATION

Tissue	Epoxybutene		Diepoxybutane	
	Rats	Mice	Rats	Mice
Blood	36±7	295±27	5±1	204±15
Heart	40±16	120±15	3±0.4	144±16
Lung	ND	33±9	0.7±0.2	114±37
Liver	ND	8±4	ND	20±4
Fat	267±14	1302±213	2.6±0.4	98±15
Spleen	7±6	40±19	1.7±0.5	95±12
Thymus	12.5±3.2	104±55	2.7±0.7	109±19
Bone marrow [1]	0.2±0.1	2.3±1.5	ND	1.4±0.3

ND=Not Detected.
[1] Bone marrow data are presented as mean pmol/mg protein ±; n=3 or 4 for each determination. Adapted from Ex. 118–13, Att. 3.

These data are shown in Table V–8.

Seaton et al. examined the activities of cDNA-expressed human cytochrome P450 (CYP) isozymes for their ability to oxidize epoxybutene to diepoxybutane. (Ex. 118–7N) They also determined the rate of formation of the diepoxide by samples of human liver microsomes (n=10) and in mice and rat liver microsomes. Seaton et al. found that two of the cytochrome P450 isozymes, CYP2E1 and CYP3A4, catalyzed oxidation of 80 uM of monoepoxide to detectable levels of diepoxide, and that CYP2E1 catalyzed the reaction at higher levels of monoepoxide (5mM), suggesting the predominance of 2E1 activity at low substrate concentrations. Hepatic microsomes from all 3 species formed the diepoxide when incubated with the monoepoxide. Seaton et al. hypothesized that the difference between these results and those of Csanady et al. (who did not detect the diepoxide when the monoepoxide was substrate in a similar microsomal assay) was due to differences in experimental methodology.

Seaton et al. noted a 25-fold variability in Vmax/Km among the 4 human livers. They reported that Vmax/Km for oxidation of the monoepoxide to the diepoxide for the 4 human samples was 3.8, 1.2, 1.3 and 0.15, while that of the pooled rat samples was 2.8, and the mouse ratio was 9.2.

The authors, using available data, calculated an overall activation/detoxification ratio (Vmax/Km for oxidation of BD to the monoepoxide) taking into account hydrolysis of the monoepoxide by epoxide hydrolase and conjugation with glutathione. The activation/detoxification ratio was estimated at 1295 for the mouse, 157 for rats and 230 for humans. However, Melnick and Kohn point out that ''when yields of microsomal and cytosolic protein content and liver size were considered, the activation to detoxification ratio was only 2.8 times greater in mice than in humans and 3.4 times greater in humans than in rats. These ratios do not take into account inter-individual variability in the activities of the enzymes involved.'' (Ex. 131)

Recently, Seaton et al. studied production of the monoepoxide in whole airways isolated from mouse and rat lung. (Ex. 118–7C) They explained the impetus to use fresh intact tissue by stating that lung subcellular fractions, as employed in experiments by Csanady et al., described above, contained mixtures of cell type ''so that the metabolizing capacities of certain cell populations may have been masked.'' They anticipated that use of airway tissue would allow more precise quantitation of differences in lung metabolism of BD.

Whole airways or bronchioles isolated from both male $B6C3F_1$ mice and male Sprague-Dawley rats were incubated for 60 min with 34 um BD. Levels of 10.4±5.6 nmol epoxybutene/mg protein were detected in mouse lungs, while 2–3 nmol/mg protein was observed in rat lung airway regions. Seaton et al. noted that while the species differences ''are not dramatic,'' they may in part contribute to the differences in carcinogenicity observed in mice and rats.

To characterize conjugation of BD metabolites with glutathione (GSH), Boogard et al. prepared cytosol from lungs and livers of rats and mice and from 6 human donor livers and incubated them with 0.1 to 100 mM diepoxide and labeled glutathione (GSH). (Ex. 118–7J) NMR (nuclear mass resonance) and HPLC techniques were used to characterize and quantitate conjugate formation.

Non-enzymatic reaction was concluded to be negligible. The conjugation rates (Vmax) in mouse and rat livers were similar and 10-fold greater than those observed in the human samples. The initial rate of conjugation (Vmax) was much higher in mouse than rat lung. Both rodent species exhibited higher initial rates of conjugation than human. This led Boogard et al. to conclude that the higher diepoxide levels observed in BD-exposed mice compared with rats ''are not due to differences in hepatic or pulmonary GSH conjugation of BDE (the diepoxide),'' and further that since humans oxidize BD to the epoxides at a low rate, the low activity of GSH conjugation of the diepoxide in human liver cytosol demonstrated in this study ''will not necessarily lead to increased BDE (diepoxide) levels in humans

potentially exposed to BD.'' They also pointed out the need to determine the rate of BDE detoxification by other means, specifically by epoxide hydrolase in all three species.

Studies of Urinary Metabolites of BD

Two metabolites of BD have been identified in urine of exposed animals by Sabourin et al. (Ex. 118–13 Att. 3) These are 1,2-dihydroxy-4-N-acetylcysteinyl-S-)-butane, designated MI, and MII, which is 1-hydroxy-2-N-acetylcysteinyl-S-)-3-butene. (Ex. 118–13–Att. 3)

These mercapturic acids are formed by addition of glutathione (GSH) at either the double bond (MI) or the epoxide (MII). MI is thought to form by conjugation of GSH with butenediol, the hydrolysis product of the monoepoxide, while MII is thought to form from conjugation of the monoepoxide with GSH.

Sabourin et al. measured MI and MII in urine from rats, mice, hamster and monkeys. Mice were observed to excrete 3 to 4 times as much MII as MI, while the hamsters and rats produced about 1.5 times as much MII as MI. The monkeys produced primarily MI.

The ratio of formation of metabolite I to the total formation of the two mercapturic acids, MI and MII, correlated well with the known hepatic epoxide hydrolase activity in the different species, suggesting that the monoepoxide undergoes more rapid conjugation with glutathione in the mouse than in the hamster or rats, and that the least rapid conjugation occurs in the monkey. The epoxide availability is inversely related to the hepatic activity of epoxide hydrolase, which removed the epoxide by hydrolysis.

In 1994, Bechtold et al. published a paper describing a comparison of these metabolites between mice, rats, and humans.[4] In workers exposed to historical atmospheric concentrations of 3 to 4 ppm BD, Bechtold measured urine levels of MI and MII by use of isotope-dilution gas chromatography, and found MI, but not MII, to be readily detectable. Bechtold et al. found that employees who worked in production areas (having 3–4 ppm BD exposure) could be distinguished by this assay from outside controls and that low level human exposure to BD resulted in formation of epoxide.

Bechtold et al. stated in their abstract that since monkeys displayed a higher ratio of MI to MI + MII than mice did, and ''because humans are known to have epoxide hydrolase activities more similar to those of monkeys than mice, we postulated that after inhalation of butadiene, humans would excrete predominantly MI and little MII.'' (Ex. 118–13 Att. 3) Their observations suggested that the predominant pathway for clearance of the monoepoxide in humans is by hydrolysis rather than conjugation with glutathione.

Bechtold et al. found when mice and rats were exposed to 11.7 ppm BD for 4 hours and the ratio of the two metabolites was then measured, for mice, the ratio of MI to MI ± MII (or the % of total which is MI) was 20%, that of rats was 52%, while humans exhibited more than 97% MI. These data also indicate the predominance of clearance by hydrolysis pathways rather than GSH conjugation in the human.

Nauhaus et al. used NMR techniques to study urinary metabolites of rats and mice exposed to ([(1,2,3,4)-^{13}C]-butadiene). (Ex. 118–7I) They characterized metabolites in mouse and rat urine following exposure by inhalation to approximately 800 ppm BD for 5 hours. Urine was collected over 20 hours from exposed and control animals, centrifuged and frozen.

The findings of this study are quite extensive and are briefly summarized as follows. Nine metabolites were detected and chemically identified in mouse urine and 5 in that of rats. Five were similar in the 2 species, though differing markedly in concentration. One was unique to the rat and four to the mouse. Nauhaus et al. observed that ''when normalized to body weight (umol/kg body weight), the amount of diepoxide-derived metabolites was four times greater in mouse urine than in rat urine.'' They further hypothesized that ''the greater body burden of (diepoxide) in the mouse and the ability of rats to detoxify [it] though hydrolysis may be related to the greater toxicity of BD in the mouse.'' Nauhaus et al. found that both mice and rats conjugated the monoepoxide with glutathione, but the rat preferentially conjugated at the two carbon, while the mouse preferentially conjugated at the one carbon. Additionally, the finding of a metabolite of 3-butenal, a proposed intermediate in the oxidation of BD to crotonaldehyde, an animal carcinogen, is suggestive of an alternative carcinogenic pathway for BD. In general, this study supports the *in vitro* findings of Csanady et al. who reported similar rates for BMO conjugation with glutathione between rats and mice. (Ex. 118–7AA)

Interaction of Butadiene With Other Chemicals

Bond et al. described use of available data to simulate the potential interaction of BD with other workplace chemicals. (Ex. 118–7V) Specifically they modeled potential interaction assuming competitive inhibition of BD metabolism by styrene, benzene and ethanol. The model predicted that co-exposure to styrene would reduce the amount of BD metabolized, but that because of its relative insolubility, BD would not effectively inhibit styrene metabolism. Benzene, which, like BD, is metabolized by P450/2E1, was also predicted to be a highly effective inhibitor of BD metabolism because of its solubility in tissues. The models predicted that ethanol would have only a marginal effect on BD metabolism at concentrations of BD ''relevant to human exposure.''

BD and styrene co-exposures often occur in the SBR industry and both are metabolized by oxidation to active metabolites, in major part, by cytochrome P450/2E1. To determine the metabolic effect of joint exposure to BD and styrene, Levans and Bond developed and compared two PBPK models, one with one oxidative pathway and competition between BD and styrene and the other with two oxidation pathways for both BD and styrene. (Ex. 118–7E) For model validation, Levans and Bond exposed male mice to mixtures of BD and styrene of 100 or 1000 ppm BD and 50, 100 or 250 ppm styrene for 8 hours. They used chamber inlet and outlet concentrations to calculate uptake and, when steady-state was reached, calculated the rate of metabolism. They analyzed blood for styrene, styrene oxide, epoxybutene and diepoxybutane by GC–MS.

Leavens and Bond found BD metabolism was inhibited when mice were co-exposed to styrene. The inhibition approached maximum value at co-exposure concentrations of styrene above 100 ppm.

The report also described the preliminary development of pharmacokinetic models to simulate the observed rate of BD metabolism in co-exposed mice. Their results supported the hypothesis that ''more than one isozyme of P450 metabolized BD and styrene and competition does not occur between BD and styrene for all isozymes.'' They were unable to accurately predict blood concentrations of styrene following exposure, and felt that '' perhaps the diepoxide may inhibit metabolism of styrene by competing for the same P450 enzyme.''

[4] A preliminary study on the human population of this study is described in the section of this preamble dealing with the genetic toxicology of BD exposure.

Although preliminary in nature and reflecting effects of relatively high exposures, these observations of interactions between styrene and BD exposure may have implications for the observed pattern of BD-induced effects in human populations jointly exposed. Specifically, the cancer effects seen in SBR production workers may underestimate the effects of BD with no styrene or benzene exposure.

Pharmacokinetic Modeling of BD Metabolism

In a recent publication, Bond et al. reviewed the results of application of a number of physiologically-based pharmacokinetic (PBPK) dosimetry models. (Ex. 118–7M) They noted that three of the models which included monoepoxide disposition (Kohn and Melnick, Johanson and Filser, Medinsky) predicted that, for any BD exposure concentration, steady-state monoepoxide levels will be higher for mice than for rats. Bond et al. further observed that ''while the three models accurately predict BD uptake in rats and mice, they overestimate the circulating blood concentrations of (monoepoxide) in these species compared to those experimentally measured by Himmelstein.'' Their results also led Bond et al. to conclude that the disagreement between model predictions for the monoepoxide and experimental data suggests that the structure and/or parameter values employed in these models are not accurate for predicting blood levels of BD epoxides, and conclusions based on model predictions of BD epoxide levels in blood or tissue may be wrong.'' (Ex. 118–7M, p. 168) OSHA agrees with these authors that BD epoxide levels should not be used in assessing risk. In the discussion, the authors pointed to the need for inclusion of diepoxide toxicokinetics (as well as that of the monoepoxide) in future modeling exercises, since they believe the diepoxide to be the ultimate carcinogenic metabolite of BD.

Kohn and Melnick, in a recent publication, used available data and attempted to apply a PBPK model to see whether it was consistent with observed *in vivo* uptake and metabolism. (Ex. 131) The model included compartments for rapidly and for slowly perfused tissues. Rate equations for monoepoxide formation, its hydrolysis, and for conjugation with glutathione were included.

Kohn and Melnick acknowledged numerous sources of uncertainty in applying the model to the data (in which there are many gaps), necessitating various assumptions. Their calculations led them to conclude that the ''model reproduces whole-body observations for the mouse and rat'' and that it predicts that ''inhalation uptake of butadiene and formation and retention of epoxybutene are controlled to a much greater extent by physiological parameters than by biochemical parameters. . . '' (Ex. 131)

When Kohn and Melnick interchanged the biochemical parameters in the mouse and human models to see if ''the differences in calculated net uptake of butadiene among the three species were due to differences in metabolic activity,'' they found that use of human parameters in the mouse model decreased the level of absorption of BD, but not to a level as low as that of the human. Kohn and Melnick noted that the model predictions of epoxybutene levels in the heart and lung of mice and rats failed to account for the observation that mice, but not rats, develop tumors at these sites. Kohn and Melnick suggested that factors other than epoxybutene levels, not accounted for in the model, are probably crucial to induction of carcinogenesis.

Conclusions

Many metabolism studies have been conducted both *in vitro* and *in vivo*, mostly in mice and rats, to determine the BD metabolic, distribution, and elimination processes, and these studies have been extended in attempts to explain, at least in part, the greater carcinogenic potency of BD in the mouse, whether the mouse or the rat is a better surrogate for human cancer and reproductive risk assessment, and what is the proper dose-metric to use in dose-response assessments. The question of whether the mouse or the rat is a better model for the human on the basis of tumor response is partly addressed in the risk assessment section of this preamble. This section more specifically considers whether these metabolic studies in total can explain the different cancer responses and potencies observed in the mouse, rat, and human. What is clear throughout the record is that most scientists who study the topic consider not BD itself, but the major epoxide metabolites of BD, BMO and BDE and 1, 2-epoxybutane-3,4-diol, to be the putative carcinogenic agents. Most of this research has focused on the relative species production of BMO and BDE. Both BMO and BDO have been reported in early studies to be carcinogenic to mice and rats via skin application and/or subcutaneous injection, with BDO being somewhat more potent. (Ex. 23–88, Ex. 125).

Metabolism of BD to BMO in both the liver and lung of mice, rats and humans is by the P450 oxidation pathway, with CYP2E1 and CYP1A6 being the major enzymes. Based on the studies reviewed by OSHA, overall the mouse metabolizes BD to the monoepoxide and the diepoxide in these organs at a faster rate than do the rat and human. This is supported by the following evidence: (1) The mouse has higher BMO and BDE levels in blood, lung, and liver (i.e., see Ex. 118–7S, Ex. 118–7D, and Ex. 118–13), which are the target organs for cancer in the mouse but not the rat; (2) the mouse has higher *in vitro* lung and liver microsome Vmax/Km ratios for both BD and BMO metabolism than do rats or humans (Ex. 118–7AA); and (3) the mouse has higher hemoglobin-BMO adduct levels than rats and much higher levels than humans. (Ex. 118–7Y) A major exception to the findings of these studies is the study by Duescher and Elfarra, who found the *in vitro* BD Vmax/km ratios to be the same in mice and human liver microsomes and 3–4 times higher than they were in rats, suggesting that mice and humans have similar BD metabolic potential, at least in the liver. (Ex. 128) Large variations, about 60 fold, were found among 10 human liver microsome BD metabolic activities. (Ex. 118–7N) A recent BD *in vitro* metabolism study by Seaton et al. on whole rat and mouse lung airway isolates found that the mouse produced about twice the amount of BMO as the rat (this difference could not explain the difference between mouse and rat tumor incidence). (Ex. 118–7C)

BMO and BDE were also measured in heart, spleen, thymus, and bone marrow (target sites for mouse but not rat tumors) following 4 hour BD inhalation exposure (62.5 ppm) to mice and rats. (Ex. 118–13) In these tissues, mouse BMO and BDE levels were 3 to 55 fold higher than rat levels for the same metabolites, although the mice organ levels of these metabolites correlated poorly with the mouse target organ cancer response at this exposure level. Only high BDE levels in the mouse lung were consistent with the mortality adjusted cancer incidence (see hazard identification—animal studies section, Ex. 114). This suggests that BD metabolite tissue levels can, at best, only partly explain differences in carcinogenic response. Differences in both species and tissue sensitivity must also be accounted for.

The Thornton-Manning and other studies also provided information about BD elimination. (Ex. 118–7I) With higher experimental exposure levels, the major route of elimination of BD is via expiration. Elimination of BMO occurs

by different pathways in different species and different organs. At higher BD exposure concentrations, some BMO is expired. The mouse liver and lung appear to eliminate BMO predominantly by direct conjugation with GSH[5]. For the rat there is approximately equal elimination by the GSH and EH mediated pathways, while for the human and monkey hydrolysis to butanediol is the major pathway for excretion. (Ex. 118–13 Att. 3) This species elimination pathway difference is a partial explanation for the higher levels of both BMO and BDE seen in the mouse, assuming that most of the BD metabolism takes place in the liver. With respect to the bone marrow BD distribution and metabolism, mouse levels of the BD metabolites in the bone marrow were lower than at any of the other target organs studied. (Ex. 118–13) *In vitro* studies by Gentler and Recio have found no detectable P4502E1 in the bone marrow of $B6C3F_1$ mice. (Ex. 118–7T) These authors conclude that this ''suggests that BD is converted to BMO outside of bone marrow and is subsequently concentrated in bone marrow, or that the conversion of BD to BMO occurs by an alternate enzymatic pathway within the bone marrow.'' The latter appears to be the more likely since Maniglier-Poulet and co-workers showed that *in vitro* BD metabolism to BMO in both $B6C3F_1$ mouse and human bone marrow occur by a peroxidase-mediated process and not via the P450 cytochrome system. (Ex. L–133) Since in their system both human and mouse bone marrow generated about the same amount of BMO/cell, this suggests that both BD distribution to bone marrow and local metabolic reactions should be considered in species-to-species extrapolations and in PBPK modeling.

Inclusion of bone marrow local reactions becomes even more important when considering the animal species to use for modeling human cancer. BD is genotoxic in the bone marrow of mice, but not in rats. (Tice et al. 1987; Cunningham et al. 1986, reported in Ex. 131) BD and BMO have been implicated as affecting primitive hematopoietic bone marrow stem and progenitor cells related to both T-cell leukemia and anemia in the mouse. (Irons et al., 1993, in Ex. 117–2) BD causes lymphoma in mice, but no lymphoma or leukemia in rats even at 8,000 ppm. Furthermore, the body of epidemiologic evidence strongly indicates that BD exposure poses an increased risk of human leukemia (see the epidemiologic section and especially Ex. 117–1).

Fat storage of BD during exposure, and release following cessation of exposure, is also a major concern, both in estimating target organ levels and in determining species differences. There is little in the record on the effect of fat storage and release. In the Thornton-Manning study discussed above, both mouse and rat fat levels of both BMO and BDE declined rapidly following cessation of exposure, suggesting little lingering effect. However, Kohn and Melnick present a model in which post-exposure release of BD from the fat would result in extended epoxide production in humans in contrast with the mouse. (Ex. 131)

Bond et al. suggest that the more rapid metabolism of BD to BMO in the mouse, and the more rapid EH BMO elimination pathways in the rat and human may be an explanation for lower, if any, BDE levels seen in rat and human liver microsomes and why BD will not be carcinogenic to humans at exposure levels seen in the environment or the workplace. (Ex. 130) They also conclude that ''Since significant tumor induction in male rats occurs only at 8000 ppm BD, BMO levels are probably not predictive of a carcinogenic response.'' Thornton-Manning et al. characterize the peak levels of BDE in the mouse lung and heart as being either greater than or equivalent to peak levels of BMO, and suggest ''that the formation of BDE may be more important than the formation of BMO in the ultimate carcinogenicity of BD.'' (Ex. 118–13) However, BMO levels in these organs were also quite high, and were higher than BDE levels in blood and bone marrow, target organs for hematopoietic system cancers. OSHA believes that the evidence is not sufficient to dismiss the potential contribution of BMO to mouse, rat or human carcinogenicity; to conclude that BDE should be considered more actively carcinogenic than BMO; or to find that BDE levels are sufficiently characterized in either mouse or human tissue to be used as the dose metric for BD human risk assessment.

Thus, OSHA concludes, based on the body of metabolic and other evidence presented, and the above discussion, that the mouse is a suitable animal model for the human for BD cancer risk assessment purposes, and that metabolism of BD to active metabolites is probably necessary for carcinogenicity. However, while the uptake, distribution, and metabolism of BD to active carcinogenic agents are important, local BD metabolic reactions and specific species sensitivities appear to have at least as large an impact on BD potency in the various species. This is likely to be especially true in the human, whose metabolic processes appear to be much more variable with respect to BD. Thus, although the metabolism studies provide insight into BD's metabolic processes in various species and organs (with the possible exception of mouse lung tumorigenicity related to lung BDE levels and protein cross linking), OSHA finds that too many questions remain unanswered, both with PBPK modeling efforts and with actual *in vivo* measurements (and the lack of such measurements in humans) to base a quantitative risk assessment on BD metabolite level equivalence between mice and humans. (Ex. L–132)

VI. Quantitative Risk Assessment

A. Introduction

In 1980, the United States Supreme Court ruled on the necessity of a risk assessment in the case of *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. (607), the ''Benzene Decision.'' The United States Supreme Court concluded that the Occupational Safety and Health (OSH) Act requires, prior to issuance of a standard, that the new standard be based on substantial evidence in the record considered as a whole, that there is a significant risk of health impairment at existing permissible exposure limits (PELs) and that issuance of the standard will significantly reduce or eliminate that risk. The Court stated that, before the Secretary of Labor can promulgate any permanent health or safety standard, he is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices. (448 U.S. 642)

In 1981, the Court's ruling on the OSHA's Cotton Dust Standard (*American Textile Manufacturers Institute* v. *Donovan, 452 U.S. 490 (1981)*) reaffirmed its previous position in the Benzene Decision, that a risk assessment is not only appropriate, but that OSHA is required to identify significant health risk to workers and to determine if a proposed standard will achieve a reduction in that risk, and OSHA as a matter of policy agrees that assessments should be put into quantitative terms to the extent possible.

For this rulemaking, OSHA has conducted a quantitative risk assessment to estimate the excess risk for cancer and consequently for premature deaths associated with

[5] One exception: Seaton et al. found evidence ''that in mouse airways hydrolysis of BMO by epoxide hydrolase (EH) contributes to BMO detoxification to a greater extent than does glutathione conjugation.'' (Ex. 118–7C)

exposure to an 8-hour time-weighted-average (TWA), 5 days/week, 50 weeks/year, 45-year exposure to BD at concentrations ranging from 0.1 to 5 ppm, the range of permissible exposure limits (PELs) considered by OSHA in this rulemaking. The data used in the quantitative risk assessment were from a National Toxicology Program (NTP) chronic inhalation study in which $B_6C_3F_1$ mice of both sexes were exposed to either ambient air or BD exposure concentrations ranging from 6.25 to 200 ppm, known as NTP II. (Ex. 90) For seven gender-tumor site combinations, multistage Weibull time-to-tumor models were fit to these NTP II data. The best fitting models were chosen via a log-likelihood ratio test.

OSHA's maximum likelihood estimate (MLE) of the excess risk of developing cancer and subsequent premature death as a result of an 8-hour TWA occupational lifetime exposure to 2 ppm BD, the PEL proposed by OSHA in 1990, was 16.2 per 1,000 workers, based on the most sensitive gender-tumor site combination, female mouse lung tumors. If the occupational lifetime 8-hour time-weighted-average (TWA) exposure level is lowered to 1 ppm BD, based on female mouse lung tumors, the estimate of excess cancer and premature death drops to 8.1 per 1,000 workers. In other words, an 8-hour TWA lifetime occupational exposure reduction from 2 ppm to 1 ppm BD would be expected to prevent, on average, 8 additional cases of cancer and probable premature deaths per 1,000 exposed workers. Based on the individual tumor site dose-response data, which were best characterized by a 1-stage Weibull time-to-tumor model, (male-lymphoma, male-lung, female-lymphoma and ovarian), on average, one would expect there to be between 1 and 6 fewer excess cases of cancer per 1,000 workers based on a 8-hour TWA occupational lifetime exposure to BD at 1 ppm versus BD at 2 ppm. Estimates of leukemia deaths at the former 8-hour TWA PEL of 1,000 ppm of BD, for an occupational lifetime, are not presented because contemporary BD exposures are generally far lower than this level.

B. Assessment of Carcinogenic Risk

1. Choice of Data Base for Quantitative Risk Assessment

The choice of data provides the platform for a quantitative risk assessment (QRA). Either animal studies which evaluate the dose-response relationship between BD exposure and tumorigenesis or epidemiological dose-response data may be suitable sources of data.

Estimates of the quantitative risks to humans can be based on the experience of animals from a chronic lifetime exposure study. Chronic lifetime inhalation bioassays with rats and mice generally last 2 years or two-thirds of the lifespan of the animal. (Ex. 114) These types of studies provide insight into the nature of the relationship between exposure concentration, duration and resulting carcinogenic response under a controlled environment. Furthermore, some researchers have estimated a variety of measures of dose of BD, including inhaled and absorbed dose as well as BD metabolites, to estimate human risks based on the observed dose-response relationship of animals in a bioassay; the form of the dose used in a dose-response analyses is called the dose-metric.

The carcinogenicity of lifetime inhalation of BD was studied in Sprague-Dawley rats by the International Institute of Synthetic Rubber Producers (IISRP) and in $B_6C_3F_1$ mice by the National Toxicology Program. The IISRP sponsored a two-year inhalation bioassay of Sprague-Dawley rats performed at Hazelton Laboratories Europe (HLE). (Ex. 2–31) Groups of 110 male and female Sprague-Dawley rats were exposed for 6-hours per day, 5 days per week to 0, 1,000, or 8,000 parts per million (ppm) of BD. The males were exposed for 111 weeks and the females for 105 weeks. Statistically significant increased rates of tumors were found in both male and female rats. Among exposed male rats, there were increased occurrences of pancreatic and testicular tumors and among the exposed female rats there were higher incidence rates of uterine, zymbal gland, mammary and thyroid tumors than in the control groups.

The National Toxicology Program (NTP) has performed two chronic inhalation bioassays using $B_6C_3F_1$ mice. (Ex. 23–1; 90; 96) The first study, NTP I, was intended to be a two-year bioassay, exposing groups of 50 male and female mice to 0, 625, or 1,250 ppm of BD for a 6-hour day, 5 days/week. The study was prematurely curtailed at 60 weeks for the males 61 weeks for the females caused by an unusually high cancer mortality rate due to malignant neoplasms in multiple organs. Despite some weaknesses in the way the study was conducted, the results of this study show that BD is clearly carcinogenic in these mice, with statistically significant increases in malignant lymphomas, heart hemangiosarcomas, lung tumors, and forestomach tumors in comparison to the controls for exposed male and female mice. (Ex. 90)

The second NTP BD chronic inhalation bioassay, NTP II, had groups of 70 (except for the group exposed to the highest concentration, which contained 90) male and female mice exposed to concentrations of 0, 6.25, 20, 62.5, 200 and 625 ppm for 6 hours/day, 5 days/week for up to 104 weeks. The NTP II bioassay provided lower exposures, closer to prevailing occupational exposure levels, than the NTP I and HLE chronic inhalation studies. The NTP II supported the pattern of carcinogenic response found in NTP I. Both male and female mice exposed to BD developed tumors at multiple sites including: lymphomas, heart hemangiosarcomas, and tumors of the lung, liver, forestomach, and Harderian gland (an accessory lacrimal gland at the inner corner of the eye in animals; they are rudimentary in man). Reproductive tissues were also adversely affected. Among the exposed males there were significant increases in tumors of the preputial gland; among females there were significant increases in the incidence of ovarian and mammary tumors.

In 1996, a retrospective cohort study by Delzell and co-workers of about 18,000 men who worked in North American synthetic rubber plants was submitted to OSHA. (Ex. 117–1) In this study researchers derived estimates of occupational exposure to BD using a variety of resources, such as work histories, engineering data, production notes, and employees' institutional memories. In their October 2, 1995 report Dr. Delzell et al., characterized their effort as follows:

> Retrospective quantitative exposure estimation was done to increase the power of the study to detect associations and to assist with the assessment of the impact of specific exposure levels on mortality from leukemia and other lymphopoietic cancers. (Ex. 117–1)

In April 1996, Dr. Delzell expressed concern with possible discrepancies between estimated cumulative exposures and actual measurements. (Ex. 118–2) OSHA believes that in a well-conducted study, retrospective exposure estimates can be reasonable surrogates for true exposures; misclassifications or uncertainty can decrease the precision of the risk estimates derived from such a study, but the problem must be severe and widespread to invalidate the basic findings.

At the time of publication of the proposed standard on occupational exposure to BD (August 1990), only the NTP I mouse and HLE rat bioassays were available for quantitative risk assessments (QRA). Presented in Table

V–9 is an overview of authorship and data sets used in the various QRAs submitted to the OSHA docket. With one exception, the rest of the QRA's in the BD Docket have relied on animal chronic exposure lifetime bioassays. Each of the five risk assessments discussed in the proposal based its quantitative risk assessment on one or both of the higher-exposure chronic bioassays (exposure groups exposed to BD concentrations ranging between 625–8,000 ppm). (Exs. 17–5; 17–21; 23–19; 28–14; 29–3; 32–27) The three QRAs conducted using bioassay data subsequent to the publication of the NTP II study used NTP II data with exposures of 6.25–625 ppm BD, closer to actual occupational exposures, for calculating their best estimates of risk. (Exs. 90; 118–1b; 32–16)

A summary of each of the ten QRA's follows:

TABLE V–9.—SUMMARY TABLE OF QUANTITATIVE RISK ASSESSMENTS (QRAS) IN ORDER OF THEIR REVIEW IN THE OSHA BD STANDARD

Exhibit	Author	Data-set
90	National Institute for Occupational Safety and Health (NIOSH) (Preliminary).	NTP II[a] bioassay (preliminary).
118–1b	NIOSH	NTP II bioassay.
118–1	NIOSH	Delzell et al. epidemiological study.
17–21	United States EPA Carcinogen Assessment Group (CAG)	NTP I[b] and HLE[c] bioassays; Epidemiological based on Fajen Exposure Data.
32–27	California Occupational Health Program (COHP) of the California Department of Health services (CDHS).	NTP I; HLE bioassays Epidemiological based on Fajen Exposure Data
32–16	Shell Oil Corporation	NTP I, NTP II and HLE bioassays.
17–5	United States EPA Office of Toxic Substances (OTS)	NTP I bioassay.
23–19	ICF/Clement Inc	NTP I bioassay.
29–3	Center for Technology, Policy, and Industrial Development at the Massachusetts Institute of Technology.	NTP I and HLE bioassays.
28–14	Environ Inc	HLE bioassay.

[a] NTP II, The National Toxicology Program, Technical Report 434, 2-year bioassay of $B_6C_3F_1$ mice to 5 exposure groups receiving between 6.25 and 625 parts per million (ppm) of BD

[b] NTP I, The National Toxicology Program, prematurely terminated longtime bioassay of $B_6C_3F_1$ mice to 2 exposure groups receiving either 625 or 1,200 ppm of BD

[c] HLE, Hazelton Laboratories Europe's, lifetime bioassay of Sprague Dawley rats, exposed groups received 1,000 ppm of BD or 8,000 ppm of BD

NIOSH-Quantitative Risk Assessments based on NTP II

In the early 1990's, two QRAs were conducted sequentially by the National Institutes for Occupational Safety and Health (NIOSH). One was a preliminary and the other a final, with the latter using final pathology data for histiocytic sarcomas and one particular type of lymphoma from NTP II. In 1991, NIOSH submitted a preliminary QRA using the then preliminary NTP II tumor pathology data for various individual organ sites (8 from the female mice and 6 from the male mice) to estimate excess cancer risk at different BD exposures over an occupational lifetime. (Ex. 90) For all gender-tumor site analyses, NIOSH excluded the 625 ppm exposure group in its best estimate of risk since the plethora of competing tumors[6] in this high exposure group provide less information for a dose-response analysis of individual tumor sites than do data from some of the lower exposure groups. Another reason for the exclusion was that the dose-time-response relationship in mice is saturated for exposures above 500 ppm and the data would thus provide very little additional information for low dose extrapolation. NIOSH's QRA relied on an allometric conversion of body weight to the three-quarters power, $(mg/kg)^{3/4}$, and equated a 900-day-old mouse to a 74-year old human. To avoid duplication of risks, NIOSH presented only maximum likelihood estimates based on the aggregate of all types of lymphomas even though dose-response data were also available for the lymphocytic lymphoma subset.

Of the fourteen gender-tumor site data sets NIOSH modeled to extrapolate animal data to humans, 12 (86%) yielded excess risks greater than 2 cancer deaths per 1,000 workers, given an 8-hour TWA lifetime occupational exposure of 1 ppm BD. Estimates of excess risks to workers based on the best fitting models for each of the six dose-time-response relationships for male tumor sites were between 0.4 and 15.0 per 1,000 workers assuming an 8-hour TWA, 45 year occupational exposure to 1 ppm BD. Among estimates based on male mice's dose-response data, the lowest and highest excess risk estimates were from the heart hemangiosarcoma and Harderian gland dose-response relationships, respectively. For estimates of excess risk based on either gender's set of individual tumor dose-response relationships, only the heart hemangiosarcoma data predicted a risk of less than 1 per 1,000 workers with an occupational lifetime exposure of 1 ppm: these data predicted 0.4 and 3×10^{-3} excess cancer cases per 1,000 workers based on the best fitting models for male and female mice, respectively.

Based on tissue sites in females, the excess risk estimates for 8-hour TWA occupational lifetime exposure to 1 ppm BD range between 4 and 31 per 1,000 workers.

NIOSH presented its findings for lifetime exposure to 2 ppm as follows:

> Based on tumors at the most sensitive site, the female mouse lung [assuming $(mg/kg)^{3/4}$ conversion], our maximum likelihood estimates of the projected human increased risk of cancer due to a lifetime occupational exposure to BD at a TWA PEL of 2 ppm is approximately 60 in 1,000 (workers). (Ex. 90)

For the linear models, if scaling were on a (mg/kg) basis rather than the $(mg/kg)^{3/4}$ used by NIOSH for allometric conversion, the revised estimate of excess cancer risk for an 8-hour TWA occupational lifetime exposure to 2 ppm BD would decrease approximately 6 fold to 9.2 per 1,000 workers based on the same female mouse lung tumor data.

In 1993, NIOSH finalized its estimates of excess risk caused by occupational exposure based on the tumorigenesis

[6] Competing tumors refers to the lack of opportunity of a later developing tumor to express itself due to the occurrence of early developing lethal tumor; Among the 625 ppm exposure group lymphocytic lymphomas were mortal early developing tumors which prevented later developing disease such as heart hemangiosarcomas from possibly developing.

experience of mice in the NTP II study. (Ex. 118–1B) The rounded maximum likelihood estimates (MLE) from the final QRA are presented in Table V–10. NIOSH expanded the gender-tumor sites to include histiocytic sarcoma for both male and female mice. NIOSH chose to present only its risk estimate based on lymphocytic lymphoma, rather than an assessment based on the aggregate of lymphomas. In the preliminary and final NIOSH QRAs, 1-stage time-to-tumor models'' rounded estimates of risk associated with lifetime exposure to 1 ppm BD ranged from 1 to 30 excess cancer cases per 1,000 workers, with estimates based on the male-lymphocytic lymphoma and the female-lung dose-response data providing the lower and upper ends of the range of risk, respectively.

As part of its sensitivity analyses, NIOSH derived the estimates of risk based on (1) equating a human lifespan to a mouse equivalent age of 784 days, a figure OSHA has used, and (2) equating a human lifespan to a mouse lifespan of 900 days (a figure more often used by NIOSH.) The best estimates of risk equating human lifespan to a mouse lifespan of 784 days were lower, by about one-third, than those assuming a human lifespan equivalency to 900 days for the mouse, all else held constant.

TABLE V–10.—NIOSH'S [a] FINAL QUANTITATIVE RISK ASSESSMENT'S (QRA) MAXIMUM LIKELIHOOD ESTIMATES (M.L.E.S) [b] PER 1,000 WORKERS OF LIFETIME EXCESS RISK DUE TO AN OCCUPATIONAL [c] EXPOSURE TO 1 PPM OF BD USING BEST FITTING MODELS, AS DESIGNATED BY NUMBER OF STAGES OF THE WEIBULL TIME-TO-TUMOR MODEL

Gender-tumor site	MLE, Final QRA (Stages)
Male mouse:	.....
Forestomach	0.03 (2)
Harderian gland	10 (1)
Heart hemangiosarcoma	0.5 (2)
Histiocytic sarcoma	8 (1)
Liver	4 (1)
All Lymphoma	NA
Lymphocytic lymphoma	0.9 (1)
Lung	10 (1)
Female mouse:	.....
Forestomach	5 (1)
Harderian Gland	7 (1)
Heart hemangiosarcoma	3×10^{-3} (3)
Histiocytic sarcoma	10 (1)
Liver	7 (1)
All lymphoma	NA
Lymphocytic lymphoma	9 (1)
Lung	30 (1)
Mammary	4 (1)
Ovarian	9 (1)

[a] Based on NTP II, excluding the 625 ppm exposure category, equating a 900-day-old mouse to a 74-year old human and assuming an allometric conversion of $(mg/kg)^{3/4}$.
[b] Rounded to one significant figure.
[c] Occupational lifetime is an 8-hour time-weighted-average, 40-hours per week, 50-weeks per year, time-weighted-average (TWA) for 45-years.

The Carcinogen Assessment Group QRA

The Carcinogen Assessment Group (CAG) and the Reproductive Effects Assessment Group of the Office of Health and Environmental Assessment at the United States Environmental Protection Agency (EPA) also conducted an assessment of the mutagenicity and carcinogenicity of BD. (Ex. 17–21) In its quantitative risk assessment, CAG used both male and female response data from the two chronic bioassays available at the time, NTP I with $B_6C_3F_1$ mice and the HLE Sprague Dawley rat study. The CAG analysis is based on EPA's established procedures for quantitative risk analyses, which fit the total number of animals with significantly increased or highly unusual tumors with the linearized multistage model and use the upper 95% confidence interval. Mice dying before week 20 and rats dying during the first year of the study (before the observation of the first tumor) were eliminated from the analysis to adjust for non-tumor differential mortality.

The dose-metric was based on a preliminary report by the Lovelace Inhalation Toxicology Research Institute of its six-hour exposure study in $B_6C_3F_1$ mice and Sprague Dawley rats at different concentrations of BD, roughly corresponding to the concentrations used in NTP I and HLE, with total internal BD equivalent dose expressed as a function of inhalation exposure concentration. Then CAG estimated the amount and percent of BD retained for various exposure concentrations in these bioassays. These internal dose-estimates were then extrapolated to humans based on animal-to-human ppm air concentration equivalence.

CAG adjusted risk estimates from the mouse study by a factor of $(\text{study duration/lifetime})^3$ to account for less-than-lifetime observations, since the NTP I study was prematurely terminated at 60 weeks for males and 61 weeks for females due to predominating cancer mortality. CAG extrapolated the short lifespan mouse data to an expected mouse lifetime, 104 weeks, in order to estimate lifetime risk to humans.

CAG estimated all risks based on continuous exposure to BD, 24 hours per day, 365 days per year, for a 70-year lifetime. The incremental unit risk estimates for the female mouse were about eight times as high as those for the female rat; for the males, the incremental unit risk estimate for mice was about 200 times as high as for rats. The CAG final incremental unit risk estimate of $0.64\ (ppm)^{-1}$ is based on the geometric mean of the upper-limit slope estimates for male and female mice and would predict an upper limit of 640 excess cancers per 1,000 people exposed to 1 ppm continuously throughout their lifetime, 70 years. Extrapolating this same estimate to an equivalent 45-year working lifetime of 240 work days per

year at an 8-hour TWA exposure to 1 ppm BD would yield an upper-limit risk estimate of 90 excess cancers per 1,000 workers. If the working day is assumed to require one-half ($10 m^3$) the daily tidal volume, the total amount of air inhale, the excess would be 135 cancers per 1,000 workers.

California Occupational Health Program (COHP) QRA

In 1990, five years after the CAG conducted its quantitative risk assessment, the California Occupational Health Program (COHP) produced its estimates of risk with a similar assessment of the carcinogenicity of BD, using the same available bioassays, with more recent information on BD risk in humans, pharmacokinetic (PK) modeling, and animal low exposure absorption efficiency. (Ex. 32–16) Using three separate dose-metrics for each bioassay and multistage models to characterize the basic dose-response relationship, CAG presented several quantitative estimates of incremental lifetime unit risks. Quantal lifetime response multistage models were fit to the data. COHP, like NIOSH, used the individual data with a multistage Weibull time-to-tumor model to characterize the dose response relationship. COHP stated that it also fit Mantel-Bryan and log-normal models to the data, and that the multistage models gave a better fit; the results obtained with these other models were not reported.

COHP performed calculations on each primary tumor site separately, and also did calculations on the pool of primary tumors that showed significantly increased tumor incidences. For their main dose-metric, COHP refined the CAG approach, using a revised estimate of low-exposure absorption via inhalation. COHP also included an estimate of the PK model derived BD monoepoxide metabolites, but de-emphasized their use by stating that these were ''presented for comparative purposes only.'' The third dose-metric was straight ppm for animal-to-human species conversion (adjusting for duration of exposure). COHP stated:

> (COHP) followed standard EPA practice and assumed that a certain exposure concentration in ppm or mg/m^3 in experimental animals was equivalent to the same exposure concentration in humans. (Ex. 32–16)

Like CAG, COHP also adjusted for less than lifetime survival in the NTP I mouse study, by using a cubic power of time, $(\text{study duration/lifetime})^3$. COHP's potency estimate adjustment for the male mouse study with 60-week survival was 5.21; for the 61-week female mouse survival the adjustment was 4.96.

With all the combinations of sites, species, sexes, models, and dose-metrics, COHP presented over 60 potency estimates for the rat and over 100 for the mouse. As with the CAG and other analyses, the estimates based on NTP I were typically one to two orders of magnitude greater than those based on the rat for similar dose-metrics, models and total tumors. COHP chose the estimates based on the male mouse as final indicators of human risk based on the ''superior quality of the mouse study.'' From these estimates, using the quantal form of the multistage model, COHP chose ''the upper bound for plausible excess cancer risk to humans.'' COHP's final cancer potency estimate of $0.32\ (ppm)^{-1}$ presented in units of continuous lifetime exposure, is based on all significant tumors in the male mouse and uses the internal BD equivalent dose conversion factor of 0.54 mg/kg-d/ppm for the mouse and animal-to-human ppm equivalency. COHP's final potency estimate was one-half the value of $0.64\ (ppm)^{-1}$ calculated by the CAG; the difference is due mainly to a low exposure absorption modification by COHP. The continuous lifetime exposure potency factor converts to a working lifetime risk of 45 to 67 excess cancers per 1,000 workers, exposed to 1 ppm of BD at an 8-hour TWA over a 45 year working lifetime.

COHP, like CAG, attempted to determine whether its animal-based risk extrapolation could predict the leukemia mortality observed in epidemiology studies. Following the approach employed by CAG in its analyses of the Meinhardt (1982) study, the COHP compared its estimates of risk from bioassays to the then most recent epidemiological studies of Downs et al. (1987) and Matanoski and Schwartz (1987). Both COHP and CAG used MLEs based on mouse lymphoma for comparing the animal-derived potency estimates with the occupational response. In addition, neither COHP nor CAG used the upward adjustment factor of approximately 5 to correct for the less-than-lifetime duration of NTP I. Because neither of these epidemiology studies (Downs et al. (1987) or Matanoski and Schwartz (1987)) had recorded exposure estimates, the COHP relied on 8-hr TWA estimates of 1 and 10 ppm taken at different but similar plants reported by Fajen et al. (1986). For lifetime unit risk estimates, COHP used the initial MLE of $0.0168\ (ppm)^{-1}$ derived from the male mouse lymphoma analysis, unadjusted for less-than-lifetime survival. This part of the analysis also assumed that a lymphocytic outcome in the animals would equate to leukemia death in humans. These assumptions yielded a range of 6 to 21 predicted lymphocytic cancer deaths (for 1 and 10 ppm exposures) versus the 8 observed by Downs et al.

Office of Toxic Substances (OTS) QRA

The Office of Toxic Substances (OTS), U.S. Environmental Protection Agency (EPA) conducted a quantitative risk assessment using only the NTP I data. (Ex. 17–5) The reasons cited for this choice include: (1) The mouse is a more sensitive test species for BD than the rat; (2) a quality control review had been done for the mouse bioassay at the time OTS wrote its risk assessment whereas none was available for the rat bioassay; (3) greater amount of histopathological data was available for the NTP I study than for the HLE rat study; and (4) the type of BD feedstock used by NTP I had a much lower dimer concentration than the BD used by HLE (increased dimer concentration results in the lowering of availability of BD for metabolism to the mono- and di-epoxides, which are thought to be the carcinogenic agents). To compensate for early termination of the NTP I study, OTS adjusted dose by a factor of (study duration/lifetime).[3] Butadiene ppm exposure concentration was used as the measure of dose and mouse-to-human species extrapolation was also on a ppm equivalence basis. OTS estimated cancer risks based on heart hemangiosarcoma and pooled tumors (grouping of sites showing statistically significant elevated incidence rates) tumors using a 1-stage quantal model. Workplace exposures to BD were converted to estimated lifetime average daily doses. Since the NTP I study was curtailed at 61 weeks, tumor incidence rates were adjusted for survival by life-table methods. Cancer risks were based on administered dose of BD and not delivered dose to various target organs. (Ex. 17–5) Estimated 95% upper confidence-limits for the excess risk of cancer from an occupational lifetime exposure to an 8-hour TWA of 1 ppm BD, for 240 days/year for 40 years, ranged between 10 and 30 per 1,000 workers, based on pooled tumor incidence for female and male animals, respectively.

ICF/Clement Estimates

In 1986, ICF/Clement (ICF) estimated the risk of cancer associated with occupational exposure to BD. (Ex. 23–19) ICF determined that only the NTP I data were suitable for a risk assessment based on animal data, (NTP II data were not available at that time) based on ICF/

Clement's concern over the discrepancies between HLE's summary statistics and individual counts. ICF chose to use individual tumor type data for some of its analyses. ICF fitted a linearized multistage quantal model to the NTP I data. Based on a preliminary study by Bond (a senior toxicologist at the Chemical Industry Institute of Toxicology), ICF adjusted the NTP I exposure concentrations for percent retention which varied inversely from 100% at 1 ppm to 5% at 1,000 ppm.

ICF assumed ppm as the proper dose-metric and ppm to ppm for the mouse-to-human species extrapolation factor. (Exs. 23–86; 23–19) The 95% upper confidence limit estimates of risk based on pooled female tumor data with a lifetime occupational exposure was 200 per 1,000 workers at 1 ppm BD, and 400 per 1,000 workers at 5 ppm BD; the non-proportionality reflects the assumption of lower percentage retentions at higher concentrations.

Massachusetts Institute of Technology (MIT) QRA

Hattis and Wasson at the Center for Technology, Policy, and Industrial Development at MIT conducted pharmacokinetic/mechanism-based analyses of the carcinogenic risk associated with BD. (Ex. 29–3) The analyses include both HLE and NTP I data. Key elements, such as partition coefficients for blood/air and tissue/blood, were not available to be measured and had to be estimated. The best estimate of excess risk of cancer given a lifetime occupational exposure of 1 ppm BD 8-hr TWA was 5 per 1,000 workers based on the NTP I female mouse data set, incorporating pharmacokinetic models which set the blood/air partition coefficient to 0.2552. Based on the HLE female rat data with a blood/air partition coefficient of 0.2552, an excess risk was estimated to be 0.4 additional cases of cancer for every 1,000 workers at an 8-hour TWA, occupational lifetime exposure to 1 ppm BD.

Environ QRA

Environ conducted a quantitative risk assessment based on the HLE rat bioassay data. (Ex. 28–14) Environ noted that the relatively high BD concentrations of the earlier bioassays (HLE with groups exposed to 8,000 and 1,000 ppm BD and NTP I with exposures of 1,250 and 625 ppm BD) made it difficult to extrapolate risks to the relevant, lower exposure levels of BD in occupational settings. Environ stated that among $B_6C_3F_1$ mice, metabolic saturation occurs with 8-hour TWA BD concentrations greater than 500 ppm; thus, the time-dose-response relationship is different at higher doses than at lower doses. Environ stated that the methodological problems and the high early mortality shown in the NTP I data contributed to the uncertainty of its relevance to human risks and therefore chose to use the HLE rat bioassay data instead. Environ believes that human metabolism of BD is more similar to that in the Sprague-Dawley rat than in the $B_6C_3F_1$ mouse. Extrapolated risks were based on estimates of absorbed dose, expressed in mg/kg, as defined in the Bond et al. (1986) absorption study. (Ex. 23–86)

Environ used the HLE female rats to estimate the extra lifetime risk of developing cancer given an occupational lifetime 8-hr TWA exposure to 1 ppm BD. Using MLEs from multistage, Weibull, and Mantel-Bryan models, based on the total number of female rats with significantly increased tumors, Environ's predicted occupational lifetime risks were 0.575 (Multistage), 0.576 (Weibull), and 0.277 (Mantel-Bryan) per 1,000 workers.

Shell Oil Company QRA

Shell Oil Company estimated excess cancer risks by the multistage quantal and the Weibull time-to-tumor models based on female heart hemangiosarcomas and pooled malignant tumors from the NTP II study. Shell estimated human risks based on various assumptions, correcting for BD retention and/or relative human epoxide dose. Shell stated that the Weibull time-to-tumor model better characterized risks since it was able to fully utilize available dose-response data, including time until onset of tumors and latency (time from initiation until detection of tumor). (Ex. 32–27) Shell used

> * * * crude time-to-tumor data consisting of early deaths to 40- weeks, 40-week interim sacrifices, deaths to 65- weeks, 65-week interim sacrifices, death to 104- weeks and terminal sacrifices * * * in-lieu of individual animal data [for NTP II data]. (Ex. 32–27)

OSHA believes that the true dose-response relationship is obscured by Shell's use of crude time-to-tumor data and its grouping of early deaths to 40 weeks, deaths to 65 weeks and deaths to 104 weeks; instead, dose-time-tumor response data for each individual mouse should have been used.

Shell did not explain why it chose one model over the other. For example, without explanation, Shell dropped the highest exposure group, 625 ppm, when estimating lifetime occupational risk for all of its Weibull time-to-tumor models and dropped additional dose groups when using some multistage quantal models. Moreover, estimates of excess risk were presented only for 5-stage Weibull time-to-tumor models, although there is no discussion of correct model specifications. For example, no reasons are given for choosing the 5-stage model rather than another. Also, Shell does not support its estimation that the latency between the induction of a tumor and its observation is for the pooled female mice malignant tumors and 40-weeks for the female mice heart hemangiosarcomas.

Based on the Shell analyses, extrapolating from pooled malignant female mice tumors, assuming 10% human BD retention efficiency at 2 ppm, and on a 5-stage Weibull time-to-tumor model, one would expect 18 excess cancers per 1,000 workers given an 8-hour TWA occupational lifetime exposure of 2 ppm BD. Based on the same data set, but assuming a mouse-to-human species conversion factor based on an epoxide ratio of 590 (mouse-to-monkey) in addition to a 10% BD retention efficiency factor, the estimate of excess risk of cancer drops to 0.3 cases per 1,000 workers with an 8-hour TWA occupational lifetime exposure of 2 ppm. Using the same pooled malignant female mice tumors, but assuming the blood epoxide estimates of the Dahl et al. study and an 8-hour TWA lifetime occupational BD exposure of 2 ppm, the estimate of excess risk of cancer is slightly lower, 0.24 per 1,000 workers. The excess risk estimates based on female hemangiosarcomas and a 5-stage Weibull time-to-tumor model and occupational lifetime exposure to 2 ppm of BD were: (a) 6.4×10^{-8} (assuming a 10% BD retention factor); (B) 6.2×10^{-15} (assuming a 10% BD retention factor and an epoxide ration of 590); and (c) 1.3×10^{-11} (assuming the blood epoxide estimates of the Dahl et al. study).

Shell also presented the Environ Inc. QRA based on the HLE Sprague-Dawley rat bioassay and made similar adjustments for BD retention and blood epoxide to those it made for the NTP II $B_6C_3F_1$ mice data. As had Environ, Shell stated that the dose- response of the rat is more relevant than that of the mice in predicting risk in humans. Shell concluded that the risk estimates derived from HLE Sprague Dawley rat data should be given greater weight than those based on the $B_6C_3F_1$ mouse data.

NIOSH's QRA Based on the Delzell et al. Study

NIOSH estimated the excess risk of workers developing leukemia based on the Delzell et al. preliminary estimates of occupational exposure categories of a retrospective cohort study. (Exs. 117–1; 118–1) NIOSH derived excess risks from

the best fitting relative risk (RR) model, the square root model, as fit by Delzell et al. who adjusted for age, years since hire, and calendar period. The preferred final model specified by Delzell et al. was:

$$\text{Relative Risk} = 1 + 0.17 \times (\text{BD ppm-years})^{0.5}$$

Under this model the age-cause specific leukemia death rates (ACSDR) are a function of cumulative occupational exposure up to that age. The occupational ACSDRs are a multiplicative function of background ACSDR times the BD-caused relative increase (0.17 * BD ppm-years) in leukemia. These total ACSDRs were then applied to an actuarial program which adjusted for competing risks to estimate lifetime excess risk of leukemia associated with 45-year 8-hour TWA occupational exposures for a number of PELs for BD. Estimates of background rates of leukemia and all causes of death were taken from the mortality rates for all males, 20 to 65 years of age, from the 1989 Vital Statistics of the United States. This model estimates the excess risk of leukemia death, given an occupational lifetime exposure of 2 ppm of BD, as 11 per 1,000 workers. Lowering the 8-hour TWA occupational lifetime BD PEL to 1 ppm, on average, one would expect there to be 8 excess leukemia deaths per 1,000 workers over a working lifetime.

In most animal bioassays, exposure to chemical carcinogens is usually associated with an elevated tumor incidence at only one or two target tissues. BD is of great concern because significantly increased incidences of tumors at multiple sites and doses were observed in both rats and mice.

OSHA's final risk assessment is based upon the NTP II bioassay. (Exs. 90; 96) In NTP II, the following tumor sites' incidence rates were elevated: Heart, lymph nodes, lung, forestomach, Harderian gland, preputial gland, liver, ovaries and mammary gland. The NTP II bioassay was preferred over the NTP I mouse and the HLE rat bioassay for several reasons. First, most of the exposure levels for NTP II (6.25, 20, 62.5 and 200 ppm) were closer to current occupational exposure levels than were those in the other bioassays (625; 1,000 and 8,000 ppm); studies with higher than typical occupational exposure concentrations may lead to difficulties in extrapolating the effects to the lower concentrations of BD which typically occur in current occupational settings. Furthermore, for doses (625 to 8,000 ppm) above the metabolic saturation level of 500 ppm, the biologically effective doses are not proportional to ppm exposure concentrations. Second, the NTP II mice were successfully randomized to exposure groups and their individual pathology reports were consistently coded. The randomization of the bioassay mouse population lends to the internal validity of the study through the similar composition of experimental and control groups. Third, Good Laboratory Practices were followed, as verified by audits. Fourth, there was a clear dose-response relationship for several cancer sites. Fifth, since the carcinogenic mechanism is still unknown, OSHA conservatively estimates excess risk to humans based on the experience of the more sensitive animal species unless there is specific evidence indicating that the choice of that species is inappropriate. Sixth, risk assessment results based on the preliminary findings from the most recent epidemiologic study suggest that the $B_6C_3F_1$ mouse is a reasonable species to use for quantitative risk assessment. (Ex. 118–1)

For its risk assessment, OSHA has focused exclusively on those tumor sites that are scientifically pertinent. From the NTP II study, the range of excess cancer risk associated with a lifetime occupational exposure to BD is estimated based on the dose-response relationships of four target tissues, three common to both genders: Heart (hemangiosarcoma), lung, and lymphoma, and one, ovarian tumors, observed in one gender only. OSHA's focus on these four individual target tissues is based not on an objection to the use of other tissue tumors and sites but rather on the judgment that the chosen animal sites are appropriate because they include both rare (e.g., heart hemangiosarcoma) and common tumors (e.g., lung) and those sites with the lowest (heart hemangiosarcoma) and highest incidence rates (lymphatic).

Three of the target organs chosen for the QRA demonstrated a significantly elevated tumor incidence in both male and female animals; ovarian tumor incidence was also significantly elevated in female animals. For both male and female mice, heart hemangiosarcomas were selected for modeling because there is virtually no background incidence of heart hemangiosarcoma among untreated mice in the NTP control population; only 0.04% of unexposed $B_6C_3F_1$ mice develop heart hemangiosarcoma, and thus any observed increase in the incidence of heart hemangiosarcoma could be attributed to BD exposure. (Ex. 114, p. 121) The earlier developing lymphocytic lymphoma caused a significant number of mice to die. Therefore, leaving mice are left at risk for the later developing tumor, heart hemangiosarcoma. (Ex. 114, p. 123) This situation is known as competing risk (the lack of opportunity for later developing tumors to express themselves because an earlier developing tumor has already caused the death of the animal. The occurrence of heart hemangiosarcomas in the NTP study is even more notable because of these competing risks.

In the absence of definitive, pharmacokinetic information, OSHA has estimated excess risks to humans based on the most sensitive species-sex-tumor site. Lung tumors are the most sensitive sites for both male and female $B_6C_3F_1$ mice and, as such, were included in OSHA's final risk assessment.

Ovarian tumors are an example of the group of reproductive tumors which also had significantly increased incidence rates among the animals in the NTP II bioassay. Other significantly increased incidence rates were seen in testicular, preputial and mammary tumors.

The increased risk of developing leukemia that has been observed in the epidemiological studies suggests that lymphomas might be the most relevant tumor site in animals for estimating the quantitative cancer risk to workers. Some have suggested that the high rate of lymphoma among $B_6C_3F_1$ mice might have been due to the presence of the murine retro virus (MuLV) and have asserted that the presence of this virus in $B_6C_3F_1$ mice may be partially responsible for the incidence of thymic lymphoma. For example, in 1990, Dr. Richard Irons reported,

> A major difference between NIH Swiss and $B_6C_3F_1$ mice is their respective exotropic retro viral background (MuLV) * * * Chronic exposure to BD (at 1250 ppm) for up to a year resulted in a fourfold difference in the incidence of thymic lymphoma between $B_6C_3F_1$ mice and NIH Swiss mice * * * The role of endogenous retro virus (MuLV) in the etiology of chemically induced murine leukemogenesis is presently not understood. (Ex. 23–104)

Dr. Melnick of the National Toxicology Program testified during his public hearing statement,

> In terms of the difference in response between the $B_6C_3F_1$ mouse or the NIH Swiss Mouse, you must be aware that the study is not a complete cancer study. It's a one-year exposure. We do not know the full response in the NIH Swiss mouse if it were conducted as a cancer study (about 2-years). (Tr. 1/16/91, p. 382)

Furthermore, NIOSH stated: ''It is not known whether the retro virus activation mechanism is operative at the lower exposure concentrations of 1,3-butadiene [below 1250 ppm].'' (Ex. 90)

There is no information in the record to show that retrovirus insertion into the $B_6C_3F_1$ mice of the NTP II study led to the induction of lymphoma. Nor is there information indicating that the murine retro virus may have led to an enhancement of butadiene-induced lymphomas in $B_6C_3F_1$ mice. The development of thymic lymphoma in BD-exposed NIH Swiss mice that do not have this endogenous virus argues against the virus alone inducing the lymphomas observed in the BD-exposed $B_6C_3F_1$ mice. (Ex. 23–104)

Tables V–11 and V–12 show the breakdown of microscopically examined tissues included in OSHA's QRA, by exposure concentration and death disposition of female and male mice. As illustrated in the tables, microscopic examination varied by tissue type, exposure group, means of death, and gender. Microscopic examinations of all tissues were made for all natural deaths, and moribund and terminal sacrifices, irrespective of exposure group.

For each gender-exposure-group, 10 animals were sacrificed at 40 and 65 weeks. Microscopic evaluations were not made for all tissue types among interim sacrifices (40 and 65 weeks). Among early sacrifices (40 weeks) for the 6.25 and 20 ppm exposure groups, there were no microscopic examinations of the relevant tissues. For the 65-week female sacrifices at the 6.25 and 20 ppm dose levels only lung and ovarian tissues were examined microscopically. No microscopic evaluations were made for male 65-week sacrifices at the 6.25 ppm exposure level, but at the 20 ppm exposure level, animals were microscopically examined for heart hemangiosarcoma and lung cancer. Male and female interim sacrifices exposed to 62.5 ppm of BD were not microscopically examined for heart hemangiosarcoma.

Only observations confirmed by microscopic examination were included in the analyses. Among natural deaths for some gender-tissue combinations, there were a few animals for which tissues were not available. Tissue unavailability was due to autolysis (cell destruction post death) and missing tissues due to the delay between accident and discovery.

TABLE V–11.—TYPES OF TISSUES MICROSCOPICALLY EXAMINED BY CONCENTRATION DOSE AND DISPOSITION GROUPS AMONG FEMALE MICE FROM NTP[a]

Concentration ppm	Natural death and moribund sacrifice	Week 40 sacrifice	Week 65 sacrifice	Terminal sacrifice
0	lymphoma, heart[b], lung, ovaries.	lymphoma, heart, lung, ovaries.	lymphoma, heart, lung, ovaries.	lymphoma, heart, lung, ovaries.
6.25	lymphoma, heart, lung, ovaries.	none[c]	lung, ovaries	lymphoma, heart, lung, ovaries.
20	lymphoma, heart, lung, ovaries.	none	lung, ovaries	lymphoma, heart, lung, ovaries.
62.5	lymphoma, heart, lung, ovaries.	lymphoma, lung, ovaries	lymphoma, heart, lung, ovaries.	lymphoma, heart, lung, ovaries.
200	lymphoma, heart, lung, ovaries.	lymphoma, heart, lung, ovaries.	lymphoma, heart, lung, ovaries.	lymphoma, heart, lung, ovaries.

[a] These organs and tissue types are those contained in the OSHA risk assessment and do not reflect all of the types of tissues which were microscopically examined.
[b] Heart, specifically Heart hemangiosarcoma.
[c] None of the four tissue types used in the OSHA quantitative risk assessment were microscopically examined.

TABLE V–12.—TYPES OF TISSUES MICROSCOPICALLY EXAMINED BY CONCENTRATION DOSE AND DISPOSITION GROUPS AMONG MALE MICE FROM NTP[a]

Concentration ppm	Natural death and moribund sacrifice	Week 40 sacrifice	Week 65 sacrifice	Terminal sacrifice
0	lymphoma, heart[b], lung,	lymphoma, heart, lung	lymphoma, heart, lung	lymphoma, heart, lung.
6.25	lymphoma, heart, lung,	none[c]	none	lymphoma, heart, lung.
20	lymphoma, heart, lung,	none	heart, lung	lymphoma, heart, lung.
62.5	lymphoma, heart, lung	lymphoma, lung,	lymphoma, heart, lung	lymphoma, heart, lung.
200	lymphoma, heart, lung	lymphoma, heart, lung	lymphoma, heart, lung	lymphoma, heart, lung.

[a] These organs and tissue types are those contained in the OSHA risk assessment and do not reflect all of the types of tissues which were microscopically examined.
[b] Heart, specifically heart, hemangiosarcoma
[c] None of the four tissue types used in the OSHA quantitative risk assessment were microscopically examined.

2. Measure of Dose

The mechanism of cancer induction by BD is unknown for both rodents and humans. One or more of the metabolites of BD, epoxybutene, diolepoxybutane and diepoxybutane, are suspected as being responsible for the carcinogenic response in at least some of the cancers. However, which of the metabolites may be responsible for how much of the carcinogenic response has yet to be determined. Bond suggests that epoxybutene and diepoxybutane may be responsible for carcinogenic responses. (Ex. 32–28) Dr. Bond wrote:

> If carcinogenic response is elicited by a metabolite, as has been suggested, mice because of their higher rate of metabolism, might be expected to yield a greater (carcinogenic) response than rats. (Ex. 17–21)

Because there are different theories about which metabolites of BD are responsible for the various carcinogenic responses, some risk assessments have characterized carcinogenic risk as a result of type of dose: External, absorbed, or retained. In the BD proposal (55 FR 32736), OSHA calculated the ^{14}C–BD equivalents that were retained in mice at the conclusion of a 6-hour exposure period and incorrectly labeled the level as ''absorbed dose.'' This does not necessarily represent all the BD absorbed through inhalation exposure. (Ex. 34–1)

The metabolic and pharmacokinetic properties of BD have not been fully characterized for either humans or animals. Despite the absence of a generally accepted pharmacokinetic model, some metabolic information can still be applied to OSHA's QRA. The overall rate of BD metabolism in $B_6C_3F_1$ mice is approximately linear at external concentrations up to 200 ppm; BD metabolism increases sublinearly as concentrations increase until it is saturated at 625 ppm. (Ex. 90) Bond reported that epoxybutene is one of the putative carcinogenic metabolites for which metabolism in the $B_6C_3F_1$ mouse becomes saturated at 500 ppm; thus, the $B_6C_3F_1$ mouse is unable to eliminate epoxybutene as quickly above 500 ppm. Bond suggests that above 500 ppm direct quantitative extrapolation of risk from mouse studies may not be justified. (Ex. 23–86) Therefore, the 625 ppm exposure group was excluded from OSHA's risk assessment. Similarly, NIOSH and Shell did not include the 625 ppm exposure group in their best estimates of risks using NTP II data. However, NIOSH did include the 625 ppm dose group in its sensitivity analyses to see how the inclusion of the data would affect the specification (the form and number of dose explanatory variables e.g., d, d^2, d^3, etc.) of the model and the estimates of risk. (Ex. 90)

3. Animal-to-Human Extrapolation

A QRA based on a mouse bioassay requires setting values for some mouse and human variables, including those used in animal-to-human extrapolations. The values of these variables were chosen before conducting the analyses. In OSHA's quantitative risk assessment, a mouse's life span was assumed to be 113 weeks. Mice were 8 weeks old at the beginning of the study and were exposed for up to 105 weeks. OSHA assumes workers will have an average lifespan of 74 years and an occupational lifetime, working 5 days/week, 50 weeks/year, of 45 years. In the NTP II study, the average male mouse weighed 40.8 grams and female mouse weighed 38.8 grams. (Ex. 90) Mice were assigned breathing rates of 0.0245 l/min. Breathing rates of workers (for an 8-hour workday) were set at 10 m^3/8-hr.

OSHA has chosen to use a straight mg/kg, body weight to the first power, $(BW)^1$, intake as the animal-to-human species extrapolation factor for dose equivalence. Other BD QRAs employed various extrapolation factors such as ppm equivalence, $(mg/kg)^{3/4}$ equivalence, BD mono-epoxide blood levels between mice and monkey equivalence, and BD total body equivalence in $(mg/kg)^{2/3}$. OSHA believes that the evidence for the use of any of the alternative extrapolation factors is persuasive, although the Agency believes that body weight extrapolation is appropriate in this case because of the systemic nature of the tumors observed in both animal bioassays. This conversion of body weight, $(BW)^1$, produces estimates of risk which are lower than those derived using $(BW)^{3/4}$, everything else held constant. For example, with a linear, 1-stage model, if OSHA used the $(BW)^{3/4}$ conversion, holding all other elements constant, one would expect the estimates of excess risk to humans to be about 6.5 times higher than if the (BW) extrapolation factor had been used because of the weight of the experimental species (between 38.8 and 40.8 grams), and their breathing rate. For the quadratic (2-stage) and cubic (3-stage) models, the effect of relying on the $(BW)^{3/4}$ conversion rather than the $(BW)^1$, holding all else constant, would be to increase the predicted excess human risk more than 6.5 fold. (Ex. 90)

4. Estimation of Occupational Dose

It is necessary to estimate the development of cancer at a variety of occupational doses. This requires occupational doses to be converted into units comparable to those used to measure the animal experimental dose. As discussed earlier, OSHA first converted animal experimental exposures measured in ppm into occupational intake dose measured in (mg/kg).

An exposure of 1 ppm BD is converted into an equivalent exposure measured in mg/m^3 using the equation:

$$1\ \text{ppm BD} = \frac{\text{Molecular Weight BD}}{\text{Molecular Weight of Air}} \times \text{density of air}$$

$$1\ \text{ppm BD} = \frac{54.1\ \text{mg / mole}}{24.45\ \text{mole / m}^3} = 2.21\ \text{BD mg / m}^3$$

Given a worker weighing 70 kg, breathing 10 m^3 of air per 8-hour day, and exposed to air containing Y ppm BD, the inhaled dose of BD in mg/kg is given by:

$$\text{Y (mg / kg) BD inhaled} = \text{Y (ppm) BD} \times 2.21 \frac{\text{mg / m}^3}{\text{ppm}} \times \frac{10\ \text{m}^3}{70\ \text{kg}}$$

Using the above formula, one can calculate the estimated equivalent inhaled BD exposure among workers based on the exposure concentrations for animals (See Table V–13).

TABLE V–13.—ESTIMATE OF TOTAL HUMAN INHALED DOSE OVER A WORKDAY FOR VARIOUS EXPOSURE LEVELS OF BD

Exposure concentrations (ppm)	Estimate of total human inhaled BD over a workday (mg/kg/8-hours)
200	63.2
62.5	19.8
20	6.3
5	1.6
2	0.6
1	0.3

5. Selection of Model for Quantitative Risk Assessment

In the proposal (55 FR 32736), OSHA estimated excess risk using a quantal form of the multistage model (in a reparameterized form as calculated by GLOBAL83), which based estimates of risk to humans on the experience of the group rather than the individual. Three of the later risk assessments, Shell, NIOSH, and COHP, used a Weibull time-to-tumor form of the multistage model to fit the mouse bioassays. (Exs. 32–27; 90; 32–16) Time-to-tumor

models use more of the available information than quantal multistage models to characterize time until the development of each observable tumor, and extrapolate risks, based on an occupational dosing pattern. Since significant increases in tumor incidence occurred at multiple sites in the NTP II bioassay and a time-to-tumor model takes these competing risks into account, a time-to-tumor method is preferred over a quantal model. (Ex. 118–1B)

Therefore OSHA used a Weibull time-to-tumor form of the multistage model to characterize the risks of development of observable tumors, using the software package, TOX__RISK Version 3.5 by ICF Kaiser. The model predicts the probability, P(t,d), of tumor onset with dose pattern d by time t. It adjusts for competing causes of death prior to time t.

The Weibull time-to-tumor model is a multistage model based on the theory of carcinogenesis developed by Armitage and Doll. This theory of carcinogenesis is based on the assumption that a single line of stem cells must pass through a certain number of stages sequentially for the development of a single tumor cell. In the reparameterized form of the model used here, a k stage model is described by a polynomial of degree k, with all dose parameters greater than or equal to zero. The number of stages necessary for a model to be correctly specified varies by type of tumor, animal, and exposure agent, or any combination of the three.

Both the MLE and the 95% upper limit of the risk of developing cancer in various tissues per 1,000 workers by time t are calculated. The 95% upper bound is the largest value of excess risk that is consistent with the observed data with two-sided 95% confidence intervals. The 95% upper bound is computed based on the Weibull time-to-tumor model for which the parameters satisfy:

-2 (Log likelihood $-$ Log likelihood$_{max}$)$\leq$2.70554

Where: Log likelihood$_{max}$ is the maximum value of the log-likelihood

A 1-stage model is linear in dose; a 2-stage model is quadratic in dose; a 3-stage Weibull model is cubic in dose. Below is a mathematical representation of a 3-stage Weibull time-to-tumor model:

$$P(t,d)=1\text{-}\exp\left[-(q_0 + q_1 d + q_2 d^2 + q_3 d^3)(t - t_0^z)\right]$$

where: t_0 designates the time of onset of the tumor, t is the variable for time the tumor was observed and is assumed to follow a Weibull distribution; d is the dose-metric and is multistage; z is a parameter to be estimated, constrained between 1 and 10; the background parameter q_o and the dose parameters, q_1, q_2, q_3, are constrained to be non-negative. Constraining the dose parameters to zero or greater is biologically based, since the dose parameters are proportional to the mutation rates of the successive stages in the development of a tumor cell. The Weibull time-to-tumor model provides reasonable fits for about 75% of the tissues in the NTP historical control data base, but the precision of the fit to the dose-response data depends on the specific agent. (Ex. 90)

Four forms of the model, one less than the number of exposure groups, for each gender-outcome were fit to the data. The correct specification of the model, the number of stages, is determined by the fit of the model to the data. The likelihood ratio test identifies which model is a better fit by determining if the log-likelihood of a model is significantly greater than another model's value. The 1-, 2-, 3- and 4-stage Weibull time-to-tumor models for each gender-outcome combination were ordered according to the value of their log-likelihood. If the log-likelihood of the higher stage model is significantly greater than that of the next lower stage model's log-likelihood, one would reject the null hypothesis (the additional stage does not create a model that better characterizes the data) and conclude that the higher stage model is a significantly better predictor of the estimates of risk in the observed range than is the lower stage model.

The steps of the likelihood ratio test are as follows:

For example, assuming an alpha of 0.05, and 1 degree of freedom (the difference in the number of parameters from 1-stage and 2-stage models), the critical value would be 3.84.

Fail to Reject H_0 if:

2 (log likelihood$_{1\text{-stage}}$ $-$ log likelihood$_{2\text{-stage}}$)$<$3.84

Reject H_0 if:

2 (log likelihood$_{1\text{-stage}}$ $-$ log likelihood$_{2\text{-stage}}$)$\geq$3.84

If two times the difference of the log likelihood values of the nth stage model and the nth + 1 stage model was less than 3.84, then the additional stage would be deemed unnecessary for goodness of fit; on the grounds of parsimony, the lower stage model would be used for the risk assessment. Otherwise, the higher stage model would be judged a better fit than the lower stage one and the process would continue.

While the likelihood ratio test is suitable for testing the significance of the next higher degree dose parameter, the biologically reasonable constraint on the background incidence parameter q_0 and dose parameters that they be non-negative q_1, q_2, q_3>=0,—may impair the log-likelihood ratio test's power to determine statistical significance.

The incidences of lymphoma, heart hemangiosarcoma, lung and ovarian tumors are shown in Tables V–14 and V–15 for males and females, respectively. The TOXRISK Weibull time-to-tumor model requires that the tumor context be described for each observation. Outcomes can be put into three context categories: (1) Censored, no tumor; (2) rapidly fatal tumor; and (3) observed, tumor incidental to the animal's survival. Since OSHA was predicting the time until onset of tumor, assuming no lag time between onset and detection of tumor, t_0 was set to zero. Therefore, estimates of risk to humans based on the contribution to the likelihood of either a rapidly fatal or incidental tumor are mathematically the same.

Tables V–16 and V–17 show the Weibull time-to-tumor model estimates of log-likelihoods, the shape parameters, intercept and dose coefficients for relevant target tissues for male and female mice, respectively. The relative performance of various staged models for a specific target tissue-gender are enumerated in the log-likelihood values. It should be noted that some of the tissue-gender combination's log-likelihood values do not vary even though there is a change in the number of the stages in the model. For example, the log-likelihood values for models of all lymphoma for males and lung tumors for males and females are $-$6.986 E+1, $-$1.763 E+2, $-$1.626 E+2, respectively, regardless of the specification, number of stages, in the model. OSHA concluded that the 1-stage models were preferred.

As identified in Tables V–16 and V–17, only heart hemangiosarcoma models are non-linear. This is consistent with NIOSH's results when fitting Weibull time-to-tumor models to these gender-tumor combinations. The quadratic (2-stage) model for males and the cubic (3-stage) model for females better characterized the dose-response relationship in modeling time to detection of heart hemangiosarcoma than did the linear models. The higher stage model necessary to fit the heart hemangiosarcoma data is driven by the absence of cases in the two lower exposure groups, shown in Tables V–14 and V–15. Unlike the other tissues studied, there were no cases of heart

hemangiosarcoma in the control and lowest exposure groups for both male and female mice. Both male and female mice had similar heart hemangiosarcoma tumor rates, almost 30%, among the 200 ppm exposure groups. The intercepts, q_0, were zero for models of both male and female mice based on the dose-response of heart hemangiosarcomas. This is consistent with what one would expect, given the absence of background incidence rates of heart hemangiosarcomas.

TABLE V–14.—UNIVARIATE ANALYSIS OF HEART, LUNG, AND ALL LYMPHOMA NEOPLASMS BY EXPOSURE LEVEL OF 1,3-BUTADIENE AMONG NTP II MALE MICE ANALYZED IN THE TIME-TO-TUMOR MODELS

Neoplasm	Outcome		
	Tumor n [a] (%N [b])	Censored [c] n (%N)	Total N
All lymphoma, 0 ppm	4 (5.7)	66 (94.3)	70
All lymphoma, 6.25 ppm	3 (6.0)	47 (94.0)	50
All lymphoma, 20 ppm	8 (16.0)	42 (84.0)	50
All lymphoma, 62.5 ppm	11 (15.9)	58 (84.1)	69
All lymphoma, 200 ppm	9 (12.9)	61 (87.1)	70
Heart hemangiosarcoma, 0 ppm	0 (0)	70 (100)	70
Heart hemangiosarcoma, 6.25 ppm	0 (0)	49 (100)	49
Heart hemangiosarcoma, 20 ppm	1 (1.7)	59 (98.3)	60
Heart hemangiosarcoma, 62.5 ppm	5 (8.6)	53 (91.4)	58
Heart hemangiosarcoma, 200 ppm	20 (29.4)	48 (70.6)	68
Lung tumor, 0 ppm	22 (31.4)	48 (68.6)	70
Lung tumor, 6.25 ppm	23 (46.9)	26 (53.1)	49
Lung tumor, 20 ppm	20 (33.3)	40 (66.7)	60
Lung tumor, 62.5 ppm	33 (47.8)	36 (52.2)	69
Lung tumor, 200 ppm	42 (60.0)	28 (40.0)	70

[a] n is number of microscopically determined outcomes per tumor-context, gender, exposure-group outcome site combination.
[b] N is the total number of gender, exposure-group, outcome site combination which were microscopically examined.
[c] Tumor's context is C (censored); animals were microscopically examined and no tumor was found at this site.

TABLE V–15.—UNIVARIATE ANALYSIS OF HEART, LUNG, ALL LYMPHOMA AND OVARIAN NEOPLASMS BY EXPOSURE LEVEL OF 1,3-BUTADIENE AMONG NTP II FEMALE MICE ANALYZED IN THE TIME-TO-TUMOR MODELS

Neoplasm	Outcome		
	Tumor n[a] (%N[b])	Censored [c] n (%N)	Total N
All lymphoma, 0 ppm	10 (14.3)	60 (85.7)	70
All lymphoma, 6.25 ppm	14 (28.0)	36 (72.0)	50
All lymphoma, 20 ppm	18 (36.0)	32 (64.0)	50
All lymphoma, 62.5 ppm	10 (14.3)	60 (85.7)	70
All lymphoma, 200 ppm	19 (27.1)	51 (72.9)	70
Heart hemangiosarcoma, 0 ppm	0 (0)	70 (100)	70
Heart hemangiosarcoma, 6.25 ppm	0 (0)	50 (100)	50
Heart hemangiosarcoma, 20 ppm	0 (0)	50 (100)	50
Heart hemangiosarcoma, 62.5 ppm	1 (1.7)	58 (98.3)	59
Heart hemangiosarcoma, 200 ppm	20 (28.6)	50 (71.4)	70
Lung tumor, 0 ppm	4 (5.7)	66 (94.3)	70
Lung tumor, 6.25 ppm	15 (25.0)	45 (75.0)	60
Lung tumor, 20 ppm	19 (31.7)	41 (68.3)	60
Lung tumor, 62.5 ppm	27 (38.6)	43 (61.4)	70
Lung tumor, 200 ppm	32 (45.7)	38 (54.3)	70
Ovarian tumor, 0 ppm	1 (1.4)	68 (98.6)	69
Ovarian tumor, 6.25 ppm	0 (0)	59 (100)	59
Ovarian tumor, 20 ppm	0 (0)	59 (100)	59
Ovarian tumor, 62.5 ppm	9 (12.9)	61 (87.1)	70
Ovarian tumor, 200 ppm	11 (15.7)	59 (84.3)	70

[a] n is number of microscopically determined outcomes per tumor-context, gender, exposure-group outcome site combination.
[b] N is the total number of gender, exposure-group, outcome site combination which were microscopically examined.
[c] Tumor's context is C (censored); animals were microscopically examined and no tumor was found at this site.

TABLE V–16.—MAXIMUM LIKELIHOOD ESTIMATES OF MODEL COEFFICIENTS FROM VARIOUS STAGES OF WEIBULL TIME-TO-TUMOR MODELS USING THREE TUMOR RESPONSES OF MALE MICE IN THE NTP II STUDY, EXCLUDING 625 PPM EXPOSURE GROUP; SELECTION OF SPECIFICATION OF MODEL IS BASED ON LIKELIHOOD RATIO TEST

Neoplasm	Stage [a]	Log-likelihood	Z [b]	q_0	q_1	q_2	q_3	q_4
Heart hemangiosarcoma	W1	−7.061	9.810	0.00	8.306 E–23			
Heart hemangiosarcoma	[c] W2	−2.783 E–1	10	0.00	0.00	3.071 E–25		
Heart hemangiosarcoma	W3	−2.712 E–1	10	0.00	1.058 E–24	2.636 E–25	2.057 E–28	
Heart hemangiosarcoma	W4	−2.659 E–1	10	0.00	1.119 E–24	2.664 E–25	0.00	9.626 E–31
All lymphoma	[c] W1	−6.986 E+1	4.743	2.709 E–11	6.136 E–13			
All lymphoma	W2	−6.986 E+1	4.743	2.709 E–11	6.136 E–13	0.00		
All lymphoma	W3	−6.986 E+1	4.743	2.709 E–11	6.136 E–13	0.00	6.540 E–33	
All lymphoma	W4	−6.986 E+1	4.743	2.709 E–11	6.136 E–13	0.00	0.00	0.00
Lung tumor	[c] W1	−1.763 E+2	3.318	1.132 E–7	2.636 E–9			
Lung tumor	W2	−1.760 E+2	3.413	7.674 E–8	1.253 E–9	3.134 E–12		
Lung tumor	W3	−1.760 E+2	3.143	7.674 E–8	1.253 E–9	3.134 E–12	0.00	
Lung tumor	W4	−1.760 E+2	3.413	7.674 E–8	1.253 E–9	3.139 E–12	0.00	0.00

[a] Stage of time-to-tumor model; W1, Weibull 1-stage time-to-tumor model; W2, Weibull 2-stage time-to-tumor model; W3, Weibull 3-stage time-to-tumor model; W4, Weibull 4-stage time-to-tumor model.
[b] Z is the shape parameter; it is bounded, (1<=z<=10).
[c] Selected Model.

TABLE V–17.—MAXIMUM LIKELIHOOD ESTIMATES OF MODEL COEFFICIENTS FROM VARIOUS STAGES OF WEIBULL TIME-TO-TUMOR MODELS USING FOUR TUMOR RESPONSES OF FEMALE MICE IN THE NTP II STUDY, EXCLUDING 625 PPM EXPOSURE GROUP; SELECTION OF SPECIFICATION OF MODEL IS BASED ON LIKELIHOOD RATIO TEST

Neoplasm	Stage[a]	Log-likelihood	Z[b]	q_0	q_1	q_2	q_3	q_4
Heart hemangiosarcoma	W1	−2.097 E+1	4.957	0.00	4.356 E–13			
Heart hemangiosarcoma	W2	–8.745	6.126	0.00	0.00	2.222 E–17		
Heart hemangiosarcoma	W3[c]	−4.866	6.770	0.00	0.00	0.00	8.088 E–21	
Heart hemangiosarcoma	W4	−4.267	7.011	0.00	0.00	0.00	2.637 E–22	1.368 E–3
Ovarian tumor	W1[c]	−6.140 E+1	2.857	1.407 E–8	.031 E–9			
Ovarian tumor	W2	−6.069 E+1	4.079	5.397 E–11	7.075 E–12	1.399 E–13		
Ovarian tumor	W3	−6.069 E+1	4.079	5.397 E–11	7.075 E–12	1.399 E–13	0.00	
Ovarian tumor	W4	−6.069 E+1	4.079	5.397 E–11	7.075 E–12	1.399 E–13	0.00	0.00
All lymphoma	W1[c]	−5.724 E+1	6.857	3.453 E–15	1.338 E–16			
All lymphoma	W2	−5.501 E+1	7.143	1.18 E–15	2.577 E–18	2.453 E–19		
All lymphoma	W3	−5.426 E+1	7.230	7.758 E–16	6.847 E–18	0.00	7.809 E–22	
All lymphoma	W4	−5.401 E+1	7.258	7.360 E–18	7.359 E–18	0.00	0.00	3.387 E–24
Lung tumor	W1[c]	−1.626 E+2	3.416	2.096 E–8	2.096 E–9			
Lung tumor	W2	−1.626 E+2	3.416	2.090 E–8	2.090 E—9	0.00		
Lung tumor	W3	−1.626 E+2	3.416	2.090 E–8	2.096 E–9	0.00	0.00	
Lung tumor	W4	−1.626 E+2	3.416	2.090 E–8	2.096 E–9	0.00	0.00	0.00

[a] Stage of time-to-tumor model; W1, Weibull 1-stage time-to-tumor model; W2, Weibull 2-stage time-to-tumor model; W3, Weibull 3-stage time-to-tumor model; W4, Weibull 4-stage time-to-tumor model.
[b] Z is the shape parameter; it is bounded, (1<=z<=10).
[c] Selected Model.

OSHA's Estimates of Risk

The estimates from OSHA's quantitative risk assessment based an 8-hour TWA, occupational lifetime, working 5 days/week, 50 weeks/year, for 45 years, at various BD PELS are shown in Table V–18. The MLEs of excess risk of material impairment of health per 1,000 workers for cancer, based on tumors of various tissue sites and the 95% upper bounds, are presented. Various 8-hour TWA PELS, ranging from 0.1 to 5 ppm, are presented to provide a context in which to evaluate the OSHA final rule PEL of 1 ppm and to explore the feasibility of other PELS, including the proposed PEL of 2 ppm. Risks at the former BD 8-hour TWA PEL, 1,000 ppm, are not presented in Table V–18. Although risks could be estimated for an occupational lifetime exposure to an 8-hour TWA of 1,000 ppm of BD from the linear models, there is little relevancy to estimating the true risk at an 8-hour PEL for BD at 1,000 ppm for an occupational lifetime, since

8-hour TWA BD exposures have been generally far lower than 1,000 ppm.

Although the estimates of carcinogenic outcomes differ, excess risks derived from tumor sites common to both male and female $B_6C_3F_1$ mice had the same relative ranking from lowest to highest risk estimates by target tissues (heart hemangiosarcomas < lymphomas < lungs) within each gender group. After a lifetime occupational exposure to BD at the proposed 8-hour TWA PEL of 2 ppm based on the above model fits to these three individual tumor sites, one would expect between 2.7×10^{-4} to 16.2 excess cancer cases per 1,000 workers, depending on which gender-tumor site dose-response relationship is used as the basis for the extrapolation to human occupational excess risks. Decreasing the BD 8-hour TWA PEL from 2 to 1 ppm, results in a reduction of the range of estimates of excess risk of cancer to between 3.4×10^{-5} to 8.1 cases per 1,000 workers.

The estimate of excess cancer risk based on male mouse lymphoma is 1.3 per 1,000 workers at an 8-hour TWA for an occupational lifetime exposure to 1 ppm BD. Extrapolating from female mouse lymphoma data results in an estimate of 6.0 extra cancer deaths per 1,000 workers at a BD 8-hour TWA PEL of 1 ppm for an occupational lifetime of exposure.

Extrapolating from the most sensitive site, the female mouse lung, based on the 1-stage Weibull time-to-tumor model, with an 8-hour TWA PEL of 2 ppm of BD for an occupational lifetime, one would expect 16 excess cancer cases per 1,000 workers. Lowering the PEL to 1 ppm would cut the expected number of excess cancers in half to 8 cases, based on the same gender-tumor site. Based on male lung tumors, the estimate of excess cancer deaths for an 8-hour TWA exposure to 2 ppm BD over an occupational lifetime was 12.8 per 1,000 workers; lowering the 8-hour TWA occupational lifetime exposure level to 1 ppm BD decreases the estimate of excess cancer risk to 6.4 per 1,000 workers, a reduction of 6 cancer cases per 1,000 workers.

OSHA's estimates of premature occupational leukemia deaths based on the 1-stage Weibull time-to-tumor models for the following outcome sites: All lymphoma, lung tumors, and ovarian tumors, ranged between 1.3 and 8.1 per 1,000 workers. Similarly, NIOSH's 14 estimates of the excess risk of death due to leukemia, based on 1-stage Weibull time-to-tumor models, as a consequence of exposure to an 8-hour TWA of 1 ppm BD over an occupational lifetime, ranged between 0.9 and 30 cases per 1,000 workers. The preliminary estimate of 8 per 1,000 from the Delzell et al. study is concordant with this range of animal-based estimates. OSHA acknowledges that there is uncertainty in the Delzell et al. estimate, perhaps due to the natural sampling variability present in any epidemiologic study plus the *possibility* of extra-binomial uncertainty stemming from exposure misclassification. While this uncertainty makes it difficult to say whether quantitative risk estimates would be adjusted up or down relative to animal-based estimates, this suggestion is far less important than the basic conclusion that the Delzell et al. study *reinforces* earlier estimates. Even if refinement of exposures caused the Delzell et al. estimate to move up or down by even as much as a factor of 5 or more, it would not change this qualitative, and roughly quantitative, agreement.

TABLE V–18.—MAXIMUM LIKELIHOOD ESTIMATES (MLE) AND NINETY-FIVE PERCENT UPPER BOUNDS OF LIFETIME EXTRA RISK TO DEVELOP AN OBSERVABLE TUMOR PER 1,000 WORKERS DUE TO AN 8-HOUR TWA FOR AN OCCUPATIONAL LIFETIME[a] OF EXPOSURE TO 1,3-BUTADIENE, USING NTP II BIOASSAY[b] AND THE BEST FITTING WEIBULL TIME-TO-TUMOR MODELS

Neoplasms	Stages	8-hour time-weighted average concentration[c]											
		0.1 ppm		0.2 ppm		0.5 ppm		1 ppm		2 ppm		5 ppm	
		MLE	95% U.B.[d]	MLE	95% U.B.	MLE	95% U.B.	MLE	95% U.B.	MLE	95% MLE	MLE	95% U.B.
Male mice:													
Heart Hemangiosarcoma	2	[e]<0.1	0.2	[e]<0.1	0.4	[e]<0.1	0.9	[e]<0.1	1.8	[e]< 0.1	3.6	0.4	9.1
All lymphoma	1	0.1	0.2	0.3	0.5	0.6	1.1	1.3	2.3	2.5	4.5	6.3	11.2
Lung tumor	1	0.7	0.1	1.3	2.0	3.2	4.9	6.4	9.8	12.8	19.4	31.7	47.9
Female mice:													
Heart Hemangiosarcoma	3	[f]<0.1	[f]<0.1	[f]<0.1	< 0.1	[f]<0.1	0.2	[f]< 0.1	0.5	[f]<0.1	1.0	[f]<0.1	2.4
Ovarian tumor	1	0.1	0.3	0.3	0.5	0.7	1.3	1.4	2.6	2.8	5.2	6.9	13.0
All lymphoma	1	0.6	0.9	1.2	1.8	3.0	4.6	6.0	9.2	12.0	18.3	29.7	45.0
Lung tumor	1	0.8	1.2	1.6	2.4	4.1	6.1	8.1	12.2	16.2	24.1	40.00	59.4

[a] Occupational lifetime, working 5 days/week, 50 weeks/year, for 45 years.
[b] Using data from NTP II for the following exposure groups: 0, 6.25, 20, 62.5 and 200 ppm; the 625 ppm exposure group was excluded.
[c] Estimated lifetime excess risk for cancer assuming: mouse life-span of 113 weeks, male mouse body weight of 40.8g; female mouse body weight of 38.8 g; worker's breathing rate is 1.25 m^3/hr; mouse to human risk extrapolated in mg/kg-day equivalent units.
[d] 95% U.B., 95% Upper Bounds is the largest value of excess risk that is compatible with the animal response data at a confidence level of 95%.
[e] MLEs ranged from $1.5\mu10^{-4}$ to $6.0\mu10^{-2}$
[f] MLEs ranged from $3.4\mu10^{-8}$ to $4.3\mu10^{-3}$

VII. Significance of Risk

A. Introduction

In the 1980 ''Benzene Decision,'' the Supreme Court, in its discussion of the level of risk that Congress authorized OSHA to regulate, indicated its view of the boundaries of acceptable and unacceptable risk. The Court stated:

It is the Agency's responsibility to determine in the first instance what it considers to be a ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D.* v. *A.P.I.*, 448 U.S. 607, 655).

So a risk of 1/1000 (10^{-3}) is clearly significant. It represents the uppermost

end of the million-fold range suggested by the Court, somewhere below which the boundary of acceptable versus unacceptable risk must fall.

The Court further stated that ''while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is significant will be based largely on policy considerations.'' With regard to the methods used to determine the risk level present (as opposed to the policy choice of whether that level is ''significant'' or not), the Court added that assessment under the OSH Act is ''not a mathematical straitjacket,'' and that ''OSHA is not required to support its findings with anything approaching scientific certainty.'' The Court ruled that ''a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection'' (448 U.S. at 655, 656).

Nonetheless, OSHA has taken various steps that make it fairly confident its risk assessment methodology is not designed to be overly ''conservative'' (in the sense of erring on the side of overprotection). For example, there are several options for extrapolating human risks from animal data via interspecies scaling factors. The plausible factors range at least as widely as from body weight extrapolation at one extreme (risks equivalent at equivalent body weights, $(mg/kg)^{1}$) to $(body\ weight)^{2/3}$ (risks equivalent at equivalent surface areas) at the other. Intermediate values have also been used, and the value of $(body\ weight)^{3/4}$, which is supported by physiological theory and empirical evidence, is generally considered to be the midpoint of the plausible values. $(Body\ weight)^{2/3}$ is the most conservative value in this series, while body weight extrapolation is the least conservative. OSHA has generally used body weight extrapolation in assessing risks from animal data, an approach that tends to be significantly less risk conservative than the other methodologies and is likely to be less conservative even than the central tendency of the plausible values.

Other steps in OSHA's risk assessment methodology where the Agency does not use the most conservative approach are selection of the maximum likelihood estimate (MLE) of the parameterized dose-response function rather than selection of the upper 95% confidence limit, and the use of site-specific tumor incidence, rather than pooled tumor response, in determining the dose-response function for a chemical agent.

Other aspects of OSHA's risk assessment methodology reflect more conservative choices, including: basing the risk estimate on the more sensitive species tested (the mouse); including lung tumors in the range of risks presented in the quantitative analysis, even though excess deaths from lung cancer have not been observed in any of the human studies; and, assuming workers will be exposed to butadiene at the maximum permissible level for 45 years. As discussed below, if workers are exposed to BD for fewer years, their estimated risks from BD will be less than indicated. This caveat, of course, does not address lifetime risks taking into account occupational exposure to other substances encountered at other jobs. For reasons already explained, OSHA believes these choices are appropriate for the BD risk assessment. OSHA also recognizes that use of the most conservative approach at every step of the risk assessment analysis could produce mathematical risk estimates which, because of the additive effect of multiple conservative assumptions, may overstate the likely risk. OSHA believes its quantitative risk assessment for BD strikes an appropriate balance.

Risk assessment is only one part of the process OSHA uses to regulate toxic substances in the workplace. OSHA's overall analytic approach to regulating occupational exposure to particular substances is a four-step process consistent with judicial interpretations of the OSH Act, such as the Benzene Decision, and rational policy formulation. In the first step, OSHA quantifies the pertinent health risks, to the extent possible, performing quantitative risk assessments. The Agency considers a number of factors to determine whether the substance to be regulated currently poses a significant risk to workers. These factors include the type of risk posed, the quality of the underlying data, the plausibility and precision of the risk assessment, the statistical significance of the findings and the magnitude of risk. (48 FR 1864, January 14, 1983) In the second step, OSHA considers which, if any, of the regulatory options being considered will substantially reduce the identified risks. In the third step, OSHA looks at the best available data to set permissible exposure limits that, to the extent possible, both protect employees from significant risks and are also technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to fulfill its statutory mandate by crafting regulations that allow employers to reach the feasible PEL as efficiently as possible.

B. Review of Data Quality and Statistical Significance

As discussed in the Health Effects section, OSHA has concluded that butadiene is a probable human carcinogen. This conclusion is based on a body of evidence comprised of animal bioassays, human epidemiological investigations, and other experimental studies that together are both consistent in their findings and biologically plausible. First, OSHA has reviewed four rodent inhalation bioassays, two mouse bioassays conducted under the National Toxicology Program (designated NTP I and NTP II), a mouse study by Irons et al. in 1989, and a rat study sponsored by the IISRP. (Exs. 2–32, 23–1, 32–28D, 90, 96) All three mouse studies found a consistently high tumor response in BD-exposed mice, relative to control animals. Several target organs were identified, particularly by the NTP II study; however, all three studies found dose-related increases in the incidences of lymphocytic lymphoma and heart hemangiosarcomas associated with exposure to BD. Most significantly, the NTP II study reported statistically significant increases in tumor incidence among mice exposed to BD well below OSHA's current PEL of 1,000 ppm (exposure to as low as 6.25 ppm was associated with a statistically significant increase in tumors, e.g., lung tumors in female mice). There was also evidence for a dose-rate effect, meaning that the observed tumor incidence in mice exposed to high concentrations over short periods of time was higher than that observed in mice administered an equivalent cumulative concentration over a long period of time. The study employing BD-exposed rats also found increased incidences of several types of cancer, albeit at lower response rates than were observed in the mouse studies. The two major epoxide metabolites of BD have also been shown to be carcinogenic in rats and mice.

OSHA has also reviewed a number of human epidemiological studies that have examined the mortality experience of styrene-butadiene rubber (SBR) workers. These studies have consistently reported an elevated relative risk of leukemia-or lymphoma-related death among BD-exposed workers. The most recent of these, the study by Delzell et al., updated and expanded previous SBR worker mortality studies and found a positive

and statistically significant dose-response relationship between cumulative exposure to BD and increased leukemia mortality, which remained statistically significant even after controlling for the potential confounder of concurrent styrene exposure. (Ex. 117–1) The Delzell et al. study thus provides further and more directly relevant evidence that an increased risk of leukemia-related death is associated with exposure to BD. Furthermore, other epidemiologic studies have reported finding an unusually short latency period (as little as 3 to 4 years from time of initial exposure to death) for exposure-related hematologic malignancies among workers who experienced exposures to BD in the past that were higher than exposures that prevail today. (Ex. 2–26, 3–34 Vol III H–1)

Evidence for the carcinogenicity of BD is further strengthened by a collection of studies showing that the epoxide metabolites of BD are mutagenic in a wide variety of *in vitro* and *in vivo* test systems. Examination of cultured lymphocytes from BD-exposed workers has revealed the presence of chromosome aberrations, an elevated frequency of chromatid breaks, and various mutations, thereby providing direct evidence of genotoxicity in occupationally-exposed humans. (Exs. 118–2A, 118–2D) Furthermore, the finding of activated K-*ras* oncogenes in tumors of BD-exposed mice provides additional support for a mutagenic mode of action; this finding has particular relevance to human risk in that K-*ras* is the most commonly detected oncogene in human cancer. (Ex. 129)

The findings from the animal bioassays and human epidemiologic studies identify the hematopoietic system as a primary target organ for BD-related carcinogenesis. Target organs for toxicity are not necessarily those for carcinogenicity. Other experimental findings are consistent with these observations. Studies in BD-exposed rodents have found concentration-dependent decreases in red blood cell counts, hemoglobin concentration, and other indicators of hematopoietic suppression. (Exs. 114, 32–38D, 23–12) There is also some suggestive evidence that workers exposed to BD at levels well below the current 1,000 ppm PEL exhibit hematological changes indicative of bone marrow depression. (Exs. 23–4, 2–28) Finally, many of the tumor types found in BD-exposed mice, including lymphocytic/hematopoietic cancer, lung cancer, mammary gland tumors, and possibly hemangiosarcomas, are tumors that are often found in association with exposure to other industrial chemicals known to cause lymphocytic/hematopoietic cancer in humans. Thus, OSHA finds that the body of scientific studies contained in the BD record, which includes well-conducted animal bioassays, human epidemiologic studies, and other experimental investigations, provides convincing evidence that BD is a probable human carcinogen.

This view is also held by other scientific organizations that have examined some or all of the same evidence. EPA considers BD to be a probable human carcinogen, and NIOSH regards BD as a potential occupational carcinogen and recommends controlling exposures to the lowest feasible level. In 1983, based on the findings of the first NTP bioassay alone, ACGIH classified BD as an animal carcinogen and, in the following year, recommended a new TLV of 10 ppm. In 1992, before the Delzell et al. study was released, IARC classified BD as a probable human carcinogen (Group 2A).

As discussed in the Quantitative Risk Assessment section, OSHA has selected the NTP II mouse bioassay for quantitative assessment of cancer risks for several reasons. Chief among these is that the NTP II study was conducted at BD concentrations that are representative of current exposure conditions and that the results demonstrated a strong dose-response relationship for several cancer sites. In addition, the study is of very high quality and pathology results from individual animals were available to the Agency, enabling OSHA to use a time-to-tumor model that could account for the early cancer-related deaths that occurred among the test animals (competing risks). OSHA also chose to base its risk estimates on the dose-response relationships for three cancer types: lung, ovarian, and lymphoma. The incidence of each was significantly elevated. It should be noted that pooling the total number of animals having any of these tumor types would have yielded risk estimates higher than OSHA's final values.

Because data were available on individual animals, including time of death, OSHA chose to use a Weibull time-to tumor form of the multistage model based on the biological assumption that cancer is induced by carcinogens through a series of events. This model has the advantage of accounting for competing risks.

The multistage model is most frequently used by OSHA; it is also a mechanistic model based on the biological assumption that cancer is induced by carcinogens through a series of independent stages. The model may be conservative, because it assumes no threshold for carcinogenesis and because it is approximately linear at low doses, although there are other plausible models of carcinogenesis which are more conservative. The Agency believes that the multistage model conforms most closely to what we know about the etiology of cancer, including the fact that linear-at-low-dose behavior is expected for exogenous agents, which increases the risk of cancer already posed by similar ''background'' processes. There is no evidence that the multistage model is biologically incorrect and abundant evidence supports its use, especially for genotoxic carcinogens, a category that most likely includes BD. OSHA's preference is consistent with the position of the Office of Science and Technology Policy of the Executive Office of the President, which recommends that ''when data and information are limited, and when much uncertainty exists regarding the mechanisms of carcinogenic action, models or procedures that incorporate low-dose linearity are preferred when compatible with limited information.'' (OSTP, Chemical Carcinogens: A Review of the Science and Its Associated Principles. Federal Register, March 14, 1985, p. 10379)

The BD record contained a great deal of commentary on the possible role of the principal epoxide metabolites of BD on the development of cancer in test animals, and on whether differences in BD metabolism, distribution, and excretion can explain the observed differences in cancer responses between BD-exposed mice and rats. In evaluating this information, OSHA explored the possibility of using a physiologically-based pharmacokinetic (PBPK) approach to estimate cancer risk among BD-exposed workers. In considering the use of PBPK modeling for estimating equivalent human dose in its final risk assessment for BD, OSHA considered several preselected criteria for judging whether the available data was adequate to permit OSHA to rely on a PBPK analysis in place of administered exposure levels. These are the same criteria that OSHA has recently used to rely on a PBPK-based analysis in its risk assessment of methylene chloride. The criteria included the following:

1. The predominant and all relevant minor metabolic pathways must be well described in several species, including humans.

2. The metabolism must be adequately modeled.

3. There must be strong empirical support for the putative mechanism of carcinogenesis.

4. The kinetics for the putative carcinogenic metabolic pathway must have been measured in test animals *in vivo* and *in vitro* and in corresponding human tissues at least *in vitro.*

5. The putative carcinogenic metabolic pathway must contain metabolites that are plausible proximate carcinogens.

6. The contribution to carcinogenesis via other pathways must be adequately modeled or ruled out as a factor.

7. The dose surrogate in target tissues used in PBPK modeling must correlate with tumor responses experienced by test animals.

8. All biochemical parameters specific to the compound, such as blood:air partition coefficients, must have been experimentally and reproducibly measured. This must especially be true for those parameters to which the PBPK model is sensitive.

9. The model must adequately describe experimentally measured physiological and biochemical phenomena.

10. The PBPK models must have been validated with other data (including human data) that were not used to construct the models.

11. There must be sufficient data, especially data from a broadly representative sample of humans, to assess uncertainty and variability in the PBPK modeling.

For the BD risk assessment, OSHA has chosen to use for animal-to-human dose equivalency mg/kg-day uptake based on the ppm exposure levels in the NTP II mouse study as the dose-metric.[7] While the body of data in the record leads OSHA to conclude that metabolism of BD to active metabolites is probably necessary for carcinogenicity, OSHA has chosen total body uptake rather than organ metabolic levels because the Agency was unable to determine from the record (a) which of the active metabolites are responsible for which observed tumors in the mice, (b) what the mouse and human metabolic equivalent doses were, (c) whether any of the PBPK models can successfully correlate with the tumor responses observed in mice and rats, and (d) whether local reactions in the mouse and human bone marrow were more important than total body burden.

[7] A dose metric is the way in which dose is expressed in describing a dose-response relationship. A dose metric may be expressed as an applied dose, such as ppm concentration or mg of intake per kg body weight, or as an internal dose, such as mg per gram wet weight of an organ or mg of total metabolite formed per kg body weight.

OSHA would have considered using BD metabolite body burden based on total human BD metabolites if the human chamber concentration data had been available, which would support estimating total human BD metabolism. Data of this type were available and used in OSHA's PBPK modeling for methylene chloride. In the absence of human chamber data or some better estimate of human equivalent dose, OSHA has chosen to use mg/kg-day BD uptake from the ppm inhalation exposure levels in the NTP II mouse bioassay as suitable for animal-to-human equivalency.

C. Material Impairment of Health

The 1 ppm 8-hour TWA PEL is designed to reduce cancer risks among exposed workers. As mentioned above and in the Health Effects section, some epidemiological studies indicate that the increased risk of leukemia posed by BD exposure may occur within a short period after initial exposure. (This is supported by the NTP mouse bioassays, in which there was high early mortality resulting from the development of BD-induced cancers, especially lymphomas.) Therefore, OSHA believes these hematopoietic cancers are likely to be fatal, will result in substantially shortened worker lifespans, and clearly represent ''material impairment of health'' as defined in the OSH Act and case law.

OSHA has also concluded that exposure to BD is associated with a potential risk of adverse reproductive effects in both males and females. This conclusion is based on the two NTP animal bioassays, which found testicular atrophy in male mice exposed to 625 ppm BD and ovarian atrophy in female mice exposed to BD concentrations as low as 6.25 ppm, as well as other animal studies that have reported dominant lethal effects (indicating a genotoxic effect on germ cells) and abnormal sperm morphology in BD-exposed male mice. (Exs. 23–74, 23–75, 117–1) There is also evidence that BD exposure is associated with fetotoxicity in mice, and a teratogenic effect indicative of a transplacentally induced somatic cell mutation was observed in one mouse study. (Exs. 2–32, 23–72, 126) OSHA believes that teratogenic effects and gonadal atrophy would also unambiguously constitute ''material impairment of health.'' Furthermore, although OSHA did not quantify reproductive risks that may be associated with exposure to BD, OSHA believes that reducing the 8-hour TWA PEL from 1,000 ppm to 1 ppm is likely to substantially reduce this risk.

D. Risk Estimates

OSHA's final estimate of excess cancer risks associated with exposure to 5 ppm BD (8-hour TWA) ranges from 11.2 to 59.4 per 1000, based on lymphomas, lung tumors and ovarian tumors seen in the NTP II mouse study (OSHA did not estimate the risks associated with exposure to the current PEL of 1,000 ppm, since workers are rarely, if ever, exposed to BD levels of that magnitude). Based on linear models the estimated risks at the new PEL of 1 ppm range from 1.3 to 8.1 per 1000, which represents a substantial reduction in risk from those associated with exposures to 5 ppm or greater.

OSHA's risk estimates for the 1 ppm PEL are similar in magnitude to, or lower than, most of the estimates contained in several risk assessments submitted to the BD record, which utilized a variety of models and dose metrics. Furthermore, NIOSH's quantitative assessment based on the Delzell et al. epidemiologic study of SBR workers yielded an estimate of 8 cancer deaths per 1,000 workers exposed to 1 ppm BD, a figure that is in close agreement with the upper end of the range of risks predicted by OSHA.

Risks greater than or equal to 10^{-3} (1 per 1,000) are clearly significant and the Agency deems them unacceptably high. OSHA concludes that the new BD standard substantially lowers risk but does not reduce risk below the level of insignificance. The estimated levels of risk at 1 ppm are 1.3 to 8.1 per 1000. The ancillary provisions including the exposure goal program will further reduce risk from exposure to BD.

E. ''Significant Risk'' Policy Issues

Further guidance for the Agency in evaluating significant risk and narrowing the million-fold range described in the ''Benzene Decision'' is provided by an examination of occupational risk rates, legislative intent, and the academic literature on ''acceptable risk'' issues. For example, in the high risk occupations of mining and quarrying, the average risk of death from an occupational injury or an acute occupationally-related illness over a lifetime of employment (45 years) is 15.1 per 1,000 workers. The typical occupational risk of deaths for all manufacturing industries is 1.98 per 1,000. Typical lifetime occupational risk of death in an occupation of relatively low risk, like retail trade, is 0.82 per 1,000. (These rates are averages derived from 1984–1986 Bureau of Labor Statistics data for employers with 11 or more employees, adjusted to 45 years of employment, for 50 weeks per year).

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Congress therefore gave OSHA authority to reduce significant risks when it is feasible to do so. Within this context, OSHA's final estimate of risk from occupational exposure to BD at levels of 2 ppm (2.5 to 16.2 deaths per 1,000 workers) or higher is substantially higher than other risks that OSHA has concluded are significant, is substantially higher than the risk of fatality in some high-risk occupations, and is substantially higher than the example presented by the Supreme Court in the benzene case. Moreover, a risk in the range of 1.3 to 8.1 per 1000 at 1 ppm is also clearly significant; therefore, the PEL must be set at least as low as the level of 1 ppm documented as feasible across all industries.

Because of technologic feasibility considerations, OSHA could not support promulgating a PEL below 1 ppm. However OSHA has integrated other protective provisions into the final standard to further reduce the risk of developing cancer among employees exposed to BD.

Based on OSHA's QRA, employees exposed to BD at the 8-hour TWA PEL limit, without the benefit of the supplementary provisions, would remain at significant risk of developing adverse health effects, so that inclusion of other protective provisions, such as medical surveillance and employee training, is both necessary and appropriate. The exposure goal program and action level trigger incorporated into the standard will encourage employers to lower exposures below 0.5 ppm to further reduce significant risk if it is feasible to do so in their workplaces. Consequently, the programs triggered by the action level will further decrease the incidence of disease beyond the predicted reductions attributable merely to a lower PEL.

As OSHA has explained, numerous issues arise in quantifying estimated risk to workers from BD. Such estimates are thus inherently uncertain; and, as more information becomes available, some of that uncertainty may be addressed and may substantially alter the risk estimate. Although OSHA believes the estimates fulfill its legal obligation to provide substantial evidence of significant risk the estimates should not be interpreted as a precise quantification of the cancer risk associated with the new PEL, or as demonstrated evidence of actual worker disease caused by BD.

OSHA's determination of significant risk is predicated, consistent with empirical evidence and the legal mandates of the OSHA Act, on determining the risk to a worker exposed to BD for a working lifetime (45 years) at the PEL. To the extent that future exposures to BD are (substantially) lower than 1 ppm, the estimated risks associated with those exposures will be (substantially) lower than the range presented in OSHA's QRA.

OSHA believes the final standard will reduce the risks of BD below those estimated using the mathematical model. The estimates of risk consider only exposures at the PEL, and do not take fully into account the other protective provisions of the standard such as medical surveillance, hazard communication, training, monitoring, and the exposure goal program. The decrease in risk to be achieved by additional provisions cannot be adequately quantified beyond a determination that they will add to the protection provided by the lower PEL alone. OSHA has determined that employers who fulfill the provisions of the standard as promulgated will provide protection for their employees from the hazards presented by occupational exposure to BD well beyond those which would be indicated solely by reduction of the PEL.

Furthermore, as discussed above and in the Health Effects section, there is evidence from the NTP bioassays that exposure to periodic high concentrations of BD may be associated with a higher cancer risk compared to an equivalent cumulative exposure administered over a longer time frame. OSHA has included a 5 ppm short-term exposure limit (STEL), averaged over 15 minutes, to provide protection to employees who are exposed to elevated BD concentrations during brief periods, such as in maintenance work.

As a result, OSHA concludes that its 8-hour TWA PEL of 1 ppm and associated action level (0.5 ppm) and STEL (5 ppm) will reduce significant risk and that employers who comply with the other provisions of the standard will be taking feasible, reasonable, and necessary steps to help protect their employees from the hazards of BD.

VIII. Summary of the Final Economic Analysis

As required by Executive Order 12866 and the Regulatory Flexibility Act of 1980 (as amended 1996), OSHA has prepared a Final Economic Analysis to accompany the final standard for occupational exposure to 1,3-butadiene (BD). (The entire analysis, with supporting appendix material, has been placed in the BD rulemaking docket. See Exhibit 137.) The purpose of the final economic analysis is to:

- Describe the need for a standard governing occupational exposure to 1,3-butadiene;
- Identify the establishments and industries potentially affected by the standard;
- Evaluate the costs, benefits, economic impacts and small business impacts of the standard on affected firms;
- Assess the technological and economic feasibility of the standard for affected establishments, industries, and small businesses; and
- Evaluate the availability of effective non-regulatory approaches to the problem of occupational exposure to 1,3-butadiene.

Need for the Standard

OSHA's final BD standard covers occupational exposures to this substance, a high-volume chemical used principally as a monomer in the manufacture of a wide range of synthetic rubber and plastic polymers and copolymers. In all, about 9,700 employees are estimated to be exposed to BD. However, for 2,100 of these employees in the petroleum refining industry, BD exposures are below the action level. The largest group of exposed workers is found in the BD end-product industry. Other BD operations in which workers are exposed are crude BD production, BD monomer production, and transportation terminals handling BD monomers (stand-alone terminals).

There is strong evidence that workplace exposure to BD poses an increased risk of cancer. Animal bioassays have shown BD to be a source of significant risk for tumors at multiple sites (i.e. lung tumors, heart hemangiosarcomas, lymphomas and ovarian tumors). BD may also potentially cause both male and female reproductive effects. To protect all BD-exposed workers from these adverse health effects, the final standard lowers the airborne concentration of BD to which workers may be exposed from the current permissible exposure limit (PEL) of 1,000 ppm as an 8-hour time-weighted average (8-hour TWA) to 1 ppm, and adds a short term exposure limit (STEL) of 5 ppm, measured over 15 minutes. (For a detailed discussion of the risks posed to workers from exposure to BD, see the Quantitative Risk Assessment and Significance of Risk sections of the preamble, above.)

OSHA's final BD standard is similar in format and content to other health standards issued under Section 6 (b)(5)

of the Act. In addition to PELs, the standard requires employers to monitor the exposures of workers; establish regulated areas when exposures may exceed one of these PELs; implement engineering and work practice controls to reduce employee exposures to BD; develop an exposure goal program; provide respiratory protection to supplement engineering controls where such controls are not feasible, are insufficient to meet the PELs, are necessary for short infrequent jobs, or in emergencies; provide medical screening; train workers about the hazards of BD (also required by OSHA's Hazard Communication Standard); and keep records relating to the BD standard. Recognizing that workers exposed to BD are at significant risk, an industry-labor working group joined together to develop joint recommendations for the final standard for BD. This group's recommendations form the basis for OSHA's final rule. The contents of the standard are explained briefly in Chapter I of the final economic analysis and in detail in the Summary and Explanation (Section X of the preamble, below).

Chapter II of the economic analysis describes the uses of BD and the industries in which such use occurs. Exposure to 1,3-butadiene occurs as a result of exposure to the monomer. Once BD is in polymer form, the exposure is minimal to non-existent. In all, OSHA analyzed 5 types of processes in which BD exposure occurs: crude BD production, where the feedstock for BD monomer is produced; BD monomer production, in which BD is refined from crude BD to a 99 percent pure monomer; BD product manufacture, where BD monomer is converted to various polymer products; stand-alone terminals, which receive, store and distribute BD monomer; and petroleum refineries, where BD may occur as an unwanted byproduct in some types of refining units. Table VIII–1 shows these industry operations and the number of workers affected by the final rule. A total of 255 facilities are estimated to be potentially affected by the standard. These establishments employ 9,700 workers who are estimated to be exposed to BD in the course of their work. The industry operation with the largest number of directly exposed employees is BD product manufacture, which has 6,500 exposed employees (over two-thirds of the total).

TABLE VIII–1.—INDUSTRY OPERATIONS AND NUMBER OF WORKERS AFFECTED BY THE FINAL RULE FOR 1,3-BUTADIENE

	Number of affected workers	Number of facilities in industry [a]
Crude 1,3-Butadiene Production	540	27
1,3-Butadiene Monomer Production	552	12
1,3-Butadiene Polymer Product Manufacture	6,461	[c] 71
Standard-Alone Terminals	50	5
Subtotal	7,603	115
Petroleum Refining Sector	[b] 2,100	140
Total	9,703	255

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis, 1996.

[a] Some facilities may fall under several industry sectors. For example, 9 monomer facilities are also crude producing facilities.

[b] Potential exposures to 1,3-butadiene are low and of extremely short duration in refining.

[c] Represents number of processes and not necessarily plants.

Chapter III of the analysis assesses the technological feasibility of the final standard's requirements, and particularly its PELs, for firms in the 5 industry operations with employee exposure identified in the Industry Profile. OSHA finds, based on an analysis of exposure data taken on workers performing the BD-related tasks identified for each operation, that compliance with the standard is technologically feasible for establishments in the industries studied. With few exceptions, employers will be able to achieve compliance with both PELs through the use of engineering controls and work practices. The few exceptions are maintenance activities, such as vessel cleaning, which have traditionally often involved the use of respiratory protection.

The exposure data relied on by OSHA in making its technological feasibility determinations were gathered by NIOSH in a series of site visits to plants in the affected industries. These data show that many facilities in the affected industries have already achieved the reductions in employee exposures required by the final rule. At least some workers in every job category work in facilities that have already achieved the PEL requirements. OSHA's analysis of technological feasibility evaluates employee exposures at the operation or task level to the extent that such data are available. In other words, the analysis identifies relevant exposure data on a job category-by-job category basis to permit the Agency to pinpoint those BD-exposed workers and job operations that are not yet under good process control and will thus need additional controls (including improved housekeeping, maintenance procedures, and employee work practices) to achieve compliance. Costs are then developed (in Chapter V of the economic analysis) for the improved controls needed to reach the new levels.

The benefits that will accrue to BD-exposed employees and their employers, and thus to society at large, are substantial and take a number of forms. Chapter IV of the analysis describes these benefits, both in quantitative and qualitative form. At the current baseline exposure levels to BD, the risk model estimates that 76 cancer deaths will be averted over a 45-year period. By reducing the total number of BD-related cancer deaths from 76 deaths to 17 deaths over 45 years, the standard is projected to save an average of 1.3 cancer deaths per year. Table VIII–2 shows these risk estimates. In addition to cancer deaths, the standard may prevent male and female reproductive effects.

TABLE VIII–2.—WORKER EXPOSURE TO BD AND LUNG CANCER RISK OVER 45 YEARS AT CURRENT EXPOSURE LEVELS AND LEVELS EXPECTED UNDER THE STANDARD

	8-hour time weighted average (ppm)							
	0–0.5	0.5–1.0	1	1.0–2.0	2.0–5.0	5.0–10.0	10+[c]	Total
Lifetime Excess Cancer Risk (per thousand workers)[a]	2.05	6.1	8.1	12.15	28.1	60	480	.....
Baseline Number of Workers Exposed	5697	354	156	598	320	440	38	7603
Estimated Excess Deaths in Baseline (Existing PEL)[b]	12	2	1	7	9	27	18	76
Predicted Number of Workers Exposed at New PEL	7177	426	0	0	0	0	0	7603

TABLE VIII–2.—WORKER EXPOSURE TO BD AND LUNG CANCER RISK OVER 45 YEARS AT CURRENT EXPOSURE LEVELS AND LEVELS EXPECTED UNDER THE STANDARD—Continued

	8-hour time weighted average (ppm)							
	0–0.5	0.5–1.0	1	1.0–2.0	2.0–5.0	5.0–10.0	10+[c]	Total
Predicted Excess Deaths at New PEL[b]	14	3	0	0	0	0	0	17

[a] Based on OSHA 1-stage Weibull time-to-tumor model for lung tumors.
[b] Computed as level of lifetime risk times the number of exposed workers.
[c] Based on a median exposure for these workers of 60 ppm.
Source: Office of Regulatory Analysis, OSHA; Department of Labor.

The costs employers in the affected industries are estimated to incur to comply with the standard total $2.9 million in 1996 dollars. These costs, which are presented in Chapter V, the full economic analysis, are annualized over a 10-year horizon at a discount rate of 7 percent. Table VIII–3 shows annualized costs by provision of the standard; the most costly provisions are those requiring engineering controls ($1.6 million per year) and respiratory protection ($0.7 million per year). Table VIII–4 analyzes compliance costs by operation and shows that BD products manufacture will incur over two-thirds of the standard's costs of compliance.

TABLE VIII–3.—ANNUAL COSTS OF THE FINAL BUTADIENE STANDARD, BY PROVISION

Provision	Annualized costs
Engineering Controls	$1,551,000
Exposure Goal Program	104,000
Respirators	685,000
Exposure Monitoring	364,000
Objective Data	3,000
Medical Surveillance	72,000
Leak and Spill Detection	27,000
Regulated Areas	4,000
Information and Training	12,000
Recordkeeping	29,000
Total	2,851,000

TABLE VIII–4.—ANNUAL COSTS OF THE FINAL BUTADIENE STANDARD, BY INDUSTRY SECTOR

Industry sector	Annualized costs
Crude Production	$333,000
Monomer	210,000
BD Products	2,252,000
Stand-Alone Terminals	53,000
Petroleum Refining	3,000
Total	2,851,000

Chapter VI of the economic analysis analyzes the impacts of compliance costs on firms in affected operations. The final rule is clearly economically feasible: annualized compliance costs are less than 0.5 percent of estimated sales in every industry and are less than 4 percent of profits in every industry (see Table VIII–5). Costs of this magnitude will not affect the viability even of marginal firms.

TABLE VIII–5.— ESTIMATED SALES AND PROFITS OF ESTABLISHMENTS AFFECTED BY THE 1,3–BUTADIENE RULE

	SIC	Sales per average establishment ($000)	Pre-tax profit per average establishment in SIC	Annualized cost per establishment	Cost as percentage of sales	Cost as percetage of profit
Crude 1,3–Butadiene Production	2869	$53,998	$5,645,237	$12,341	0.02	0.22
1,3–Butadiene Monomer Production	2869	53,998	5,645,237	17,502	0.03	0.31
1,3–Butadiene Product Production:						
—ABS Resins, Butadiene Copolymers (<50% butadiene)	2821	38,000	2,015,155	31,724	0.08	1.57
—Butadiene Copolymers (.50% butadiene), Neoprene, Nitrile Rubber, Chloroprene Rubbers, EPDM Polymers, Styrene-Butadiene Rubber (SBR Latex), Polybutadiene	2822	16,243	1,328,956	31,724	0.20	2.39
—Adipontrile/Hexamethylene	2869	53,998	5,645,237	31,724	0.06	0.56
—Fungicides	2879	42,694	1,681,885	31,724	0.07	1.89
Petroleum Refining	2911	525,273	19,100,851	22	Negligible	Negligible
Stand-Alone Terminals	4226	2,400	287,273	10,556	0.44	3.67

Source: US Department of Labor, OSHA, Office of Regulatory Analysis, 1996.
Negligible denotes less than 0.005 percent.

Under the Regulatory Flexibility Act, OSHA is required to determine whether its regulations have a significant impact on a substantial number of small entities. The small firm standards established by the U.S. Small Business Administration (SBA) for industries using 1,3-butadiene are as follows: 1,500 employees for firms in SIC 2911 (petroleum refining); 1,000 employees for firms in SICs 2869 (industrial organic chemicals, which includes BD crude and monomer producers) and 2822 (synthetic rubber); 750 employees for firms in SIC 2821 (plastic Table VIII–5 materials and resins); 500 employees for firms in SIC 2879 (agricultural chemicals, which includes some producers of BD products); and annual receipts of $18.5 million for firms in SIC 4226 (special warehousing and storage, which includes stand-alone terminals). Using these definitions, OSHA identified two small firms among crude

BD producers, one small firm among monomer producers, 10 small firms among BD product manufacturers, and no small firms among stand-alone terminals. Because the ownership of one stand-alone terminal could not be identified, OSHA assumed that there would be one small stand-alone terminal. For each of these industries, OSHA estimated revenues and costs for small firms based on the average size of the small firms using BD. The typical petroleum refining establishment has fewer than 1,500 employees. However, because OSHA did not have data on the number of firms with fewer than 1,500 employees, the Agency relied on establishment data to examine possible impacts on small petroleum refineries.

Table VIII–6 presents the results of the regulatory flexibility screening analysis and shows estimated compliance costs and economic impacts relative to revenues and pre-tax income for affected small businesses at the four-digit SIC code level. This approach reflects extreme case impacts because the impacts on small firms are analyzed using average per-establishment compliance costs. As shown in the table, compliance costs as a percentage of industry revenues never reach one percent; they range from less than 0.005 percent to 0.44 percent for establishments in all affected industries. Estimates of compliance costs as a percentage of profits range from less than 0.005 percent to 3.67 percent. Such impacts are not large enough to be significant. In addition, the impacts reflected in the table are likely to be overestimated because Table VIII–6 they are based on extreme-case costs.

TABLE VIII–6.—ESTIMATED SALES AND PROFITS OF ESTABLISHMENTS AFFECTED BY THE 1,3-BUTADIENE RULE

	SIC	Definition of small entity per the SBA	Average sales per small establishment ($million)	Pre-tax profit per small establishment in SIC	Annualized cost per establishment	Cost as percentage of sales	Cost as percentage of profit
Crude 1,3-Butadiene production	2869	1,000 employees ...	51.30	$5,363,182	$12,341	0.02	0.23
1,3-Butadiene Monomer production	2869	1,000 employees ...	10.60	1,108,182	17,502	0.17	1.58
1,3-Butadiene product production:							
ABS Resins, Butadiene Copolymers (<50% butadiene).	2821	750 employees	50.00	2,651,515	31,724	0.06	1.20
Butadiene Copolymers (.50% butadiene), Neoprene, Nitrile Rubber, Chloroprene Rubbers, EPDM Polymers Styrene-Butadiene Rubber (SBR Latex), Polybutadiene.	2822	1,000 employees ...	24.00	1,963,636	31,724	0.13	1.62
Adiponitrile/Hexamethylenediamine	2869	1,000 employees ...	10.60	1,108,182	31,724	0.30	2.86
Fungicides	2879	500 employees	30.40	1,197,578	31,724	0.10	2.65
Petroleum refining	2911	1,500 employees ...	45.80	1,655,455	22	Negligible	Negligible
Stand-alone terminals	4226	$18.5 million (receipts).	2.40	287,273	10,556	0.44	3.67

Source: US Department of Labor, OSHA, Office of Regulatory Analysis, 1996.
Negligible denotes less than 0.005 percent.

Thus, because this standard will not have a significant impact either on the smallest establishments (as defined by the SBA) or on the typical establishment in this industry, OSHA certifies that this final standard will not have a significant economic impact on a substantial number of small entities.

OSHA also examined the impact of this standard on increased expenditures by State, local or tribal governments. OSHA found that none of the affected employers were State, local, or tribal governments. Further, since the total costs of the standard are $2.8 million, the stand will not increase expenditures for the private sector by more than $100 million. As a result, OSHA certifies that, for the purposes of the Unfunded Mandates Reform Act of 1995, as well as E.O. 12875, this rule does not include any federal mandate that may result in increased expenditures by State, local and tribal governments, or increased expenditures by the private sector of more than $100 million.

IX. Environmental Impacts

In accordance with the National Environmental Policy Act (NEPA), OSHA has reviewed this standard for occupational exposure to BD and determined that this action will have no significant impact on the external environment. The new standard can be achieved through a combination of engineering controls, work practices, and respirator use in maintenance situations. OSHA reviewed the extent to which any of the engineering controls or work practices might have an environmental impact. OSHA found that these controls will have no significant adverse impact on the eternal environment because no additional solid waste would be contaminated with BD and that any new releases to the external atmosphere would constitute an insignificant increase in emissions. Indeed, most of the recommended controls would prove advantageous from an environmental viewpoint. For example, such controls as replacing slip-tube gauges with magnetic gauges, use of closed loop sampling systems, and the use of dual mechanical seals all serve to reduce both worker exposures and emissions to the environment. Other controls, such as exhaust ventilation in laboratories, leave environmental emissions unchanged.

Based on its review, OSHA concludes that there will be no significant impact on the environment external to the work place as a result of the promulgation of this standard.

X. Summary and Explanation of the Final Standard

OSHA has determined that the requirements set forth in this final standard are those which, based on currently available data, are necessary and appropriate to provide adequate protection to employees exposed to BD. In the development of this standard, OSHA carefully considered the comments received in the docket in response to the proposed rule as well as information received in the BD docket by OSHA since initiation of this

rulemaking. OSHA believes that these provisions are, in large part, similar to the requirements recommended by the labor/industry group in the recent reopening of the BD rulemaking record. (Ex. 118–12A)

A. Scope and Application

The final rule covers all occupational exposure to 1,3-butadiene, with certain exceptions which are described below. OSHA does not believe there are any impacts in construction or maritime employment, but, consistent with OSHA's policy, the standard is being made applicable to these sectors to avoid gaps in coverage and to protect workers in unusual circumstances. Coverage in longshoring and marine terminals would only be triggered if BD is present outside sealed intact containers.

The final rule contains three exemptions from the scope and application; all three exemptions are typically included in OSHA chemical-specific health standards. These exemptions address situations in which the Agency has concluded that the likelihood of significant exposure is quite low. The final rule's exemptions are as follows:

(a)(2)(i) Except for the recordkeeping provisions in paragraph (m)(1), this section does not apply to processing, use, or handling of products containing BD or to other work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate that the work operation or the product or the group of products or operations to which it belongs may not reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under either the expected conditions of processing, use, or handling that will cause the greatest possible release or in any plausible accident.

(a)(2)(ii) This section also does not apply to work operations, products or streams where the only exposure to BD is from liquid mixtures containing 0.1% or less of BD by volume or the vapors released from such liquids, unless objective data become available that show that airborne concentrations can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release.

(a)(2)(iii) Except for labeling requirements and requirements for emergency response, this section also does not apply to storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid.

The language of this section, with a single exception, reflects the joint recommendations of the labor-industry group. The exception relates to the suggested language in the labor/industry agreement ''or in any credible accident'' at the end of paragraph (a)(2)(i).[8] (Ex. 118–12A) OSHA believes that this phrase lacks clarity and has chosen to use the word ''plausible'' instead of ''credible'' to better convey the Agency's intent. Dow Chemical Company, which reviewed a draft of the Agreement, objected to the use of the phrase ''credible accident'' because Dow personnel were unsure of its meaning. (Ex. 118–16, p. 3) Additionally, OSHA has modified the definition of objective data to more clearly delineate its intended source and use.

Although the agreement itself offered little explanation for each of the recommended exemptions, the submission of CMA, a participant in the joint discussions, sheds some light on the issue of why the term ''credible accident'' was included. They felt that the ''focus in applying the (objective data) exemption should be on reasonably predictable conditions of processing, use or handling associated with each product, stream or work operation.'' (Ex. 118–13, p. 3) CMA said that the addition of the phrase ''credible accident'' was meant to trigger only the emergency response requirements of the standard when objective data demonstrate that exposures may reasonably be foreseen to exceed the action level or STEL during a ''credible accident.''

OSHA believes that the phrase ''credible accident'' is unnecessary because paragraph (a)(2)(i) already states that objective data may be used to address situations that can reasonably be foreseen. However, OSHA has decided to include the phrase ''any plausible accident'' to stress the point that the objective data criteria are not intended to be so circumscribed that it is impossible to meet them. OSHA acknowledges that a constellation of unforeseen circumstances can occur that might lead to exposure above the action level or STEL even when the objective data demonstration has been correctly made, but believes that such occurrences will be rare. OSHA further believes that compliance with other regulations, such as the Process Safety Management standard (29 CFR 1910.119), will provide additional assurance that such accidents will not occur.

OSHA proposed to exempt ''processing, use, or handling of products containing BD where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release * * *'' (55 FR 32736 at 32803) The proposed regulation also included a requirement that the employer keep the data supporting the exemption as long as such data were relied upon.

Roger Daniel of the CMA BD panel objected to the requirement that in order to be relied upon as objective data, the data must reflect include the ''greatest possible release.'' He argued that ''* * * to verify the greatest possible release and thereby obtain an exemption, employers could be forced to conduct extensive worst case analyses for every product.'' (Ex. 112, p. 133)

OSHA agrees that a worst-case demonstration for each product is not necessary to qualify for this exemption under the ''objective data'' provision of the scope and application paragraph of the standard. Due to concern that the proposed language might be overly difficult to interpret, OSHA has modified the language in the standard to reflect this and added a definition of the term ''objective data.'' The definition now states that ''objective data means monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.'' The exemption allows use of objective data, and states that when objective data are used to exempt employers from the BD standard, the data must demonstrate that the work may not ''reasonably be foreseen'' to release BD above the action level or the STEL.

The objective data may be, at least partially, comprised of monitoring results. For example, data collected by a trade association from its members that meet the definition of objective data may be used. However, a single employer's initial monitoring results would not be sufficient to meet the criteria for objective data under this standard (see discussion of objective data in Definitions section of this preamble). A showing by initial monitoring that the level of BD is below the action level does greatly reduce the responsibilities of the employer; however, it would not support an

[8] This section does not apply to processing, use, or handling of products containing BD or to other work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate that the work operation or the product or the group of products or operations to which it belongs may no reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under either the expected conditions of processing, use, or handling that will cause the greatest possible release or in *any credible accident.*

exemption from the standard. Instead, to qualify as objective data, OSHA means employers' reliance on manufacturers' worst case studies, laboratory studies, and other research that demonstrate, usually by means of exposure data, that meaningful exposures cannot occur. Paragraph (a)(3) requires that all such data be maintained by the employer as long as they are relied upon to support the exemption.

In comments received during the recent re-opening of the record, Total Petroleum suggested that objective data be kept as long as they are relied upon and for 5 years thereafter. (Ex. 118–5) However, OSHA believes that keeping these data for as long as they are used is a better use of resources, and this requirement is included in the final rule.

OSHA has allowed the use of objective data in past standards to exempt employers from initial monitoring requirements and hence, from most of the provisions of these standards, e.g., formaldehyde 29 CFR 1910.1048, asbestos 29 CFR 1926.1101. The American Petroleum Institute (API) and others voiced support for this approach. (Ex. 108; 112)

The objective data definition is discussed more extensively in the definition section of this preamble.

The following paragraphs deal with the comments and testimony received during the rulemaking on topics related to the scope and application of the standard. Some of these comments would appear to address both the objective data exemption and an exemption for materials containing less than 0.1% BD. This is due, in part, to the fact that the proposal did not contain an exemption for the latter materials, and commenters objected to having to make a demonstration using objective data that materials containing less than 0.1% BD would not release BD at levels in excess of the action level or STEL in order to be exempted. OSHA has reexamined the issue and has included the 0.1% BD cutoff in the final rule paragraph (a)(2)(ii).

Crude Oil and Refinery Products

Oil refiners indicated that BD is absent from crude oil, and requested that OSHA explicitly exempt oil and gas well drilling, production and servicing operations, and transportation of crude oil from the standard. (Ex. 108; 109; 91) They also indicated that, although BD may be an undesirable intermediate by-product with trace quantities in enclosed streams in modern petroleum refinery processes, BD is normally destroyed, so it would not be present in refined products, such as gasoline, motor fuel, or other fuels. They asked for an exemption for those refined products.

A site visit report was submitted to the rulemaking record by OSHA's contractor, Kearney/Centaur, which described the processes at a refinery. (Ex. 23–119) The site visit report contained the following conclusions:

> The concentrations of 1,3-butadiene in the process streams studied rarely if ever exceed 2500 ppm. * * * The contents of the streams are released to the atmosphere only in extremely small quantities through sampling, or by significant spills, leaks or accidents. * * * Employees are rarely in close proximity to the sampling points or any other potential release point. * * * Monitoring data show that exposures are well below the proposed limits, below the actions levels and even below measurable levels in most cases. (Ex. 23–119)

Based on these comments and data in the docket, OSHA has included the exemption for ''streams'' containing less than 0.1% BD, such as those found in refineries, and in the final rule has included streams among the items for which an objective data exemption can be claimed.

Polymers

Duke Power asked OSHA to exempt finished BD polymer from the BD standard to be consistent with the vinyl chloride and acrylonitrile standards, so that the utility would not need to maintain records of objective data. (Ex. 32–12) The Rubber Manufacturers Association (RMA) said that ''synthetic rubbers made from polymerized BD are used extensively by (their 200 companies) members in manufacturing a wide range of these rubber products.'' (Ex. 32–13). In the preamble to the proposal, OSHA acknowledged that ''[i]t is likely that in a number of products made from, containing or treated with BD, there may be insignificant residual BD present to the extent that minimal exposure would be expected.'' (55 FR 32736 at 32787) RMA indicated that four studies indicated the levels of BD in the samples from their plants range from 4 ppb to 0.2 ppm. These values are clearly well below the 0.1% cutoff in the final rule and the percentage exemption would therefore apply.

Intact Containers

Exxon Chemical Company, a producer of BD, which ships it by several modes of transportation (ship, barge, tankcar, tanktruck and pipeline) indicated that there is no potential for BD exposure since BD-containing streams are totally contained in pressurized equipment during transportation. (Ex. 32–17) Exxon said: ''The developing and maintaining the 'objective' data would be very cumbersome (for many carriers and shipment points and various kinds of BD-containing streams) * * * time-consuming and would not contribute to reduced exposure.'' Exxon asked OSHA to provide a general exemption for intact transportation containers. The Independent Liquid Terminals Association (ILTA), whose members own or lease facilities in which BD is stored, asked OSHA to establish a concentration cutoff and to grant reasonable exemptions from the standard. (Ex. 32–18) Roger Daniel of the CMA panel made a similar request. (Tr. 1/18/91, p. 1174) The labor-industry agreement also recommended exemption of intact containers and pipelines from the standard except for labeling and emergency provisions. (Ex. 119)

OSHA is allowing the exemption of ''storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid,'' OSHA is not excluding by this exemption, the situation where BD-containing material is being transferred to or from containers, pipelines, or vehicles. Data have shown that there is a potential for significant exposure to BD during these operations. For example, exposure data indicate high potential exposure during unloading of railcars and tank trucks in both monomer and polymer production facilities. (Ex. 30) Such operations are not exempt from the standard-they are not considered ''sealed'' for purposes of this standard and do not ''fully contain BD vapors or liquid.''

Mixtures of Less Than 0.1% BD

The final rule contains a specific, though qualified, exemption for instances where materials containing less than 0.1% BD are present.

In the proposal, OSHA discussed the application of the Hazard Communication Standard (29 CFR 1910.1200) to materials containing less than 0.1% of BD, a carcinogen, but did not specifically include an exemption for these materials.

Jack Hinton of Texaco, representative of API, which represents over 250 companies involved in all aspects of the petroleum industry, indicated that

> * * * many petroleum streams and products will have little or no BD present (and that) much of the petroleum industry, such as production, transportation and marketing operations would qualify for these case-by-case exemptions. (Ex. 74; Tr.2/20/91, p.1842–44).

Since the ''objective data'' obligation could impose a burden on their

industry, Mr. Hinton urged OSHA to expand the exemption to include the processing, use and handling of streams containing BD, as well as products. (Tr. 2/20/91, pp. 1842–44)

Similarly, CMA stated, ''* * * facilities that manufacture, process or use BD often have very extensive, integrated operations.'' (Ex. 32–28, p. 108; Ex. 112, p. 134) At these facilities, BD is found at quantities below 0.1% not just in the immediate area of BD production, but in many other streams and products as well. Under these circumstances, the burden of generating ''objective data'' which would qualify for the exemption would be ''so enormous as to largely eliminate its value.'' (Ex. 112, p. 134).

Exxon Chemical Company also indicated that ''BD is present in a large number of product and intermediate streams throughout chemical plants and refineries.'' (Ex. 32–17) According to Exxon, there is very little exposure potential at low levels, since precautions are taken to contain these flammable materials and its rapid dispersion as a gas at ambient condition. Exxon suggested an exemption for product and intermediate streams containing less than 0.1 percent BD ''as is used in the Hazard Communication Standard and in the Benzene Standard.'' They claimed that their resources to develop ''objective data'' could be devoted to ''more productive activities aimed at exposure reduction.'' Arco Products Company stated that ''potential exposures are of extremely short duration in the refining business'' and asked for the exemption of ''streams with less than 0.1% as in the benzene final standard.'' (Ex. 32–20)

OSHA has found that, on the basis of the record and comments of participants in the rulemaking, as well as the recommendations of the labor/industry group, the exemptions as stated above are justified. The criteria for each exemption are helpful in assuring that only very low exposure to BD is possible when the exemptions apply.

The exemptions from the scope of the standard closely resemble those in the benzene standard. The exclusion of products containing less than 0.1 percent BD is consistent with the Hazard Communication Standard, which has this as a cutoff for application of certain requirements to carcinogens (paragraph (a)(2)(ii)).

The basis for the exemptions for sealed containers and pipelines containing mixtures with more than 0.1 percent BD is that it is unlikely for such containers and pipelines to leak sufficient BD to expose employees over the action level on a regular basis. Further, sealed containers and pipelines with liquids containing more than 0.1 percent BD are covered by the emergency provisions of the standard (e.g., personal protective equipment, medical screening). Sealed containers and pipelines are also covered by the Hazard Communication Standard, 29 CFR 1910.1200. If the containers or pipelines contain more than 0.1 percent BD, employers are required to: label the containers and pipelines to indicate that they contain BD, a carcinogen; to have employee training specifying what to do if the container was opened or broken; and to supply employees with material safety data sheets. Labeling and training provisions of the Hazard Communication Standard provide protection in normal situations where a container or pipeline breaks so that employees will know how to handle and clean up the material safely. The emergency provisions of the Hazardous Waste and Emergency Response Standard would cover emergency situations caused by major releases.

Further, operations where the containers and pipelines are opened or the chemicals contained in them are used are covered because of the possibility of exposure above the action level or PELs. It should be noted that while the Hazard Communication Standard generally exempts materials containing less than 0.1 percent of a carcinogen, any material containing BD (defined as a potential carcinogen in this standard) that is capable of causing exposure above the action level is covered even if the 0.1 percent exemption applies. Specifically this provision states:

> If the chemical manufacturer, importer or employer has evidence to indicate that a component present in the mixture in concentrations of less than one per cent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees in those concentrations, the mixture shall be assumed to present the same hazard. (29 CFR 1910.1200(d)(5)(iv))

OSHA also notes that a similar provision is included in the standard for DBCP (1,2-dibromo-3-chloropropane). (29 CFR 1910.1044).

B. Definitions

Action level means airborne concentration of BD of 0.5 ppm calculated as an eight (8)-hour time-weighted average (TWA). OSHA has determined that the final PEL for BD is 1 ppm and the final action level for BD is one half that level, 0.5 ppm. OSHA notes that this is the action level recommended in the Labor-Industry Joint Recommendations. (Ex. 119)

Due to the variable nature of employee exposures to airborne concentrations of BD, an action level provides a means by which the employer may have greater assurance that employees will not be exposed to BD over the PEL on days when measurements are not taken.

The action level also increases the cost-effectiveness and performance orientation of the standard while improving employee protection. Employers who can, in a cost-effective manner, develop innovative methodology to reduce exposures below the action level will be encouraged to do so in order to save on the expenses for the monitoring and medical surveillance provisions of the standard. Their employees will be further protected because their exposures will be less than half of the permissible exposure limit. They will also avoid the need to implement controls specified under paragraph (g) of this section, Exposure Goal Program.

The statistical basis for using an ''action level'' has been discussed in connection with several other OSHA health standards (see, for example, acrylonitrile (29 CFR § 1910.1045; 43 FR 45809 (1978)). In brief, the standard does not require the employer to monitor employee exposure on a daily basis. This would be prohibitively expensive. Use of the action level is a method that gives the employer confidence that if employees are exposed to less than the action level on days when measurements are taken, they are most likely not exposed over the PEL on days when no measurements are taken—all other factors being equal. Where exposure measurements are above the action level, the employer cannot reasonably be confident that the employee may not be overexposed. Therefore, requiring periodic employee exposure measurements to be made where exposures are at or above the action level provides the employer with a reasonable degree of confidence that employee exposures have been adequately characterized. (Ex. 23–59)

Use of the action level concept will result in the necessary inclusion of employees under this standard whose exposures are above the action level and for whom further protection is warranted. The action level mechanism will also greatly limit the percentage of workplaces covered under the standard because employers whose employees are under the action level will be exempt from most provisions of the standard. The action level concept,

therefore, provides an objective means of tailoring different sections of the standard to those employees who are at the greatest risk of developing adverse health effects from exposure to BD.

Unique to the BD standard is paragraph (g), Exposure Goal Program, which is also triggered at the action level. This program, which OSHA included at the recommendation of the Labor/Industry group, is described further in the Summary and Explanation of paragraph (g).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures, or any other person authorized by the Act or regulations issued under the Act. Due to the highly hazardous nature of BD exposure, the number of persons designated as authorized should be limited, insofar as possible.

Business day is newly defined in the final rule as any Monday through Friday, except those days designated as federal, state, local or company holidays. (Ex. 18–12A) This term is used in the paragraph dealing with employee notification of monitoring results, (d)(7), in which OSHA had proposed that notification occur within 15 working days after the receipt of monitoring results. The joint labor/industry group recommended 5 business days instead. In addition, they recommended that the notification of the corrective action being taken when monitoring results indicate exposures in excess of the PELs be required within 15 business days, (paragraph (d)(7)(ii)). OSHA has accepted the recommendations because it is protective of workers. As a general rule, OSHA health standards require notification within 15 days of receipt of results. Quicker notification is, of course, desirable, but feasibility considerations usually make the 15-day period the shortest practical. However, in this case, the parties agreed that 5-day notification is feasible and desirable and OSHA wholeheartedly endorses the concept.

OSHA has also allowed 15 business days between medical evaluations and notification of employees of their results. This change was recommended by the labor/industry agreement and was not proposed by OSHA in 1990. OSHA believes that the requirement of paragraph (j)(7) requiring that written notification of the medical opinion be provided by the employer within 15 business days of the examination or other medical evaluation is reasonable and adequately protective of worker health.

1,3–Butadiene means an organic compound with chemical formula $CH_2=CH-CH=CH_2$ which has a molecular weight of 54.15 gm/mole. Its Chemical Abstracts Registry Number is 106–99–0. The definition was needlessly lengthy in the proposal and has been shortened.

OSHA has added a definition for the *complete blood count* required in the medical screening and surveillance section. Because the definition may vary, OSHA believes that a definition which includes each component of what the Agency requires to be included in a *complete* blood count is needed. These components (which are laboratory tests performed on whole blood specimens) are: White blood cell count (WBC), hematocrit (Hct), red blood cell count (RBC), hemoglobin (Hgb), differential count of white blood cells, red blood cell morphology, red blood cell indices, and platelet count.

Day means any part of a calendar day. Therefore, if a requirement is applicable to an employer whose employee is exposed to BD on 10 days in a calendar year, that requirement is applicable if the employee is exposed to BD for any part of each of 10 calendar days in a year.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee. This definition remains unchanged from that in the proposal.

OSHA proposed that *Emergency situation* would mean an occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in a substantial release of BD that could cause employee exposures that greatly exceed the PELs.

The provisions that the employer must comply with in case of an emergency situation include Respiratory Protection, Medical Screening and Surveillance, and Employee Information and Training. As is also the case in the benzene standard, OSHA does not intend that every leak will automatically constitute an emergency situation. The exposure must be high and unexpected. Thus, the nature of the emergency provisions is performance-oriented and relies upon judgement, for it is not possible to specify detailed circumstances which constitute an emergency.

In objecting to the proposed definition of emergency, Shell noted that ''a release does not necessarily equate to high employee exposure.'' (Ex. 32–27) OSHA also sought additional guidance in its definition of ''emergency;'' when the record was re-opened for comment on the labor/industry draft agreement, OSHA raised the issue by presenting a revised definition for comment. This was:

> * * * any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

The revised definition changed the conditions of release to qualify as an emergency from ''unexpected'' to ''uncontrolled'' to more clearly define what the agency considered to be an emergency situation which would trigger specific provisions of the standard (e.g., respirator use, limited medical screening and surveillance). OSHA asked whether the change provided adequate guidance to the public. Relatively few commenters dealt specifically with this issue. However, Bridgestone/Firestone, Inc. stated that ''* * * a controlled release, even in significant quantities, is not an emergency precisely because it can be controlled.'' (Ex. 118–14, p. 5) They recommended that OSHA define what constitutes a significant release as an ''uncontrolled release of BD that presents serious danger to employees in the workplace,'' noting that OSHA defined catastrophic release in 29 CFR 1910.119 as one posing a ''serious danger to employees.'' Bridgestone/Firestone feared that defining emergency as proposed might result in application of it to situations which are ''lawful, safe and managed by the standard through respirator use.'' (Ex. 118–14, p. 6)

Dow Chemical Company also submitted comments in support of defining emergency in terms of ''uncontrolled significant release of BD'' because of its consistency with other standards. (Ex. 118–16, p. 3)

Akzo Nobel Chemicals, Inc. suggested that the definition of an emergency should be:

> An uncontrolled dangerous event due to a combination of unforeseen circumstances, such as the spill of significant quantities of hazardous substances, fire or explosion, massive failure of equipment/personnel or other occurrences which require an immediate response by persons not working in the immediate area, except maintenance activities and which could result in harmful

exposures during hazardous activities, fires or explosions. (Ex. 118–3)

They also expressed the belief that use of the term ''uncontrolled'' is essential to the definition of an emergency, and that ''daily, foreseeable events are not emergencies.'' Azko Nobel gave, as an example, the rupture of a container, which they felt would constitute an emergency ''only when a dangerous amount of material escaped.'' Akzo Nobel felt that the definition of emergency should also depend on the type of responder needed to deal with the situation—that ''if the responders are persons outside the work area (other than maintenance type personnel) that fact suggests that an emergency is occurring.'' Akzo Nobel believes the definition of emergency must be tied to the amount of hazardous material released and the exposure resulting from it.

All these comments in general support OSHA's revised definition. Therefore, OSHA is adopting the revised definition for the reasons stated in the comments.

Employee exposure means exposure to airborne BD which would occur if the employee were not using respiratory protection. This definition is intended to apply to all variations of the term ''employee exposure'' that have essentially the same meaning, such as ''exposed employee'' and ''exposure.'' The definition is consistent with OSHA's previous use of the term ''employee exposure'' in other health standards (Asbestos, 29 CFR 1910.1001; Benzene, 29 CFR 1910.1028; Ethylene Oxide, 29 CFR 1910.1047; Cadmium, 29 CFR 1910.1027).

Objective data are redefined in the final rule to clarify and better define what OSHA believes they entail. Objective data are defined as:

> monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.

In the proposed rule, the term ''objective data'' was used to provide an exemption from the scope and application of the rule and was not specifically defined in the definition section.[9]

There appeared to be some confusion as to what was meant by objective data as presented in the proposal. OSHA has determined that a specific definition of objective data is necessary, and it has included it in the definition section.

OSHA believes that objective data may include such data as: (1) Information provided by the manufacturer or a determination that air concentrations will not exceed the action level or STEL, under foreseeable conditions of use, based on the information provided by the manufacturer; (2) representative data or collective industry data which are relevant to the materials, process streams, and products for which the exemption is being documented, under foreseeable conditions of use.

Charles Adkins, then Director of OSHA's Health Standards Programs Directorate, explained at the hearing that ''. . . you are allowed to make a calculation to determine whether or not you need to do monitoring or not. . . . If you're below the action level, you do not need to do anything.'' (Tr. 1/15/91, pp. 29–31) Indeed, to qualify for an exemption does not necessarily ''. . . have to be actual data collected or experimental data. . . . (The employer) . . . can make . . . appropriate calculations, and if he can support his calculation, that would be considered part of his objective data.'' (Tr. 1/15/91, p. 30)

The definition of objective data contained in the final rule adopts the one contained in the Labor-Industry Joint Recommendations. (Ex. 119) OSHA believes that such a definition meets the intent of the proposal. While OSHA does not require employers to perform complex modeling to avail themselves of the objective data exemption, it should be noted that there may be times when it would be difficult or inappropriate to attempt to use objective data. This issue was discussed in the formaldehyde standard, wherein the Agency stated that complex modeling exercises may not be a substitute for employee exposure monitoring

> . . . in workplaces where many complex factors must be considered to use objective data, a high degree of uncertainty will be associated with trying to assess employee exposure from objective data. In these instances employers should conduct exposure monitoring instead of relying on objective data so that they can have confidence that they are in compliance with the standard's provisions. (52 FR 46100, 46255–46256, 12/4/87)

However, if carefully used in appropriate circumstances, OSHA believes that objective data may be useful in minimizing needless exposure monitoring.

Permissible Exposure Limits, PELs means either the 8 hour Time Weighted Average (8-hr TWA) exposure or the Short-Term Exposure Limit (STEL). The two limits are often referred to as PELs in various documents and this definition clarifies what is meant by ''PELs.''

Physician or Other Licensed Health Care Professional has been incorporated into the standard's medical screening and surveillance provisions to include persons certified, registered, or licensed to perform various activities required by the standard. OSHA's authority does not supersede a state's right to license, register, or certify individuals to perform these tasks. Therefore, in the final rule, OSHA has replaced the word ''physician'' with the phrase ''physician or other licensed health care professional'' to allow individuals to perform duties under the provisions of the standard which they are permitted to perform in their jurisdiction through their licensure, registration, or certification.

Regulated area means an area where airborne concentrations of BD exceed or can reasonably be expected to exceed the permissible exposure limits. The definition of regulated areas in the final rule is the same as the proposed definition. Texaco was concerned that the phrase ''can reasonably be expected'' is open to varied interpretations or could be misunderstood, and recommended that regulated areas be required only where exposure monitoring indicates that air concentrations of BD are above the PELs. (Ex. 32–26) OSHA believes workers will be better protected where a regulated area is required even if one of the PELs is not exceeded at all times. The specific requirements for a regulated area are discussed in the summary and explanation for paragraph (e) below.

This section is newly defined in the final rule to clarify that this term is synonymous with the 1,3-Butadiene Final Rule.

C. Permissible Exposure Limits

Since 1970, the PEL for 1,3-butadiene has been 1,000 parts per million (ppm) as an 8-hour TWA. The final rule reduces the permissible exposure limits to 1 ppm as an 8-hour time-weighted average (TWA) and to 5 ppm as a 15-minute short-term exposure limit (STEL). As part of this rulemaking, OSHA is deleting from Table Z–2 of 29 CFR 1910.1000 the exposure limit of 1000 ppm as an 8-hour TWA for BD. OSHA has determined that the former PEL presented a significant risk of cancer to employees exposed to BD and

[9] This section does not apply to the processing, use or handling of products containing BD where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release. (55 FR 32803)

that compliance with the new standard will substantially reduce that risk. The basis for the 8-hour TWA–PEL and STEL is discussed in the sections of this preamble dealing with health effects, risk assessment, significance of risk, and in the economic analysis. This section briefly summarizes some of that discussion.

As discussed earlier in the Health Effects section, in the NTP bioassays, mice exposed to BD via inhalation developed cancer at multiple sites. When these data were used to estimate risk via a quantitative risk assessment, the data indicated that risk at the former PEL was quite high and should be lowered. In addition, epidemiologic studies of BD-exposed worker groups have suggested that BD induced leukemia in a dose responsive manner. In the proposal, OSHA's preliminary risk assessment found its ''best'' estimate of risk, derived from the female mouse heart hemangiosarcoma data using the multistage model, predicted 147 excess deaths per 1,000 workers at the former PEL of 1,000 ppm.

In 1990 OSHA proposed a PEL of 2 ppm as an 8-hour TWA and 10 ppm as a short-term limit, based in part on its preliminary risk assessment, which estimated an excess cancer risk of 5.1 per 1,000 workers at the proposed PEL of 2 ppm. As discussed earlier in this preamble, economic and technologic feasibility considerations led OSHA to propose a PEL of 2 ppm, although the preliminary risk assessment estimated that there was still significant remaining risk at that level of BD. As discussed in the Quantitative Risk Assessment section, OSHA used a more recent lower dose NTP mouse study to estimate risk. That estimate using lung cancer in female mice, the most sensitive cancer site in the most sensitive species, was 8.1 excess cancers per 1,000 workers exposed to 1 ppm BD over a 45-year working lifetime (the estimate at 2 ppm for this site was 16.2 lung cancers per 1,000 workers).

In light of the need to reduce the significant residual risk remaining at a PEL of 2 ppm, OSHA determined that it must reevaluate the record evidence to assure that significant risk is reduced to the extent feasible. This review, discussed at length earlier in this preamble, has led OSHA to conclude that an 8-hour time-weighted average permissible exposure limit of 1 ppm is both feasible and is needed to further protect worker health.

Throughout this rulemaking there was consensus that the existing PEL adopted by OSHA in 1971, 1,000 ppm, which ACGIH had developed as a TLV for BD to prevent irritation and narcosis, was inadequate to protect workers from the hazard presented by this chemical (e.g., IISRP, Ex. 34–4, CMA Ex. 32–28, American Lung Association, Ex. 32–10). However, there was *not* unanimity as to the appropriate level. OSHA's expert witness, Dr. Philip Landrigan, stated the following:

> * * * I was distressed to see that in setting the PEL at two parts per million that you decided to accept the occurrence of five excess deaths per thousand exposed workers which translates to 5,000 excess deaths per million exposed workers. It seems to me that this is not consistent with optimal practice and if the agency has a chance to reconsider that risk assessment and possibly lower the standard from the proposed PEL of two parts per million, I certainly would like to ask you to reconsider. * * * Five thousand cancer deaths seems like a lot to me. (Tr. 1/15/91, p. 204)

In testimony and submissions to the rulemaking record, NIOSH recommended that the permissible exposure level be set at the lowest feasible levels and recommended 6 parts per billion on the basis of its assessment of risk. (Ex. 32–25, Tr. 1/17/91, p. 681) NIOSH's quantitative risk assessment was based on NTP's lower dose mouse study and application of a time-to-tumor model (see Quantitative Risk Assessment and Ex. 90). Although some of the underlying assumptions made by NIOSH in its analysis differ from those OSHA has used in a subsequent time-to-tumor analysis, the level of risk estimated by NIOSH further contributed to OSHA's concern regarding the level of risk estimated to remain at the proposed PEL of 2 ppm.

Other risk assessments were submitted which yielded lower estimates of risk. (Shell Oil Company, Ex. 32–27; CMA, 28–14) Each of the risk assessments in the record is discussed in the section of this preamble dealing with the quantitative risk assessment.

At the time of the public hearings, industry representatives opposed lowering the PEL below 2 ppm. For example, participants from Shell stated that they had already ''set an internal standard at 2 ppm,'' and felt a lower level would not increase employee protection. (Shell, Ex. 32–27, 34–7) This was echoed in the comments of styrene-butadiene latex manufacturers. (Ex. 34–5) In fact, IISRP felt that a 10 ppm PEL was low enough to eliminate significant risk. They described the difficulties the polymer industry anticipated at lower PELS. (Ex. 34–4, 32–33)

Labor representatives, particularly the United Rubber Workers, and supporters, among them: Irving Selikoff, Cesare Maltoni, Sheldon Samuels, Myron Mehlman, and Louis Beliczky, urged OSHA to adopt a PEL of 0.2 ppm. (Ex 32–1, 34–6) Diane Factor, representing the AFL–CIO, said that ''OSHA must conduct an analysis that attempts to show feasibility below 2 ppm and not stop at the industry acceptable level.'' (Tr. 1/17/91, p. 839)

Dr. Myron Mehlman, Professor of Environmental and Community Medicine at UMDNJ, Robert Wood Johnson Medical School, New Jersey, testifying on behalf of the United Rubber, Cork, Linoleum and Plastic Workers of America, AFL–CIO, and the Sierra Club, stated his opinion that a PEL of 2 ppm was ''dangerously high.'' (Ex. 79) He urged OSHA to ''adopt a 0.05 to 2 ppm PEL and 0.2 to 1 ppm STEL to protect the health of workers and the environment. (Tr. 2/20/91, p. 1776) The Department of Health Services, State of California, performed a quantitative risk assessment using the NTP–I mouse study data and urged OSHA to ''* * * consider the feasibility of adopting 1 ppm or a lower level.'' (Ex. 32–16)

The issues raised by participants and OSHA's concern about the level of risk remaining at the 2 ppm PEL led OSHA to conclude that further scrutiny and re-analysis of the record data were necessary and prudent to assure that the limit set by the Agency is that which is reasonably necessary and appropriate and that reduces significant risk to the extent feasible, particularly in view of the high degree of carcinogenicity of BD.

Joint Recommendations of Labor/Industry Group Regarding PELs

The March 1996 industry/labor agreement recommended that OSHA adopt a PEL of 1 ppm and a STEL of 5 ppm (also an action level of 0.5 ppm). OSHA is pleased that this group of interested parties have reached the same conclusion as the Agency in this regard. The joint recommendations suggest a STEL of 5 ppm, but questioned whether the record would support this STEL. IISRP nonetheless agreed that the PELs included in the recommendation are feasible in view of the fact that the final rule allows the use of respirators in intermittent, short-duration work. OSHA's own analysis also shows that a 1 ppm TWA and 5 ppm STEL are technologically and economically feasible and necessary to substantially reduce significant risk of material impairment of health. (See the extensive discussions in the health effects, risk assessment, significant risk and feasibility sections.) Therefore, OSHA is promulgating these limits in its final rule for BD.

Short-Term Exposure Limit (STEL)

The proposed STEL was five times the proposed PEL, 10 ppm. The final rule includes a STEL which is five times the new 8-hour TWA limit, or 5 ppm.

The choice of the level of the STEL was a concern to a number of rulemaking participants. The CMA Butadiene Panel did not feel a STEL was needed at all and strongly objected to its being lower than 10 ppm. (Ex. 32–28) The SB latex manufacturers expressed a similar view. (Ex. 34–5) CMA alleged that the STEL provision lacked a legal basis and that the analyses on which OSHA based its proposed STEL were flawed. (Ex. 32–28) Others objected to the STEL on the basis that BD lacked acute health effects. (Ex. 32–19; 32–26; 32–27; 32–33; 60)

A major labor participant in the rulemaking, URW, urged OSHA to adopt a lower STEL of 1 ppm. (Ex. 34–6) As Kenneth Cross stated in his testimony for URW,

''Based on more recent toxicological, medical and epidemiological data, some of which was unavailable to OSHA when it sent its proposed standard to OMB about two years ago, the URW feels more secure with a 0.2 part per million PEL and one part per million STEL.'' (Tr. 2/20/91, p. 1750)

OSHA's expert witness, Dr. Ronald L. Melnick of NTP, presented data suggesting that a STEL will reduce risk. He performed a ''stop-exposure'' study that he described as follows:

Groups of 50 male mice were exposed to one of the following regimens: (a) 625 ppm for 13 weeks; (b) 200 ppm for 40 weeks; (c) 625 for 26 weeks; or (d) 312 ppm for 52 weeks. After the exposures were terminated, these groups of animals were placed in control chambers for the remainder of the 104 week studies * * * Survival was markedly reduced in all of the stop-exposure groups due to the development of related malignant tumors. The tumor incidence profiles in the * * * groups show that lymphocytic lymphomas, hemangiosarcomas of the heart, alveolar-bronchiolar neoplasms, forestomach squamous cell neoplasms, Harderian gland neoplasms, and preputial gland neoplasms were increased compared with controls even after only 13 weeks of exposure to 625 ppm * * * at comparable total exposures, the incidence of lymphocytic lymphoma was greater with exposure to a higher concentration of 1,3-butadiene for a short time compared with exposure to a lower concentration for an extended duration. (Ex. 42)

Dr. Melnick concluded as follows:

The stop-exposure studies show that multiple organ site neoplasia occurs in mice after only 13 weeks of exposure to 1,3-butadiene. It is likely that shorter exposure durations would also produce a positive carcinogenic response * * * the stop-exposure studies show that *the concentration of 1,3-butadiene is a much greater contributing factor than is the duration of exposure* [emphasis added]. (Ex. 42, p. 17)

Industry representatives objected in particular to using the thymic lymphomas induced in the mouse due to the potential role of an endogenous retrovirus in eliciting this response, and more generally, to the use of this study as the basis for imposing a STEL. (e.g., Exs. 112, 113) In its post-hearing comments, the CMA 1,3–Butadiene Panel stated:

The relevance of these studies to an assessment of the human cancer risks from 15-minute exposures to butadiene at levels up to 64 ppm (the highest exposure that would be consistent with an 8-hour TWA of 2 ppm) is highly doubtful. This is particularly the case where: (1) A dose-rate effect is evident in mice only for lymphomas and only at high exposure concentrations; (2) the MuLV retrovirus is known to be a significant factor in BD-induced lymphomas in the $B_6C_3F_1$ mouse; (3) the lymphomas do not appear to play a significant role in BD-induced carcinogenicity in the * * * mouse at the lower levels of exposure of interest to OSHA * * * (4) there is no evidence that concentration is more important than duration of exposure for any other tumor type.

NIOSH disagreed, and objected to OSHA's omission of the lymphomas from the quantitative risk assessment provided in the proposal. NIOSH stated:

OSHA's justification for eliminating these tumors was that lymphomas may be related to the presence of an endogenous leukemia virus in the $B_6C_3F_1$ mouse used in the NTP bioassay. The endogenous leukemia virus should have increased the background rate of lymphoma in both the control and exposed animals, and thus the potential confounding effect of this virus was controlled for in OSHA's risk assessment. It is still possible that the increased lymphoma incidence observed in the * * * mouse was related to an interaction between the virus and 1,3-butadiene. However, OSHA also cites evidence that a similar lymphoma response was observed in a study of NIH-Swiss mice exposed to BD, and indicated that this strain of mice is not known to carry the leukemia virus * * * (Ex. 32–25, p. 4)

NIOSH also cited evidence that retroviruses may be associated with certain leukemias and lymphomas in humans and pointed out that ''even if 1,3-butadiene interacts with a leukemia virus, a similar mechanism might conceivably be involved in producing tumors'' in exposed workers. (Ex. 32–25, p. 5) OSHA agrees with the opinion expressed by NIOSH and rejects industry's arguments that the observations in the ''stop-exposure'' study are irrelevant.

Some further support for a STEL comes from a recent report describing analysis of an epidemiologic study of BD-exposed workers entitled ''A Follow-up Study of Synthetic Rubber Workers'' by Delzell et al. (Ex.117–1) One part of this study pertains to the risk of leukemia in workers exposed to BD in what the authors termed ''peak-years.'' Peak years are estimates of the number of times per year a worker was exposed above 100 ppm (a peak) during 15 minute periods. This estimate was then multiplied by 225, the number of workdays in a year. This value was used as a variable in Poisson regression analysis. There was an association between peak-years and leukemia risk, even after controlling for BD ppm-years (cumulative BD exposure) as well as other covariates. The relationship was said to be ''irregular'' since the risk ratios were 1.0, 2.6 and 0.8 for BD peak-years categories of 0, >0–199 and 200+, respectively. The underlying reason for the lack of a dose-response is unclear; however, the finding of a statistically significant elevation in relative risk for peak exposure, even when total cumulative exposure is accounted for, is of concern and appears to support the need to control peak exposures.

OSHA further notes that the basis for adopting a STEL does not rest solely on the points raised above; in 1986, the US Court of Appeals for DC reviewed OSHA's ethylene oxide standard, which did not contain a STEL. (*Public Citizen Health Research Group* v. *Tyson,* 796 F2d, D.C. Cir., 1986). The reason given by OSHA for not including a short-term limit in the ethylene oxide standard was that a dose-rate effect had not been demonstrated by record data. The Court held that the OSH Act compels the Agency to adopt a short term limit if the rulemaking record shows that it would further reduce a significant health risk and is feasible to implement regardless of whether the record supports a ''dose-rate'' effect (796 F. 2nd at 1505). This decision states that

If in fact a STEL would further reduce a significant health risk and is feasible to implement, then the OSH Act *compels* the agency to adopt it (barring alternative avenues to the same result). OSHA *shall* set the standard which most adequately assures, to the extent feasible, on the basis of best available evidence, that no employee will suffer material impairment of health.'' (29 U.S.C. 655(b)(5) (1982)) Since OSHA has found that a significant health hazard remains even with the 1 ppm PEL, the agency must find either that a STEL would have no effect on that risk or that a STEL is not feasible. (796 F.2d 1479 (D.C. Cir. 1986))

Without a STEL, employees could have exposures to BD as high as 32 ppm, albeit for short periods (15 minutes). Since many workers experience intermittent exposure to BD,

for example, during sampling, transport and laboratory work, imposing an 8-hour limit alone would not control these higher peak exposures. The STEL by controlling such peak exposures, will reduce total cumulative dose, thereby reducing significant risk further, as stated by the Court. In addition, properly installed and maintained engineering controls should prevent high variability in exposures generally. As a general rule, it is good industrial hygiene policy to control excessive variabilities as a STEL will do.

OSHA has concluded that the adoption of a 5 ppm STEL for BD is appropriate to further reduce the significant residual risk of cancer that remains from exposure to BD at the revised TWA PEL of 1 ppm. In addition, there is some evidence of a dose-rate effect as described above. Specifically: (a) The ''stop-exposure'' study of Melnick which demonstrated that ''at comparable total exposures, the incidence of lymphoma was greater with exposure to a higher concentration of BD for a short time compared with exposure to a lower concentration for an extended duration'' (Ex. 114, p. 125); (b) although a retrovirus in $B6C3F_1$ mice likely played a role in the induction of thymic lymphoma, the fact that BD exposure in another strain of mouse that did not express the virus also developed the same type of cancer, strongly suggests that BD induced this tumor very early after exposure; and, (c) the suggestive data from the cohort study of Delzell et al., indicating the importance of ''peak-year'' exposure to risk of leukemia.

D. Exposure Monitoring

Section 6(b)(7) of the OSH Act (29 U.S.C. 655) mandates that any standard promulgated under section 6(b) shall, where appropriate, ''provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees.'' The purposes of requiring air sampling for employee exposure to BD include the prevention of overexposure of employees; the determination of the extent of exposure at the worksite; the identification of the source of exposure to BD; and collection of exposure data by which the employer can select the proper control methods to be used to reduce exposure and to evaluate the effectiveness of the control methods selected. Monitoring helps employers to meet the legal obligation of the standard to assure that their employees are not exposed to BD in excess of the permissible exposure levels, and to be able to notify employees of their exposure levels. In addition, collection of exposure monitoring data enables the examining physician to be informed of employee exposure levels, which may be useful in forming the physician's medical opinion (see paragraph (k)).

Many provisions of the final rule are quite similar to those proposed. However, some felt that clearer or more concise language should be used. Thus, the specific language of the exposure monitoring provisions varies somewhat from that of the proposal. Moreover, additional modifications have been made, as appropriate, in response to record information and recommendations contained in the record.

The final rule does not require that exposure monitoring be performed wherever BD is present. Under certain circumstances, outlined in the scope and application (paragraph (a) of this section), objective data may be used in lieu of the monitoring required by paragraph (d) of the final rule.

In the final rule, as in other standards, various provisions of the standard are triggered if an employee is exposed above the action level, and are not required if the employee is exposed below the action level. Thus the importance of correctly determining employee exposure cannot be over emphasized.

Paragraph (d)(1) requires the employer to determine the exposure for each employee exposed to BD. This does not mean that separate measurements for each employee must be taken but rather that the rule allows this obligation to be fulfilled by determining ''representative employee exposure.'' Paragraph (d)(1)(I) requires that samples collected to fulfill this requirement be taken within the employee's breathing zone (also known as ''personal breathing zone samples'' or ''personal samples''). (Area sampling is required under the standard only following emergencies.) The samples used to determine whether an employee is exposed above the action level must represent the employee's exposure to airborne concentrations of BD over an eight-hour period without regard to the use of respirators (See ''Employee exposure'', as defined in the definitions section).

In certain circumstances sampling each employee's exposure to BD may be required for initial monitoring. However, in many cases, the employer under paragraph (d)(1) may monitor selected employees to determine ''representative employee exposures.'' Representative exposure sampling is permitted when there are a number of employees performing essentially the same job, with BD exposures of similar durations and magnitude, under essentially the same conditions. Where there are groups of employees whose job functions are similar, OSHA permits the use of representative monitoring to characterize employee exposures to enable the employer to design a cost-effective monitoring program. In designing a representative monitoring plan, OSHA intends that employers select a sufficient number of employees within a group of employees who are engaged in similar work for sampling such that their exposures adequately characterize the exposures of all employees within the group. In addition, the employees who are judged as likely to have the highest exposures to BD within the group should be selected for monitoring to ensure that exposures of the remaining employees in the group are not underestimated. Although the employer is free to use formal statistical approaches for characterizing the exposures of a group of similarly exposed employees, OSHA does not require such approaches be used, and allows the employer to use professional judgement to select employees for monitoring and for attributing exposure results to employees whose exposures were not measured. The rationale for designing the representative monitoring plan and for selecting employees whose exposures were monitored can be retained as part of the exposure monitoring records required to be maintained by the employer under paragraph (l)(2) of the final rule.

To measure representative 8-hour TWA exposures, at least full-shift sampling must be conducted for each job function in each job classification, in each work area, and for each shift (paragraph (d)(1)(ii)). At least one sample covering the entire shift, or consecutive representative samples taken over the duration of the shift, must be taken. Representative 15-minute short-term employee exposures are to be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the short term exposure limit for each shift for each job classification in each work area (paragraph (d)(1)(iii)).

To eliminate unnecessary monitoring and improve the cost-effectiveness of the standard, paragraph (d)(1)(iv) also allows employers who can document that exposure levels are the same for similar operations during different work shifts to sample only the shift for which the highest exposures are expected to

occur. The employer must be able to demonstrate that employees on the shifts who are not monitored are not likely to have exposures higher than those of employees on the shifts monitored.

Paragraph (d)(2) requires all employers who have a place of employment covered under the scope of this standard to perform initial monitoring for their employees. In addition, the final standard requires that the initial monitoring be conducted within 60 days of the effective date of the final standard or the introduction of BD into the work place. This effective date provision (proposed paragraph (d)(2)(ii)) has been moved to the paragraph containing the other start-up dates, paragraph (m)(2)(I). Although Dow in a recent submission expressed concerns that additional time might be needed to set up an exposure monitoring program, OSHA believes that initial monitoring can be completed within the allowed period of time. (Ex. 118–16) The parties to the labor/industry agreement also recommended a start-up date for the initial monitoring under the standard of 60 days from the effective date. (Ex. 118–12A) Additional flexibility is provided in paragraph (d)(2)(ii), in that monitoring data collected up to two years prior to the effective date may be relied upon as initial monitoring data, provided that it has been collected in accordance with the requirements of this paragraph.

The employer is required to perform initial monitoring of employee exposures to BD where objective data are not available to satisfy the condition for exemption. If the results of initial monitoring indicate employee exposures are below the action level, the employer may discontinue monitoring for those employees and is relieved of some other obligations under the final rule (e.g., medical surveillance, use of personal protective equipment, development of an exposure goal program, establishment of regulated areas). Thus, the employer can focus attention and resources on employees whose exposures are more significant. Therefore, even if operations are not specifically exempted from the proposal, keeping exposure levels below the 0.5 ppm ''action level'' will relieve employers from some duties under the standard. A similar approach is used in a number of OSHA standards (acrylonitrile, 29 CFR 1910.1045; arsenic, 29 CFR 1910.1018; ethylene oxide, 29 CFR 1910.1047).

Paragraph (d)(2)(ii) of the proposal has been modified as shown in paragraph (d)(1)(ii) in the final rule to allow monitoring data produced within 2 years prior to the effective date of the standard to be relied upon to satisfy the initial monitoring requirement. OSHA had proposed a one year limit on the use of this grand-fathered monitoring data, but at the suggestion of a number of participants in the rulemaking and the labor/industry agreement, OSHA has agreed that allowing a two year period is reasonable for this standard. (Ex. 112; 113; 118–12) Dow Chemical Company in comments on a draft of the labor/industry joint recommendations asked that OSHA allow the use of data which are over two years old to serve as initial monitoring data. (Ex. 118–16) Dow said that such data ''that are consistent with current data reflecting no process changes that might have increased exposure over the time period of interest'' should be included as initial monitoring data. OSHA believes that expanding the period to two years allows adequate latitude to the employer in determining the need for initial monitoring.

In addition, the final rule now more clearly states what OSHA means by conditions under which historical monitoring data may not be used and initial monitoring is required. Rather than stating that historical data may be used only if the conditions under which the monitoring was conducted ''remain unchanged,'' it now states that the conditions ''* * * have not changed in a manner that may result in new or additional exposures.'' This language was recommended by the labor/industry group and has been found acceptable and OSHA believes that it more clearly articulates its intent than the corresponding provision in the proposal; therefore it is included in the final rule. (Ex. 118–12A) However, OSHA notes that employers will likely wish to monitor following installation of controls to determine their effectiveness.

Paragraph (d)(3) describes the requirement for periodic monitoring and its frequency. CMA suggested that the OSHA BD standard should have the same monitoring frequency as OSHA's benzene standard. (Ex. 112) The initial submission of the labor/industry group recommended that OSHA require more extensive sampling than the Agency had proposed to qualify as initial monitoring and establish a baseline. Specifically the group recommendation stated:

> Establish a baseline of at least 8 samples. The samples may be taken in a single year, so long as at least one sample is taken in each quarter, and no two are taken within 30 days of each other. The employer may utilize monitoring data from the previous two years to satisfy the initial monitoring requirement as long as process has been consistent. (Ex. 119)

The labor/industry group also recommended less frequent periodic monitoring than the quarterly monitoring OSHA proposed when exposures exceeded the PELs. The labor/industry group recommended:

> After the baseline has been established, monitoring is * * * every 6 months if exposure exceeds PEL or STEL * * * Annually if exposure is at or above the AL [action level] but below the PEL. (Ex. 119)

In the Federal Register notice re-opening the record, OSHA raised its concerns as follows:

> OSHA is concerned that the taking of 8 samples to establish a baseline may not be an effective use of scarce industrial hygiene resources in that the number of samples taken may be far less important than the quality of the samples used to characterize the exposure of BD employees. Are there other ways to improve OSHA's traditional approach of monitoring at least the one most exposed employee in each job classification on each shift? (61 FR 9381, 9383, 3/8/960)

In its submission, Texas Petro Chemicals objected to the 8 sample baseline because they said that they do not have BD exposure for four quarters of the year and do not monitor in winter due to ''high mobility'' of their employees during the winter and the ''strong potential for samples to be invalid'' due to problems with the sampling devices during bad weather. (Ex. 118–6) Dow Chemical Company objected to specification of the number of sampling events and the schedule suggested by the agreement. Dow felt this did not allow the employer adequate flexibility in evaluating employee exposures. (Ex. 118–16, p. 4) Hampshire Chemical Corporation felt that it was unclear what was meant by the 8 baseline samples described in the notice. (Ex. 118–8) The American Petroleum Institute expressed its preference for a more performance-oriented approach to exposure monitoring strategies. (Ex. 118–11)

In comments of the Chemical Manufacturers Association, who participated in the labor/industry discussion resulting in the agreement, the following view was expressed:

> The parties to the negotiations have revisited the exposure monitoring provisions. The agreement's monitoring scheme now would follow OSHA's traditional requirement for initial representative monitoring to detect job classifications where the action level is exceeded * * * It is only the periodic monitoring that is required where there are exceedances that could involve the taking of eight samples * * * After this periodic monitoring had been completed, additional periodic monitoring would occur at the

frequency proposed * * * sampling could be terminated when there are two consecutive low measurements. (Ex. 118–13, p. 4–5)

Similar comments were received from the International Institute of Synthetic Rubber Producers, Inc. (Ex. 118–12, p. 4)

The labor/industry agreement was more fully discussed by the group in a submission received during the period when the record was re-opened for comment. (Ex. 118–12) Numerous modifications to OSHA's proposed provisions for an exposure monitoring program for BD were endorsed by the group. (Ex. 119) Primarily these dealt with the sampling strategy. OSHA has carefully evaluated the suggested changes and has, for the most part, included them in the final rule.

The periodic monitoring paragraphs have been modified upon the basis of the record and the recommendations of the labor/industry group. Paragraph (d)(3) states that ''If the monitoring required by (d)(2) of this section reveals exposure at or above the action level but at or below both the 8-hr TWA and the STEL, the employer shall repeat the representative monitoring required by paragraph (d)(1) every twelve months.'' OSHA proposed that such monitoring be repeated at least every six months. However, OSHA believes that the additional monitoring[10] required in the final rule for those whose BD levels remain above the PELs will compensate for less frequent periodic monitoring in situations where the level is likely to remain lower. It must be noted here that additional monitoring requirements are triggered whenever there is a change in process or personnel which may result in new or additional exposures to BD. A similar schedule for periodic monitoring is required in the benzene standard. (29 CFR 1910.1028)

The results of initial monitoring represent the data which will be used to determine when further periodic monitoring will be required. If the initial monitoring of employees reveals exposures that are between the action level and the 8-hour TWA, then the employer must repeat monitoring annually (paragraph (d)(3)(I)). While these employees have been shown to be exposed to levels of BD below the 8-hour TWA, their levels of exposures are not so far below the PELs that monitoring could safely be discontinued. Even minor changes in engineering controls or work practices could result in exposures increasing to levels above the PEL. Remonitoring on an annual basis will enable the employer to be confident that the controls are working or, in the event exposures are shown to exceed the 8-hour TWA, will alert the employer as to the need for additional controls, and for changes to a more frequent monitoring program.

The draft regulatory text submitted by the labor/industry group recommended marked changes to paragraph (d)(3) (ii) and (iii) which OSHA believes will provide even greater protection to workers than that proposed by the Agency in 1990. (Ex. 118–12A)

The requirements in paragraphs (d)(3) (ii) and (iii) of the final rule provide for periodic monitoring in situations in which either the 8-hr TWA or STEL is exceeded to be carried out quarterly ''until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period * * * after which such monitoring must occur at least every 6 months.'' However, if the monitoring result indicates that exposure is below the action level as indicated by 2 consecutive samples taken at least 7 days apart, monitoring may cease unless the conditions change, (see (d)(5)). A single low sampling result is inadequate to allow monitoring to terminate; for various reasons, it may be artifactually low perhaps due to process changes during the time of sampling. OSHA believes that such differences are unlikely to persist for more than a week and has determined that this period is minimal to assure that exposures are truly low enough for the employer to stop monitoring.

Paragraph (d)(3)(iv) has also been modified to allow less frequent monitoring when the initial monitoring results exceed either PEL, but two consecutive subsequent samples taken at least 7 days apart indicate that BD levels no longer exceed either PEL but remain above the action level. In this situation, monitoring is required annually. OSHA proposed that such monitoring take place every six months.

OSHA believes that although this approach differs from the Agency's usual approach to monitoring, it will meet the need for determining the level of BD exposure in the workplace and will focus on situations having higher exposure potential. The conditions of use of BD in production and manufacturing present exposure patterns that are more likely to be predicted by initial monitoring than is the case for some of the other substances OSHA has regulated, such as asbestos, where exposures primarily occur during disturbing or removing the material in various forms. OSHA agrees that monitoring carried out as scheduled in the agreement is more likely to reflect the ''true'' exposure level in a workplace than monitoring at a single point in time. OSHA notes, however, as is the case in other standards, the sampling must be performed according to provisions of the standard—i.e., they must be personal samples, representative of each shift and job, etc.

If exposures are above the 8-hour TWA limit, then the employer must remonitor every six months. If the employee's exposure is above the STEL, the employee shall repeat such monitoring at least every six months until the employee's exposure falls to or below the STEL. If, in subsequent monitoring, results indicate that an employee's exposure, as determined by two consecutive measurements taken at least seven days apart, falls from above the 8-hour TWA to between the 8-hour TWA and the action level, then monitoring need only be done annually, unless production changes lead to higher exposures. Similarly, when two consecutive measurements indicate that the exposure has dropped below the action level, further monitoring can be discontinued.

Paragraph (d)(4) allows employers to terminate monitoring for those employees whose initial monitoring results are below the action level. When the two consecutive exposure measurements (paragraph (d)(3)), taken at least seven days apart, indicate that exposure has dropped below the action level, further monitoring for these employees can be discontinued, unless production changes lead to higher exposures. OSHA recognizes that monitoring may be a time-consuming, expensive endeavor and therefore offers employers the incentive to be allowed to discontinue monitoring for employees whose sampling results indicate exposures below the action level. The intent of this provision is to allow the employer to stop monitoring employees whose exposure to BD falls below the action level. OSHA believes that this provision will encourage employers to keep exposures to BD below the action level in their workplaces, thereby keeping exposures to a minimum and saving employers the time and expense of monitoring. Moreover, employers will also benefit because most of the other requirements of the standard are not triggered when exposures are below the action level.

Employees will continue to be protected from excess BD exposure,

[10] If the monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the 8-hour TWA (or STEL), the employer shall repeat the representative monitoring required by paragraph (d)(1)(ii) (or d(1)(iii)) at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

even after periodic monitoring has ceased, because of the requirements in paragraph (d)(5) (additional monitoring). Additional monitoring is required by paragraph (d)(5)(i) when there has been a process or production change or a change in control equipment, personnel or work practices which may result in new or additional exposures to BD. When the employer suspects a change which may result in new or additional BD exposure, the employer is obligated to obtain new employee exposure measurements. Instead of listing or trying to define every situation where the employer must monitor for new or additional exposures to BD, OSHA intends by this provision that employers will institute this additional monitoring when the employer has any reason to suspect a change. It should be noted that since the PEL and action level are relatively low, even a small change in production procedures may cause employees whose exposures were below the action level to have exposures that are above the PELs.

Paragraph (d)(5)(ii) requires additional monitoring to be conducted whenever leaks, ruptures or other breakdowns occur. Such occurrences can result in very high exposures. After the clean-up or repair of the leak, employers must re-determine airborne exposure levels for those employees who may be exposed at their worksites. These additional exposure measurements provide a good method of ascertaining that proper corrective methods have been effective and employee exposures are not significantly altered from what they were prior to the leak or spill.

In commenting on the requirement to do additional monitoring after leaks or breakdowns, BP felt that ''This requirement seems arbitrary since BD is volatile and will rapidly dissipate, especially if the leak is outdoors.'' (Ex. 32–8) CMA suggested OSHA delete the requirement to ''repeat the monitoring which is required by paragraph (d)(2)(I)'' and instead require employers to ''monitor (using personal or area monitoring as appropriate) after the clean up of the spill or repair of the leak, rupture or other breakdown to insure that exposures have returned to the level that existed prior to the incident.'' (Ex. 112) The labor/industry group recommended a similar change which OSHA has determined to be appropriately protective. Paragraph (d)(5)(ii) of the final rule states:

> Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the 8-hour TWA limit or above the STEL, the employer shall monitor (using leak source (e.g., direct reading instruments), area or personal monitoring, as appropriate) after the cleanup of the spill or repair of the leak, rupture or other breakdown to ensure that exposures have returned to the level that existed prior to the incident.

OSHA believes that this provision will allow the employer greater flexibility in deciding whether additional monitoring is necessary and to determine whether the level of BD in the workplace has returned to low levels following such incidents. OSHA further notes that since the odor threshold for BD is very near the permissible limits, if the odor is detected, then a release has occurred and monitoring must take place to assure that exposure has returned to a level below the action level. OSHA recognizes that not every worker will recognize the odor of BD at a specific concentration in air.

Paragraph (d)(6) requires employers to use monitoring and analytical methods which have an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for airborne concentrations of BD above a PEL and within plus or minus 35% for airborne concentrations of BD at or above the action level and below the TWA limit of 1 ppm. Methods of measurement are presently available to detect BD to this accuracy level (±25% or ±35%) at levels of 0.155 ppm. One such method is described in Appendix D.

Sampling and analysis may be performed by portable direct- reading instruments, real-time continuous monitoring systems, passive dosimeters or other suitable methods. Employers have the obligation to select a monitoring method which meets the accuracy and precision requirements of the standard under the unique conditions which exist at the worksite.

Paragraph (d)(7)(i) further requires that employers notify each of their employees in writing, either individually or by posting in an appropriate location accessible to affected employees, the results of personal monitoring samples. OSHA proposed that the employer do this within 15 working days after the receipt of the results. However, the labor/industry agreement recommended a period of 5 business days for the notification by the employer to take place. (Exs. 119, 118–12a) OSHA agrees that this will provide information to the employee in a more expedient way. The quicker notification takes place, the better. Evidence indicates that this industry can comply with a shorter, and more desirable, time period. (Ex. 118–12A)

When exposures over the PEL occur, paragraph (d)(7)(ii) requires the employer to notify affected employees in writing of what corrective action is being taken to lower exposure to BD to below the PEL, and to inform the employee of the schedule to complete this action. Such notification must be completed within 15 business days of the employer's receipt of the sampling results. (See paragraph (b) for the definition of ''business day.'') The requirement to inform employees of the corrective actions the employer is going to take to reduce the exposure level to below the PELs is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required by section 8(c)(3) of the Act. Mandating the schedule for the completion of such activities is needed so that the employee can be informed when to expect correction of the situation and the employee can be assured that corrective action will take place in a specified time frame.

Paragraph (d)(8) requires employers to allow employees or their designated representatives an opportunity to observe employee exposure monitoring. This provision is also required by section 8(c)(3) of the OSH Act. The proposed rule contained this provision in a separate paragraph (paragraph (l)), however, in developing the final rule, OSHA determined that observation of monitoring more logically belonged in the paragraph dealing with exposure monitoring and has included it in paragraph (d).

E. Regulated Areas

Paragraph (e) (1) of the final rule requires employers to designate areas in which occupational exposures to BD exceed or can reasonably be expected to exceed the PELs as ''regulated areas.'' In response to comments, the wording of this requirement was made consistent with the definition of ''regulated area'' used in the standard. (Exs. 32–26; 32–27; 32–28) A similar recommendation was made by the labor/industry group. (Ex. 118–12A)

The purpose of a regulated area is to ensure that employers make employees aware of the presence of BD in the workplace at levels above either of the PELs, and to limit access to these areas to as few employees as possible. The establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to pose a risk of material impairment of health or functional capacity. Because of the serious nature of the outcome of possible exposure to BD and the need for persons entering the area to be provided with properly fitted respirators, the number of persons given

access to the area must be limited to the employees needed to perform the work in the area.

Paragraphs (e)(2) and (e)(3) are identical to the proposed paragraphs. Paragraph (e)(2) limits access to regulated areas to authorized persons. This provision makes clear that exposure over the PEL triggers the need for a regulated area, but that inadvertent releases which are covered under paragraph (i), Emergency Situations, would not trigger the requirement for a regulated area.

Consistent with the performance orientation of the standard, paragraph (e)(3) does not specify how employers are to demarcate their regulated areas. Factors that the Agency believes are appropriate for employers to consider in determining how to mark their areas include consideration of the configuration of the area, whether the regulated area is permanent, the airborne BD concentration, the number of employees in adjacent areas, and the period of time the area is expected to have exposure levels above the PEL. Permitting employers to choose how best to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on their knowledge of the specific conditions of their workplaces.

Paragraph (e)(4) requires that whenever an employer at a multi-employer worksite establishes a regulated area he or she must communicate effectively the location and access restrictions pertaining to the regulated area to other employers with work operations at the worksite. Such communication will lessen the possibility that unauthorized persons will enter the area or that workers not involved in BD-related operations will be inadvertently exposed. OSHA requires employers whose employees are exposed to BD at concentrations above either of the PELs to be responsible for coordinating their work with that of other employers whose employees could suffer excessive exposure because of their proximity to the source of exposure to BD. Only one comment was received on the proposed multi-employer provision. (Ex. 32–27) That commenter requested OSHA to clarify that this provision applies only to employers whose employees are potentially exposed to BD. This interpretation is correct: the intent of this provision is to ensure that employers who establish regulated areas communicate with other employers whose employees could inadvertently enter the area. However, in response to this comment and at the suggestion of the labor/industry group, OSHA has made clear that the workers who may have access to the regulated area must be told where such areas exist and of their restricted access to them. Accordingly the phrase ''whose employees may have access to these areas'' has been added to paragraph (e)(4).

The regulated area provision underscores OSHA's concern that employees at nearby sites be aware of the existence of a BD exposure hazard so that they will remain outside the boundaries delineating the regulated area. Requiring the employer who establishes a regulated area to notify other employers whose employees might be placed at risk by the presence of high concentrations of BD is consistent with other OSHA standards, e.g., 29 CFR 1910.1048 (Formaldehyde).

F. Methods of Compliance

The final standard, like the proposed standard, requires employers to institute engineering and work practice controls to reduce the exposures of employees to or below the permissible exposure limits (both the 8-hour TWA limit and the STEL), to the extent feasible. If the employer establishes that engineering and work practice controls are inadequate to lower exposures sufficiently to or below either of the PELs, the employer must nevertheless implement engineering and work practice controls to reduce exposures as low as possible and provide supplemental protection with respirators selected in accordance with paragraph (h). The methods of compliance requirements in the final rule are similar to those in all of OSHA's other substance-specific health standards.

The primary reliance on engineering and work practice controls to maintain employee exposures to or below the PELs is consistent with good industrial hygiene practice and with the Agency's traditional adherence to this hierarchy of controls. This hierarchy specifies that, in controlling exposures, engineering controls and work practices are to be used in preference to respiratory protective equipment. In this final rule, respirators may be used by employees only in emergencies; where engineering and work practice controls are not feasible, adequate, or have not yet been installed; or during intermittent, non-routine work operations that are limited in duration.

Engineering controls involve the installation of equipment, such as forced air ventilation, or the modification of a process to prevent or contain chemical releases. Work practice controls reduce employee exposures by altering the manner in which a task is performed. An example of a work practice control would be to train a tank car unloader to stand upwind rather than downwind of the tank car's hatch during the operation.

Respirators have traditionally been accorded the last position in the hierarchy of controls because of the many problems associated with their use. For example, the effective use of respirators requires that they be individually selected and fitted for each employee, conscientiously worn, carefully maintained, and replaced when necessary; these conditions may be difficult to achieve and maintain consistently in many workplace environments. Furthermore, unlike engineering and work practice controls, which permit the employer to evaluate their effectiveness directly by air monitoring and other means, it is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. Finally, in the case of butadiene, respirator cartridges and canisters used to purify the air inhaled by the employee have limited capacity. Data relied on by OSHA to develop the respiratory protection requirements of the final rule show that cartridges will not be able to provide adequate protection over an entire workshift (see discussion for paragraph (h), Respiratory Protection).

Industry representatives were in agreement that respirators should not be relied upon as a first line of defense if feasible engineering and work practice controls are available to protect employees from exposure to butadiene. (Ex. 34–4; 60; 61; 66A; 113). For example, James L. McGraw, representing the IISRP, commented as follows:

> It has long been recognized that engineering controls should be the primary means of reducing occupational exposures to regulated substances. Respirators are useful as supplementary controls to protect workers during emergencies, if engineering controls fail or break down, while feasible engineering controls or work practices are being designed or implemented, or for mobile or short-term work, such as some maintenance operations * * *. At ASRC and, as I understand, throughout the industry, respirators are generally used only for short-duration tasks where the potential for exposure may be relatively high, (and) * * * are generally worn by workers for only a small fraction of the shift * * *. Moreover, because they inhibit worker mobility, obstruct vision and make communication among workers difficult, serious safety risks may be posed

where respirators are used over long periods of time * * *. The required use of respirators over extensive periods of time is also psychologically stressful, especially for employees not accustomed to such use. All of these factors significantly impair worker mobility and productivity. (Ex. 34–4, pp. 7–9)

Thus, according to the hierarchy of controls concept, use of installed equipment, such as well-designed and maintained local exhaust ventilation, is a superior compliance method because its effectiveness does not depend to any marked degree on human behavior, and the operation of such equipment is not as vulnerable to human error as is the use of personal protective equipment. The Agency has also found that modified work practices can aid in achieving compliance with the PELs without introducing the safety and comfort problems inherent with respirator use.

Based upon the evidence in the rulemaking record and the Economic Analysis, OSHA finds that the use of engineering and work practice controls will reduce employee exposures to or below the butadiene PELs for practically all work situations, without having to rely on excessive respirator use. Some of the controls applicable to the production of butadiene monomer and polymers include:

—Installation of closed-loop sampling ports for quality-control sampling of process streams;
—Use of self-circulating-type sampling cylinders;
—Replacement of pumps equipped with single mechanical seals with those having dual seals;
—Use of an on-line chromatographic system to minimize the need for manual process sampling;
—Replacement of slip-tube gauges with magnetic level gauges in loading/unloading operations;
—Routine venting and purging of transfer lines between loading and unloading operations;
—Prohibiting air recirculation in quality-control laboratories (i.e., use of 100 percent make-up air);
—Ensuring that samples are removed from sample cylinders within enclosed, ventilated cabinets, and implementing closed-systems for injection into chromatographs;
—Voiding and purging sample cylinders outside of the laboratory or within an exhausted hood; and
—Purging process lines with nitrogen followed by steam or water cleaning prior to performing equipment maintenance.

OSHA recognizes that there may be situations where engineering and work practice controls are not feasible due to a unique feature or condition. These situations are recognized in paragraph (f)(1) of the final rule, which permits the use of approved respiratory protection where employers can demonstrate that engineering and work practice controls are not feasible. In such situations, the burden of proof is appropriately placed on the employer to make and support a claim of infeasibility because the employer has better access to information specific to the particular operation that is relevant to the issue of feasibility.

Paragraph (f)(2) requires employers whose employees are exposed above either of the PELs to establish and implement a written compliance plan that describes the methods to be used to reduce employee exposures to or below the PELs. The plan must provide for this to be accomplished where feasible with engineering and work practice controls, which must include surveys for leak detection on a periodic basis. The written plan must include a schedule for implementation and must be furnished upon request for examination and copying to OSHA, NIOSH, and affected employees or their representatives.

In the preamble to the proposal, OSHA raised concerns about and solicited comments on the suggestion in the JACA report that worker exposures to BD originating from pump leaks could be controlled more cost-effectively with the use of leak detection programs rather than by engineering means, such as installation of pumps with dual mechanical seals. (Ex. 30) OSHA also questioned whether use of a continuous air monitoring system equipped with an alarm might be an equally effective alternative control technology (55 FR 32736 at 32791).

In response, OSHA received many comments indicating that implementation of engineering controls is a far superior control strategy than primary reliance on leak detection, and these comments urged the Agency to retain its original performance-oriented language in the methods of compliance paragraph. For example, Michael J. Murphy of Monsanto commented as follows:

> It is Monsanto's position that the actual method of maintaining the integrity of engineering controls and process equipment should not be specified by OSHA. The appropriate utilization of preventative maintenance programs, periodic leak detection surveys, continuous monitoring systems and an educated workforce should be left up to the employer's professional judgment. So long as the overall process is maintained in a fashion which minimizes employee exposures as determined by personal monitoring, the actual method of compliance should not be a specific item. (Ex. 32–19, p. 6)

In their post-hearing comments, NIOSH indicated that continuous monitoring systems might be useful in some situations, but only as an ''* * * adjunct to engineering containment features * * *.'' (Ex. 101, p. 2) Similarly, Dr. Norman Morrow, of Exxon Chemical Company and chairman of the CMA Butadiene Panel, commented that use of double seals on pumps combined with a good leak detection and repair program would provide more protection to workers than would continuous monitoring systems. (Ex. 54, p. 7) The feasibility of relying primarily on continuous monitoring systems to maintain low worker exposures was also questioned by CMA in their post-hearing submission:

> In a monomer or crude facility which is out of doors and spread over a large area, a very large number of such analyzers would be required to provide any warning of potential high ambient levels. It is likely that even a very large and costly system would fail to detect butadiene excursions because of changing wind patterns, areas not covered, downtimes for maintenance, cycle times between measurements, etc. * * * [B]y contrast, engineering controls such as dual or tandem pump seals serve as a true primary safeguard against worker exposure. * * * Thus, OSHA should expressly recognize that continuous analyzers or monitoring systems, although perhaps beneficial in certain situations as part of a leak detection program, should not supplant engineering controls which directly protect workers against butadiene exposures. (Ex. 112, p. 125)

After reviewing these comments, OSHA is convinced that primary reliance on either manual leak detection programs, as suggested by JACA, or continuous monitoring systems, would not provide worker protection equivalent to that afforded by engineering and work practice controls; therefore, OSHA is retaining the performance-oriented language originally proposed for the methods of compliance requirements, which allows employers to design their own compliance programs so long as they adhere to the general principles for the hierarchy of controls set forth in paragraph (f)(1).

Furthermore, in paragraph (f)(2) of the final rule, OSHA specifies that the compliance program must include a leak detection program, but leaves the specific design of the program up to the employer. OSHA believes that leak detection is a vital element of the compliance program for butadiene, given the high volatility of the substance, and given that leaks, if not

detected in timely fashion, can be a significant source of employee exposure.

Howard Kusnetz of Shell Oil objected to the proposal's requirement that compliance programs include leak detection:

> OSHA should not require the compliance program to include a periodic leak detection survey. If this is to be an effective performance standard, the facility needs the maximum flexibility to develop an effective program. The engineering control or work practice that reduces exposure may not need leak detection to be effective. This requirement will be a significant drain of resources and not result in enhanced employee protection. This is a significant departure from other health standards such as benzene and is already being addressed by EPA requirements. (Ex. 32–27, p.2)

Other rulemaking participants identified leak detection as an important component of an effective compliance program for butadiene. For example, Frank Parker of Environmental Technologies Incorporated, testifying for OSHA, stated that use of double seals on pumps combined with a good leak detection and repair program would effectively control exposures to butadiene (Tr. 1/17/91, p. 534). In post-hearing testimony, NIOSH explained that leaks from process equipment were one of the major sources of employee exposure:

> NIOSH supports the contention that 1,3-butadiene processing involves closed systems and that exposures are the direct result of leaks in these systems. There are only relatively few points * * * in which the integrity of these closed systems are likely to be (intentionally) broken. * * * Prompt repair of leaks can appreciably reduce exposures, and techniques such as Hazard and Operability Studies * * * should help even more by anticipating and preventing the leaks. (Ex. 101, pp. 1–2)

Similarly, as discussed above, several participants agreed that leak detection programs combined with primary reliance on engineering controls were the most effective approach for maintaining low employee exposures to BD; a routine leak detection program is one of the control elements specified in the exposure goal program recommended in the joint labor/industry agreement. (Ex. 118–13A) Furthermore, contrary to Mr. Kusnetz's assertion, OSHA has required compliance programs to contain provision for leak detection in its final rule for another highly volatile carcinogen, ethylene oxide (See 29 CFR 1910.1047(f)(2)(ii)).

OSHA believes that the language contained in paragraph (f)(2) of the final rule gives employers considerable latitude in designing effective leak detection programs. OSHA has not specified a minimum frequency for performing leak detection, the methods to be used by employers for performing leak detection, nor the locations where periodic leak detection must be performed. OSHA believes that the employer, with his or her knowledge of specific processes and workplace conditions, is in the best position to make these decisions. The employer must perform leak detection as often as is reasonable, given the specific circumstances of the work operation. The intent of the provision as worded in the proposal was to ensure that employers include a leak detection program as appropriate to their workplace within the compliance program, and that this information be available to affected employees or their representatives. Because the preponderance of professional opinion contained in the record provides support that leak detection programs are important supplements to engineering control programs, OSHA has accordingly retained this requirement in the final rule.

The paragraph describing the proposed written compliance program requirements also contained a cross reference to paragraph (h) of the proposed standard dealing with written emergency plans. OSHA has deleted this cross reference in the final rule, recognizing that the written emergency plan is required regardless of whether the requirement for a written compliance program is triggered by exposures exceeding the PELs. This deletion was also included in the regulatory text from the joint labor/industry agreement.

Paragraph (f)(2)(iv) prohibits the use of employee rotation as a method of reducing exposure to BD to or below the PELs. This requirement, which remains unchanged from the proposal, reflects a long-standing Agency policy that rotation of employees is an unacceptable practice for reducing exposures of employees to potential carcinogens. Although this approach may reduce the risk of cancer among individual workers who are periodically rotated out of tasks involving such exposure, the practice places a larger pool of workers at risk. OSHA received no objection to retaining this requirement for the butadiene standard, and its inclusion was supported by the joint labor/industry agreement. OSHA wishes to make clear that other kinds of administrative controls are acceptable so long as they do not involve exposing employees who would otherwise not be exposed. Acceptable practices include methods such as scheduling certain maintenance tasks where there is a potential for high exposures during the work shift where there are the fewest employees present in the area.

The text of the joint labor/industry joint recommendations included one other change in the language of proposed paragraph (f), clarifying that no written compliance program would be required ''if the initial (exposure) reading has been reliably determined to have been in error.'' (Ex. 118–13A) None of the participants of the joint agreement provided a specific rationale explaining the need to include this language; however, one rulemaking participant, Richard Olson of Dow Chemical, offered an explanation after reviewing a draft of the agreement:

> Occasionally, one sample may be over a permissible exposure level because of some circumstance such as an analytical error or perhaps an unusual, unanticipated action taken by the employee. In such cases, the situation surrounding the data point should be investigated but that individual sample should not necessarily instigate a full-blown program as it may not be representative of actual average conditions. (Ex. 118–16, p. 6)

For these reasons, Mr. Olson suggested that the language contained in the draft regulatory text from the agreement not be limited to circumstances involving only analytical error, but also be applied to other unusual events.

In the final rule, OSHA did not include the language regarding erroneous sample results that was contained in the labor/industry regulatory text. Clearly, no employer action should ever be based on an erroneous reading. In addition, OSHA believes such language is unnecessary since it has never been the Agency's intent or practice to require employers to comply with a provision of a standard based on the results of a single sample so long as the employer has adequate documentation that the result is unusual and does not reflect typical workplace conditions. Conversely, OSHA would not expect an employer to discontinue complying with a provision of the standard simply because a single sample suggests employees are not exposed above either of the PELs, if the weight of information available to the employer indicates otherwise. Indeed, OSHA believes it more likely that gross sampling and analytical errors will tend to understate rather than overstate exposures for a variety of reasons (for example, due to sampling pump fault or failure, taking samples under conditions of high humidity or where other hydrocarbons are present, sample loss from breakthrough or due to improper sample storage or handling, or

inefficient desorption of the sample from the media).

OSHA believes that employers should base their compliance actions on the totality of information and data available to them about their workplaces and employee exposures, and on their best professional judgment. If in the employer's best judgment, a sample result is obtained that is not credible or is perceived as unlikely, the employer should, as Mr. Olson suggests, investigate the probable causes by ensuring that process and engineering equipment are functioning properly, by talking with affected employees to determine if there were any unusual occurrences or practices that may be associated with the result, and conduct repeat monitoring to help confirm that the questionable result is not representative of typical workplace conditions. On the other hand, should the employer instead choose to rely on a minimal program to assess employee exposures and a sample result indicates that an operation is associated with worker exposures above the PELs, OSHA believes it is prudent to presume that the result reflects typical exposure conditions and that a plan for implementing corrective measures is necessary.

G. Exposure Goal Program

Paragraph (g) of the final rule contains requirements for the employer to establish an exposure goal program where employee exposures are above the action level of 0.5 ppm TWA. As part of the exposure goal program, which was recommended by the labor/industry agreement, the employer must implement the following control measures:

—A leak prevention, detection, and repair program;
—A program for maintaining effectiveness of local exhaust systems;
—Use of technologies that minimize BD emissions from pumps;
—Use of gauging devices designed to limit employee exposures during loading operations;
—Use of controls such as vapor return systems to limit exposures during unloading operations; and
—A program to maintain BD concentrations below the action level in control rooms.

The employer is not required to implement the controls specified above if he or she demonstrates that the controls are not feasible, will not be effective in reducing exposures to or below the action level, or are not necessary to achieve exposures to or below the action level. In addition, nothing in the exposure goal program requires employers to use respiratory protective equipment to achieve the action level. The exposure goal program must be implemented within three years from the effective date of the standard, in accordance with paragraph (m); this is one year beyond the date that employers are required to have installed engineering and work practice controls to achieve the PELs.

The requirements in this paragraph were not originally included in the proposal, but were proposed as part of the joint labor/industry agreement for BD. In its supplemental Federal Register notice, OSHA requested comments on the exposure goal program. (61 FR 9382) Specifically, OSHA was concerned whether including specification-oriented requirements for engineering controls in the exposure goal program would lead to situations where:

—The use of alternative control methods that would be equally or more effective in reducing exposures would be discouraged or ignored;
—The employer would be unable to comply because the specified controls are not applicable to the operation(s) where exposures exceed the action level; or
—The required controls would not be needed because exposures could be reduced to or below the action level by work practices alone, thus forcing employers to spend capital resources unnecessarily to comply with the letter of the requirement.

Several other participants raised concerns similar to those of OSHA's, generally preferring a more performance-oriented approach that did not mandate the use of specific control methods. For example, Paul Bailey, representing the American Petroleum Institute, submitted the following comment:

> API has some concerns with the ''Exposure Goal Program'' * * *, particularly shifting the burden to employers (to prove that the required controls are not feasible or effective) * * *. The listed elements of the exposure goal program may be useful tools for controlling exposures, but it is important to provide flexibility for use of new exposure control technologies that may become available. (Ex.118–11)

API recommended that the specific elements of the program be contained in a non-mandatory appendix rather than specified in the regulatory text; this approach was also supported in Richard Olson's submission on behalf of Dow Chemical. (Ex. 118–16) Mr. Olson also stated that the exposure goal program would establish the action level as a ''de facto PEL,'' and expressed the concern that specifying control measures might cause employers to implement controls for operations that do not contribute to employee exposures exceeding the action level. However, Mr. Olson acknowledged that the language contained in the draft agreement would allow employers to exclude specified elements of the program where they are not needed to attain the action level. Representatives of three refineries or chemical producers submitted similar comments (Exs. 118–5, 118–6, 118–8), arguing that the program should not include specifically mandated control methods since it would ''discourage * * * (the use of) process-based controls in favor of equipment based controls * * *'' (Ex. 118–5) and would be ''* * *counterproductive to innovating new control strategies * * *'' (Ex. 118–6)

However, in describing the program further, the CMA Olefins Panel commented that the regulatory language contained in the labor/industry agreement addressed these concerns. They said:

> The program is meant to supplement, not replace, the requirement that an employer ''institute engineering controls and work practices to reduce and maintain employee exposure to or below'' the PEL * * *. Since the program is required only where exposures are above the action level, it in fact creates incentives to develop improved engineering controls or work practices that achieve greater reductions in exposure.
>
> In addition, under the program, an employer would not need to implement the listed components of an exposure goal program if the employer could show that the components are not feasible, effective, or necessary to reduce exposures to at or below the action level * * *. Thus, OSHA's concerns that the program may impose inapplicable or unwarranted requirements are unfounded. (Ex. 118–13, p. 6)

The Panel further stated that the program ''* * * is an innovative concept aimed at addressing industry feasibility concerns while creating incentives to minimize worker exposure by encouraging the use of specified engineering controls with which the industry has experience.'' According to the Panel, incentives for developing improved exposure control methods are brought about because the exposure control program would not be required where exposures are at or below the action level (Ex.118–13, p. ii).

The submission by the IISRP explained that the exposure goal program is part of a three-pronged framework developed to address concerns about minimizing worker exposures in a feasible manner. According to IISRP:

* * * OSHA's record does not demonstrate that a 2 ppm (TWA) PEL or a 10 ppm STEL is feasible in polymer operations. Recognizing, however, that union representatives wished to see butadiene exposures even lower than 1 ppm, industry worked to develop an overall standard that would minimize exposures and still be feasible. The result was a three-part framework:

(1) A PEL of 1 ppm, STEL of 5 ppm, and action level of 0.5 ppm, coupled with

(2) The flexibility to employ respirators to achieve such exposures for non-routine intermittent and limited in duration activities and

(3) The exposure goal program.

* * * [T]he exposure goal program does not raise the concerns expressed by OSHA. No goal program need be initiated when exposures are already below the action level by whatever engineering controls or work practices. Better * * * controls * * * are thus not discouraged; they may always be used to achieve (the) action level or lower exposures. (Ex. 118–12, pp. 4–5)

After considering these comments, as well as the actual regulatory language recommended in the joint labor/industry agreement, OSHA finds that it is both reasonable and appropriate to include the specified control measures in the requirement for the exposure goal program. First, OSHA finds it reasonable in that the control measures specified in the exposure goal program represent those that are readily available to industry and have been proven effective to achieve the action level in at least some workplaces. OSHA's analysis of the technological feasibility of the standard, based largely on the NIOSH study of BD plants, identified some of these controls as approaches that have been successfully used to achieve exposure levels well below the PELs (see the Economic Analysis discussion in this preamble). For example, Shell Oil in Deer Park, Texas, achieved median exposure levels of 0.3 ppm (TWA) by implementing a collection system to capture emissions from loading operations as well as a combination of magnetic and slip-tube gauges (Ex. 16–29); use of magnetic gauges for all loading operations would likely reduce exposures further. Replacement of pumps having single mechanical seals with dual-seal pumps, which is an improved pump technology specified under the exposure goal program, has been occurring within the BD industry over the past several years (see the Technological Feasibility chapter of the Economic Analysis). Other elements of the exposure goal program are not equipment-oriented, but instead are designed to ensure that process equipment and engineering controls are optimally maintained to minimize or capture BD releases; these elements include a leak prevention, detection and repair program and a program to maintain the effectiveness of local exhaust ventilation equipment. Finally, all of the control measures specified in the exposure goal program are those that labor and industry representatives jointly agreed were reasonable to include. (Ex. 118–13A)

OSHA also finds that the exposure goal program requirements are appropriate for two reasons. First, OSHA has determined that a significant risk of cancer is associated with lifetime exposure to the action level of 0.5 ppm; the estimated risk to workers exposed at this level is about 4 per 1,000 (see the Quantitative Risk Assessment section of this Preamble). OSHA finds that it is appropriate to expect employers who have not already done so to implement the commonly used approaches detailed in paragraph (g) for controlling exposures to BD in an effort to further reduce this risk. Second, OSHA believes it appropriate to craft the exposure goal program requirements in specification language because to do otherwise would effectively blur the distinction between the exposure goal program and the methods of compliance requirements of paragraph (f), a distinction that the CMA emphasized was critical. (Ex. 118–13, p. 6) OSHA has not made a determination that a 0.5 ppm TWA exposure level for BD was generally feasible in affected industry sectors; therefore, the burden of proof to demonstrate the infeasibility of engineering and work practice controls for achieving the 0.5 ppm action level in an operation cannot be placed on the employer. If the requirements for the exposure goal program were developed in performance-oriented language, even with the aid of a non-mandatory appendix to guide employers and OSHA in its interpretation, OSHA believes that the requirement would have no real meaning in terms of performance measures by which employers, employees, and OSHA could judge compliance. In this situation, the action level might well be interpreted as a ''*de facto* PEL'', as suggested by Mr. Olson. By including a minimum specification for the content of the program, employers and their employees, as well as OSHA, are provided with a clear set of performance measures while maintaining a distinction between the exposure goal program and methods of compliance requirements for the PELs.

Nevertheless, OSHA believes the final rule's requirement for the exposure goal program, as worded, provides employers with considerable flexibility in the design of the program. Key to providing this flexibility is the 3-year phase-in date for the program. OSHA believes that by extending the implementation date for the exposure goal program one year beyond the date for which employers must implement controls to achieve the PELs, employers will have sufficient time to explore whether the use of alternative engineering approaches, process modifications, or work practices will permit them to reduce exposures to or below the action level.

OSHA also finds that commenters' concerns about the program's supposed lack of flexibility in allowing for the use of alternative technologies is unwarranted, since the extended phase-in period for implementation of the exposure goal program will provide employers with additional flexibility to design their own programs using alternative engineering control methods and work practices. The longer phase-in period for the exposure goal program is also appropriate because it allows employers to focus their initial efforts on reducing employee exposures to or below the PELs, as required under paragraph (f).

However, if the required implementation date of the exposure goal program is approaching and employee exposures still remain above the action level, either because the alternative controls were not sufficiently effective or the employer was not proactive in identifying alternatives, OSHA finds it appropriate to require that the employer implement, at a minimum, the controls that have been proven effective within the BD industry and identified in the exposure goal program, to the extent that such controls are feasible and applicable to the affected operations, and will be effective in further reducing employee exposures to BD.

The exposure goal program in paragraph (g) of the final rule incorporates two modifications from the language contained in regulatory text proposed by the joint labor/industry agreement (Ex. 118–12A). The joint agreement proposed that worker rotation be permitted as part of the exposure goal program. OSHA did not include this language in the final rule because of the Agency's long-standing policy of not allowing worker rotation to be used to control employee exposures to a carcinogen. As explained above in the Summary and Explanation for paragraph (f) (Methods of Compliance), employee rotation places a larger than necessary pool of workers at risk from exposure to BD. In other words, it would result in some employees being exposed to a cancer hazard to which they might not otherwise be exposed.

Since OSHA has estimated the lifetime cancer risk from exposure to BD to be about 4 per 1,000 workers at the action level of 0.5 ppm, use of employee rotation to achieve the action level provides no assurance that employees who are rotated into jobs with exposures around the action level will not be exposed to BD at levels representing a significant risk. Therefore, OSHA finds that employee rotation is not an appropriate method for achieving the action level. The second change involves the addition of clarifying language in the exposure goal program. The regulatory text contained in the joint labor/industry agreement stated that employers need not apply the control measures specified in the exposure goal program if such methods would not be ''effective.'' OSHA modified this language to make clear that such controls need not be implemented if the employer could demonstrate that they will ''not be effective in reducing employee exposures.'' OSHA believes that this better reflects the intent expressed in the joint labor/industry agreement.

H. Respiratory Protection

The respiratory protection requirements of the final standard for BD are in keeping with the requirements for respiratory protection in other OSHA health standards (e.g., Occupational Exposure to Lead, 29 CFR 1910.1025; Occupational Exposure to Benzene, 29 CFR 1910.1028), and with recent developments in the field. The provisions contained in the final rule have been changed from the proposal in some important respects in response to information and comments placed in the record. Comments received on the proposed BD respiratory protection provisions addressed broad issues of fit testing protocols, protection factors for various respirator classes, and other general respiratory protection issues. OSHA is currently evaluating these generic issues in the context of revising 29 CFR 1910.134, which is expected to be promulgated in the near future. The discussion of the appropriate respiratory protection for BD exposure that follows will identify those areas that are relevant to the broader issues being dealt with in the revision of 29 CFR 1910.134. The respiratory protection provisions contained in the final rule on BD reflect OSHA's current thinking on how some of these respiratory protection issues should be addressed. OSHA thus believes that the final rule for BD will be consistent with the revision of 29 CFR 1910.134.

Use of Respiratory Protection. Respirators are necessary as supplementary protection to reduce employee exposures when engineering and work practice controls cannot achieve the necessary reduction to or below the PELs. Paragraph (h)(1) identifies instances where the use of respiratory protection is permitted when employee exposures exceed the PELs. These are:

1. During the time interval necessary to install or implement feasible engineering and work practice controls;
2. In work situations where feasible controls are not yet sufficient to maintain exposures below the PELs;
3. During emergency situations; and
4. During non-routine work operations that are performed infrequently and in which exposures are limited in duration.

The first three instances are identical to those that were contained in the proposal. As to the fourth instance, i.e., ''non-routine work operations,'' OSHA originally proposed that respirators would be permitted for non-routine, limited-duration work operations *if the employer could demonstrate that engineering and work practice controls were infeasible.* OSHA received numerous comments arguing that OSHA should not impose a burden of proof on employers to demonstrate the infeasibility of engineering controls during such work operations.

The CMA Panel expressed support for allowing respirator use ''during the period necessary to install feasible engineering controls and where feasible * * * controls are not yet sufficient to reduce exposures below the PEL.'' (Ex. 118–13) However, in this submission and preceding ones, they objected to the proposal, which stated that respirators shall be used ''In work operations such as maintenance and repair activities, vessel cleaning, or other activities for which engineering and work practice controls are demonstrated to be infeasible, and exposures are intermittent in nature and limited in duration.'' (55 FR at 32805, 8/10/90) CMA's concern centered on the requirement to demonstrate the infeasibility of engineering controls before respirators could be used in short-term, intermittent work. (Ex. 112, p. 141–145) They felt that there were certain activities for which the infeasibility of engineering controls could not be demonstrated in ''an absolute technological sense,'' but the use of engineering controls would nevertheless be ''highly impracticable'' because the work activities are performed infrequently and the controls would prove to be very expensive. (Ex. 112, p. 142) CMA witness, Mr. Roger Daniel, gave the following example of such an activity:

> You may have 300 (pumps) in the plant and no one of those has to have any maintenance or cleaning activities to reestablish the integrity of the signal to that instrument more frequently than every two years. But because of the nature of the material that you're handling and the fact that it can slowly accumulate material * * * Periodically this has to be dealt with * * * you could put in lines to each of these blow-downs and collect from these 200 instruments just a little bit of liquid that has to be discharged * * * but from a practical standpoint, * * * [it] doesn't seem to make good sense. (Tr. 1/18/91. p. 1234–5)

In a pre-hearing submission CMA enumerated some situations where they believed engineering controls to be ''highly impracticable.'' Two of these were discussed in some detail. (Ex. 32–28) The first, ''blowing down of meter leads'' to clear instrument lines of accumulated debris was described as occurring only once every several years per instrument. CMA felt that installation of permanent blow-down lines leading to the flare, which would ensure the containment and destruction of BD, was not justified in this case. Second, they described breaking into and degassing pumps for maintenance as a work task that is performed twice weekly and lasts less than 10 minutes per occurrence. They felt that although it might be possible to build an enclosure around each of the pumps, the high cost of doing so was unjustified, due to the short-term nature of the task. (Ex. 32–28)

During the public hearing, Charles Adkins, then Director of OSHA Health Standards Programs, stated that in the context of the BD proposal, OSHA did not intend the term ''infeasible'' to mean an absolute technological infeasibility in the strictest sense, but that the intent was to limit respirator use to intermittent short duration situations where engineering controls are impracticable. He said that OSHA has:

> * * * always recognized that there [are] some situations that you don't consider it feasible. You don't put in an elaborate ventilation system to control exposures to some device that may break once every five years * * * and you * * * spend 30 minutes repairing that device. That's an appropriate time to use personal protective equipment. (Tr. 37, 1/15/91)

OSHA witness Frank Parker, a Professional Engineer and Certified Industrial Hygienist, testified that engineering controls were generally cost-effective, but that even when engineering controls are technologically feasible, respirators are ''going to be the most useful, practical approach'' in those situations in which there is ''sporadic (exposure) under unique conditions.'' (Tr. 1/17/91, p. 546)

In several other health standards, including the benzene standard, OSHA has specified some examples of activities for which engineering controls are not feasible. In the benzene rule respirators are required, ''In work operations for which the employer establishes that compliance with either the TWA or STEL, through the use of engineering and work practice controls are not feasible, such as some maintenance and repair activities, vessel cleaning, or other operations where engineering and work practice controls are infeasible because exposures are intermittent in nature and limited in duration.'' (29 CFR 1910.1028(g)(1)(ii)).

In the preamble to the benzene standard OSHA stated that

* * * engineering controls are often infeasible when exposures are intermittent in nature and limited in duration. For the same reason as maintenance and repair activities, extensive attempts at engineering controls are often not practical where exposures are both brief and occasional. It is both difficult to keep operable and a not very productive use of valuable industrial hygiene time, as well as often very costly, to try to provide engineering controls for very brief, intermittent exposures * * * In addition, for such intermittent and irregular exposures, employees can wear respirators with less difficulty. (52 FR at 34544, 9/11/87)

The labor/industry group recommended that respirators be specifically allowed ''in non-routine work operations which are performed infrequently and in which exposures are limited in duration.'' (Ex. 118–12A) OSHA considered all available information on this issue and has determined that such a provision is justified for BD. OSHA has therefore included the above language in the final rule in paragraph (h)(1)(ii).

The intent of this provision is not to allow employers to organize their workplace operations such that work is artificially broken down into tasks of small increments of time to allow wholesale respirator use when engineering controls are clearly practicable and therefore feasible under paragraph (f).

High exposures have been documented for workers performing certain activities such as cylinder voiding and sampling. Such activities may be performed intermittently and resulting exposures have been shown to be of short duration; however, since such operations are performed routinely, engineering controls need to be used to control exposures. OSHA does not intend that such routine activities be included in the paragraph (h)(1)(ii) exemption from the usual preference for engineering and work practice controls. Rather, paragraph (h)(1)(ii) contemplates that brief incidental maintenance activities be included. On the other hand, in the case of cylinder voiding (which would not be covered by paragraph (h)(1)(ii)), NIOSH recommended use of a laboratory hood or a vacuum exhaust with an enclosure. (Ex. 16–38; 16–39) For maintenance activities, NIOSH said ''maintenance technicians should follow decontamination procedures when working on process equipment. However, if it is not possible to completely decontaminate a process prior to the procedures, then respirators with organic vapor cartridges should be worn.'' (Ex. 16–38; 16–39)

In keeping with OSHA's intention to use a performance-oriented approach, where appropriate, the Agency has not defined either ''non-routine,'' ''infrequently,'' nor ''limited in duration'' in the final rule. Reasonable interpretations must be made. To qualify for the narrow exemption that permits the use of respirators without demonstrating the infeasibility of engineering or work practice controls, the task must meet all three criteria; it must be non-routine, infrequent, and of limited duration. OSHA believes that the vast majority of such activities qualifying under paragraph (h)(1)(ii) will consist of brief, intermittent maintenance operations such as those described by CMA (e.g., blowing down meter leads for 5 minutes once a year, or opening pumps for maintenance for 1 hour quarterly). (Ex. 32–28, p. 116)

Emergency Situations. Paragraph (h)(1)(iv) requires employers to ensure that employees use respiratory protective equipment during emergencies. The joint labor/industry agreement suggested changing ''emergencies'' to ''accidental release emergencies.'' Submissions by CMA (Ex. 118–13) and IISRP (Ex. 118–12) provided no explanation supporting the need to change the language in paragraph (h)(1)(iv). OSHA did not incorporate this change in the final rule since the language suggested by the labor/industry agreement may imply to some that a release must occur before an emergency is declared and respirators would be required. The language that was originally proposed and retained in the final rule, along with the definition of ''emergency'' in paragraph (b), make clear that employers must ensure that employees use respiratory protection during an unusual condition or occurrence where there is a *potential* for a release of BD, even if an actual release has not occurred. OSHA believes that this reflects common practice in the chemical industry. This provision of the final rule is consistent with other OSHA health standards and is necessary to ensure that employees do not become exposed should an unusual condition result in a release.

Respirator Selection. Paragraph (h)(1) of the final standard requires that employers provide respirators to employees when necessary and ensure that employees use the respirators properly. As in other OSHA standards, employers are to provide the respirators at no cost to the employees. OSHA views this allocation of costs as necessary to effectuate the purposes of the Act. This requirement makes explicit an Agency position which has long been implicit in the promulgation of health standards under section 6(b) of the Act.

Employers must select respirators from those certified as being acceptable for protection against BD or organic vapors by the National Institute for Occupational Safety and Health (NIOSH), under the provisions of 42 CFR part 84.

Paragraph (h)(2) of the final rule requires employers to select and provide respirators in accordance with the criteria specified in Table 1. In the proposal, OSHA would not have permitted the use of cartridge-type negative-pressure respirators because of concern that they would not be sufficiently protective due to the short breakthrough times associated with high BD concentrations. OSHA requested additional data and comment on the issue, and asked NIOSH to conduct another breakthrough study to provide more information about the effectiveness of organic vapor cartridges in atmospheres containing lower BD concentrations.

The respirator selection table in the proposal was the subject of numerous comments addressing two principal issues. (Ex. 32–3; 32–4; 32–7; 32–8; 32–14; 32–20; 32–22; 32–25; 32–27; 32–28; 112; 118–6; 118–12; 118–16) First, commenters stated that the table should allow the use of cartridge type respirators in limited applications, and that the table should include other kinds of available respiratory protective equipment, such as half-mask supplied air respirators and loose-fitting powered air purifying respirators. (Ex. 32–4; 32–22; 32–27; 32–28; 112; 118–6; 118–12; 118–16) Second, commenters questioned the assigned protection factors (APFs) used in the proposal, stating that OSHA should use APF's similar to those used in other OSHA health standards or those of the ANSI

Z88.2–1992 standard. (Ex. 32–7; 32–25; 112; 118–6; 118–16) NIOSH stated that if respirators other than a self-contained breathing apparatus (SCBA) or a supplied air respirator with auxiliary SCBA that NIOSH recommended are permitted, OSHA should use the APFs in the 1987 NIOSH Respirator Decision Logic. (Ex. 32–25) The ANSI Z88.2–1992 standard and NIOSH decision logic apply the same APFs to half-mask, negative-pressure respirators (10) and PAPRs equipped with a tight-fitting half mask (50); for other respirator types, ANSI generally assigns a higher APF than does NIOSH.

OSHA has determined that cartridge-type respirators will provide adequate protection for BD, based on new evidence and data on breakthrough times at low BD concentrations (described in the discussion of *Service Life* below) and on comments concerning whether BD had adequate odor warning properties that would permit employees to detect breakthrough well in advance of their being overexposed. (Ex. 32–25; 32–28; 112) NIOSH stated that BD does not have adequate warning properties, citing the paper by Amoore and Hautala (Odor as an aid to chemical safety: odor thresholds compared with threshold limit values and volatilities for 214 industrial chemicals in air and water dilution. *J. Appl. Toxicol.* 3:272–290) that lists an air odor threshold of 1.6 ppm for BD. (Tr. 1/17/91. p. 741) However, this value is a geometric average of all the literature survey odor data that Amoore and Hautala used in devising their odor threshold tables. On the other hand, Tom Nelson, testifying on behalf of CMA, cited the American Industrial Hygiene Association (AIHA) report, *Odor Thresholds for Chemicals with Established Occupational Standards,* which lists BD as having a geometric mean odor threshold of 0.45 ppm for detection and 1.1 ppm for recognition. (Ex. 32–28c) According to CMA, the AIHA report represents a more recent compendium of odor threshold data for chemical agents than does the Amoore and Hautala study. (Ex. 112) Since the mean odor threshold identified by this source is about half of the 1 ppm PEL, and more than 10-fold below the 5 ppm STEL, OSHA finds that most wearers of air purifying respirators should still be able to detect breakthrough before a significant overexposure to BD occurs. Accordingly, OSHA is permitting the use of air purifying respirators equipped with either organic vapor cartridges or canisters in the final rule. In addition, OSHA will permit employers to provide single-use, half mask respirators equipped with organic vapor cartridges for employees working in environments containing up to 10 ppm BD.

In the final rule, OSHA has used the APFs for the various respirator classes contained in the NIOSH Respirator Decision Logic. (Ex. 32–25) The ANSI Z88.2–1992 APF values have not been adopted, although they were relied on in the recommended standard from the joint labor/industry agreement. As discussed earlier in this section of the preamble, OSHA is currently engaged in evaluating extensive data and evidence on APFs as part of its 29 CFR 1910.134 revision. However, in the case of the BD standard, OSHA's decision to rely on the more protective NIOSH APFs is based on evidence showing that organic-vapor cartridges and canisters have limited capacity for adsorbing BD and may have too short a service life when used in environments containing greater than 50 ppm BD. This evidence (discussed in detail in the section below entitled *Service Life of Organic Vapor Cartridges and Canisters*) consists of laboratory test data showing that organic vapor cartridges and canisters have a useful service life of no more than about 1.5 hours when challenged with air containing greater than 50 ppm BD, and that, at these concentrations, service life declines rapidly with increasing BD concentration. Allowing for a reasonable margin of protection, and given that test data were available only for a few makes of cartridges and canisters, OSHA believes that air-purifying devices should not be used for protection against BD present in concentrations greater than 50 ppm, or 50 times the 1 ppm PEL. Thus, OSHA finds that the ANSI APFs of 100 for full-facepiece, air-purifying respirators and 1,000 for PAPRs equipped with tight-fitting facepieces are inappropriate for selecting respirators for BD.

The proposal contained a provision (g)(2)(iii) requiring employers to provide employees with the option of using a positive-pressure respirator if the employee is unable to use a negative-pressure device. John Hale of Respirator Support Services objected to this provision since it would take respirator selection, the most critical aspect of a respirator program, out of the hands of the program administrator who is most knowledgeable about respirators and put it into the hands of the worker. (Ex. 32–3) Hale questioned whether the provision's language implied that the individual's medical condition would preclude the wearing of any respirator, since the breathing resistance of a modern negative pressure respirator is not a concern for a healthy worker. Mr. Hale also questioned the additional cost of supplying these alternative respirators. The International Institute of Synthetic Rubber Producers (IISRP) stated that, ''this provision is unwarranted because employees who are not medically fit should not be assigned to a job where respiratory protection is required.'' (Ex. 34–4)

OSHA has similar provisions requiring that the employer supply alternative respirators, either upon employee request or if the employee has difficulty wearing a negative-pressure device, in other substance specific standards such as inorganic arsenic (1910.1018), lead (1010.1025), cadmium (1910.1027), benzene (1910.1028), formaldehyde (1910.1048), and MDA (1910.1050). It has been OSHA's experience that this requirement has not proven to be a burden to implement and has proved to be a way to improve worker acceptance of respirator use. The language used in the BD proposal was the same as the language used in the benzene standard, 1910.1028 (g)(2)(iii). However, commenters felt the language in question implied that medically unfit workers would be allowed to wear PAPRs or supplied air respirators in place of a negative pressure respirator. (Ex. 32–3; 34–4) This is not the intent of this provision. The final provision (h)(2)(iii) has been modified to clarify that employers must determine that employees are able to use positive-pressure respiratory devices before upgrading an employee's respirator from a negative-pressure device. OSHA believes that this change in language better reflects the Agency's intent that employees who are unable to wear negative-pressure respirators be permitted to wear positive-pressure devices only after the employer takes appropriate steps to ensure the employee's ability to do so safely.

Some commenters pointed out that Table 1 of the proposal contained an error in that it would have permitted the use of PAPRs and self-contained breathing apparatus operated in a negative-pressure demand mode at any BD concentrations exceeding 50 ppm, which could result in a potentially dangerous situation since no maximum use concentration for these types of respirators was specified. (Ex. 32–28; 32–25; 32–3; 32–14) OSHA agrees that its proposed respiratory selection table was in error and has revised Table 1 of the final rule to reflect the appropriate maximum use concentration for PAPRs. OSHA deleted SCBA operated in negative-pressure demand mode from Table 1 since this type of respirator is not typically used in industrial settings.

Respirator Program. The proposal required (paragraph (g)(3)) that employers institute a respirator program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f). It was pointed out by one commenter that since 29 CFR 1910.134 is under revision, these references to specific paragraphs may change. (Ex. 32–3) The language of this provision has been revised to eliminate any reference to specific paragraphs in 29 CFR 1910.134, but still retains the requirement that a respirator program in accordance with the respiratory protection standard be implemented that contains the basic requirements for proper selection, fit, use, training of employees, cleaning, and maintenance of respirators. For employers to ensure that employees use respirators properly, OSHA has found that the employees need to understand the respirator's limits and the hazard it is protecting against in order to appreciate why specific requirements must be followed when respirators are used.

Service Life of Organic Vapor Cartridges and Canisters

The proposal in paragraph (g)(4)(i) required that the air purifying filters be replaced at 90% of the expiration of service life. The service life of organic vapor cartridges and canisters relates to the amount of time that the charcoal filter effectively purifies the breathing air before contaminants break through the filter and enter the facepiece. In laboratory testing for service life, air containing a known concentration of contaminant is passed through a cartridge or canister at a predetermined flow rate. The concentration of contaminant is measured in the air exiting the filter element on the other side. The time required for the contaminant concentration to reach a target level after passing through the filter element is known as the breakthrough time, and represents a measure of the service life of the filter element when used in atmospheres containing concentrations of the contaminant near the challenge concentration.

OSHA received comments on the proposed provision that would require replacement of organic vapor filters at 90% of the service life. The joint labor/industry agreement supported the proposed provision and recommended its inclusion in the final rule. (Ex. 118–12) However, John Hale of Respirator Support Services questioned how anyone could be expected to know when an element had reached 90% of its service life, or even come close to guessing it, since service life is dependent on the filter's inherent capacity (sorbent efficiency, bed depth, and other design factors) and even more so on respirator use conditions. (Ex. 32–3) Mr. Hale recommended that OSHA simply require filter elements to be replaced at the end of each shift.

In contrast, Tom Nelson, testifying for CMA (Ex. 32–28 C; 107–22), recommended that service life be taken into account to permit the use of organic vapor cartridges against BD, pointing out that there were test data contained in the BD record that would permit employers to establish cartridge change schedules suitable for their individual workplaces (these test data are discussed below). Specifically, Mr. Nelson suggested modifying paragraph (g)(4)(iii) of the proposal to permit the use of cartridge style respirators, provided that the cartridges have a minimum service life of at least 110% the anticipated duration of respirator use. Mr. Nelson also recommended that service life be tested under worst-case conditions of use, i.e., at a flow rate of 64 lpm at 25°C and at a relative humidity of 85%.

OSHA agrees with Mr. Nelson that adequate service life data are currently available both to support the use of organic vapor cartridges for BD and to establish schedules for changing filter elements. For example, NIOSH has performed respirator cartridge breakthrough testing at various exposure levels. (Ex. 23–83; 90) The BD record also contains other reports of service life testing of organic vapor filters, one a published report by Mr. Mark Ackley (Chemical cartridge respirator performance: 1,3-butadiene. *Am. Ind. Hyg. Assoc. J.* 48:447–453 in Ex. 32–28, Vol. II, App. B), and the other an unpublished report prepared by Mr. William Myles of Dow Chemical (Ex. 32–28, Vol. II, App.C). A summary of service life test data from these reports is presented in Table 2. Most of the breakthrough tests conducted for BD used high challenge concentrations relative to the PEL (most exceeding 50 ppm). In addition, the data from Myles and those from Ackley measured breakthrough times for a target concentration of 10 ppm, which was the ACGIH TLV at the time testing was conducted. However, after the informal hearing, NIOSH conducted breakthrough tests at lower challenge (10 to 50 ppm) and target (2 to 10 ppm) concentrations; some of these data are also summarized in Table X–1. (Ex. 90)

TABLE X–1. SUMMARY OF BREAKTHROUGH TEST DATA FOR RESPIRATOR CARTRIDGES AND CANISTERS CHALLENGED AGAINST BUTADIENE

Upstream Concentration (ppm)	Breakthrough Concentration (ppm)	Temperature, Relative Humidity (RH), Flow Rate (lpm)	Breakthrough Time (min)	Reference
CARTRIDGES				
500	10	27°C, 85% RH, 64 lpm	36	Myles (Ex. 32–28C).
100	10	25°C, 50% RH, 64 lpm	132.8, 142.0	Ackley (Ex. 32–28C).
100	10	25°C, 50% RH, 32 lpm	240.7, 245.1, 260.0	Ackley (Ex. 32–28C).
100	10	27°C, 85% RH, 64 lpm	108	Myles (Ex. 32–28C).
100	10	27°C, 85% RH, 32 lpm	174	Myles (Ex. 32–28C).
75	0.75	25°C, 85% RH, 64 lpm	55	NIOSH (Ex. 23–83).
93	0.93	25°C, 85% RH, 64 lpm	92	NIOSH (Ex. 23–83).
50	2	25°C, 85% RH, 64 lpm	159.1 [a]	NIOSH (Ex. 90).
20	2	25°C, 85% RH, 64 lpm	201.1 [a]	NIOSH (Ex. 90)
10	2	25°C, 85% RH, 64 lpm	217.3 [a]	NIOSH (Ex.90).
CANISTERS				
500	10	27°C, 85% RH, 64 lpm	42	Myles (Ex. 32–28C)
100	10	27°C, 85% RH, 64 lpm	102	Myles (Ex. 32–28C)

TABLE X–1. SUMMARY OF BREAKTHROUGH TEST DATA FOR RESPIRATOR CARTRIDGES AND CANISTERS CHALLENGED AGAINST BUTADIENE—Continued

Upstream Concentration (ppm)	Breakthrough Concentration (ppm)	Temperature, Relative Humidity (RH), Flow Rate (lpm)	Breakthrough Time (min)	Reference
100	10	27°C, 85% RH, 32 lpm	234	Myles (Ex. 32–28C).

[a] Mean values reported.

The more recent NIOSH data (Ex. 90) show that organic vapor cartridges, when tested in the range of 10 to 20 ppm, can provide about 3 to 3.5 hours of protection against BD under worst case test conditions (see Table X–1). However, at concentrations above 20 ppm, NIOSH test data (Ex. 23–83, see Table X–1) show that breakthrough time begins to decline rapidly; breakthrough times of about 2.5, 1, and 1.5 hours were obtained at test concentrations of 50, 75, and 93 ppm, respectively. More limited data on canister performance provided by Myles (see Table X–1) suggest that canisters will provide little gain in service life compared to cartridges. At a challenge concentration of 100 ppm and a target concentration of 10 ppm, breakthrough of organic vapor canisters occurred in 102 minutes under worst-case test conditions.

After reviewing the record evidence and comments on filter service life for BD, OSHA has modified its proposal to include a required schedule for the replacement of organic vapor cartridges and canisters (paragraph (h)(4)(i) and Table 1). Alternatively, employers may use other existing data or conduct additional tests to evaluate cartridge or canister service life in BD-contaminated atmospheres, and establish schedules for filter replacement based on 90% of the service life (paragraph ((h)(4)(ii)), as originally proposed. Employers may adopt the second approach, rather than use the default schedule in Table 1, so long as the written respirator program clearly describes the basis for the filter replacement schedule and demonstrates that employees will be adequately protected. In conducting this evaluation, employers should consider any workplace-specific factors that may affect filter service life, such as pattern and intensity of exposure to BD, temperature and humidity, and presence of other air contaminants that may shorten service life. In addition, where air-purifying respirators are used intermittently throughout the day, the filter replacement schedule developed by the employer must consider the effects of BD migration through the filter element during periods of non-use, and the impact of this effect on service life.

Under the default schedule in the final rule, cartridges and canisters for negative- pressure respirators must be replaced every 4 hours at BD concentrations less than or equal to 5 ppm, every 3 hours at concentrations between 5 and 10 ppm, every 2 hours at 10 to 25 ppm, and every hour at 25 to 50 ppm (see Table 1 of the final rule). The record contained no specific evidence on the performance of PAPR cartridges against BD. Therefore, the default change schedule for PAPR cartridges is based on that of negative-pressure devices, i.e., PAPR cartridges must be replaced every 2 hours or every 1 hour at BD concentrations less than or equal to 25 ppm or 50 ppm, respectively. Under the default replacement schedule, the maximum service time permitted in Table 1 begins from the time that the filter seal is broken, regardless of whether the respirator is actually put into immediate use, and runs continuously regardless of the pattern of respirator use. For example, if the seals of a pair of cartridges for a negative-pressure half mask respirator are broken at 8 am and the respirator is used in atmospheres not exceeding 5 ppm BD, the cartridges must be replaced no later than 12 pm, even if the respirator was only used intermittently for a few minutes. OSHA believes that it is necessary to define the replacement schedule requirement in this manner to account for BD migration throughout the cartridge during periods of non-use, and to ensure simplicity in administering the respirator program.

In setting the service lives of air purifying respirators for BD, OSHA has taken a conservative approach in evaluating the service life testing data. Temperature, humidity, air flow through the filter, the work rate, and the presence of other potential interfering chemicals in the workplace all can have a serious effect on the service life of an air purifying cartridge or canister. High temperature and humidity directly impact the performance of the activated carbon in air purifying filters. Humidities of 85% and temperatures of 25 °C or higher are commonly reached in the summer at BD polymer processing plants located on the Gulf Coast. An air flow rate of 64 liters per minute (lpm) used to test cartridges represents an air flow that may be achieved at a moderately high work rate. In addition, filter elements from different manufacturers may exhibit different service lives depending upon the types and amounts of charcoal used. OSHA realizes that lower humidity, temperature, and air flow through the filter would increase the estimates of service life. However, OSHA believes that, in establishing a default schedule for filter replacement that applies to all work situations involving exposure to BD, it is important to base the schedule on worst case conditions found in the workplace, since this will provide the greatest margin for safety in using air purifying respirators with BD. NIOSH in its comments (Ex. 32–25) stated that filters should be tested at worst case conditions of temperature, humidity, and BD concentration, and in combination with the other gases and vapors present in the workplace, since they may drastically affect service lives.

OSHA believes that specifying a schedule for filter changes based on service life data, or allowing employers to develop schedules based on BD-specific test data, is key to permitting the use of organic vapor cartridge respirators for protection against BD, since the service life data described above clearly demonstrate that organic vapor cartridges will not provide adequate protection if used over an entire work shift. In addition, OSHA believes that specifying a default filter change schedule for organic vapor cartridges will simplify compliance for those employers who do not have access to additional breakthrough data for BD.

Furthermore, OSHA finds that the odor warning properties of BD will provide an additional margin of protection in the event that the filter replacement schedule contained in Table 1 is not adequate for certain work situations. The regulatory text recommended by the joint labor/industry agreement suggested that OSHA add language in paragraph (h)(4) to require that employers replace air-purifying elements as soon as possible if an employee detects the odor of BD while using the respirator. OSHA agrees that this is an appropriate precaution,

and has included the language in the final rule.

Respirator Use. The proposal required (paragraph (g)(4)(i)) that canisters be labeled with the date they were put into service. A date alone was all that was needed since the proposal would have allowed for their use for a full work shift before replacement. However, in the final rule, OSHA will now be allowing the use of air purifying cartridges for BD exposures, and the service life of these cartridges is less than a full work shift. Therefore, the proposed provision has been modified in the final rule (paragraph (h)(4)(iii)) to require the labeling of air purifying filter elements with both the date and the time of the start of use to allow for their prompt replacement once the service life listed in Table 1 is reached.

The final standard (paragraph (h)(4)(v)) permits employees to leave the regulated area to readjust the respirator facepiece to their faces for proper fit. The respirator wearer who detects the odor of BD or who feels eye irritation should leave the area immediately and replace the air purifying elements before reentry. It also permits employees wearing respirators to leave the regulated area to wash their faces and respirator facepieces to avoid potential skin irritation associated with respirator use.

End-of-Service-Life Indicators. End-of-service-life indicators (ESLI) for BD do not now exist. The final standard contains a provision (paragraph (h)(4)(iv)) that would allow the use of such a NIOSH-approved ESLI. OSHA originally proposed permitting the use of a NIOSH-approved ELSI for BD, and inclusion of this requirement was supported by the joint labor/industry agreement. This provision is intended to encourage respirator manufacturers to develop a reliable ESLI for organic vapor cartridges and canisters used to protect against BD. Respirator manufacturers have been reluctant to develop filter elements with ESLI without an indication from OSHA that it would allow the use of an ESLI.

In its comments on the proposed standard, NIOSH stated that if OSHA chooses to allow air purifying respirators for BD, OSHA should require the use of an ESLI along with the requirement for doing a service life determination based on the worst case BD exposure level expected, at high humidity levels and high temperatures encountered at that plant location. (Ex. 32–25) Since a NIOSH approved ESLI for BD does not yet exist, OSHA cannot make their use a prerequisite for air purifying respirator use with BD, since by doing so OSHA would preclude the use of air purifying respirators. However, OSHA does encourage employers to use ESLIs when they are approved by NIOSH.

John Hale of Respirator Support Services objected to the practice of relying on mechanical end-of-service-life indicators, stating that since mechanical devices do fail, it is preferable instead to rely upon breakthrough to dictate when to replace air purifying elements. (Ex. 32–3) However, since the permissible exposure limits for chemicals such as BD are being lowered to levels almost at the odor threshold, a reliable ESLI would not replace breakthrough detection by the wearer, but would instead provide an additional means of ensuring that air purifying elements are replaced before their service life expires.

Air purifying filter elements with end of service life indicators (ESLI) may be used until the ESLI indicates that filter replacement is necessary. For cartridges and chin style canisters this may mean that their service lives with an ESLI would be longer than the conservative service lives listed in Table 1. However, the final rule includes a requirement to replace the cartridge or canister at the beginning of the next work shift, regardless of any residual service life left, due to the problem of BD migration through the filter element during the time the previously exposed filter element is not in use (e.g., overnight).

Fit Testing. Paragraph (h)(5) of the final BD rule requires employers to perform either qualitative (QLFT) or quantitative (QNFT) fit testing at the time a tight-fitting negative-pressure respirator is first assigned to an employee who is working in atmospheres containing 10 ppm or less of BD, and annually thereafter. At BD concentrations above 10 ppm, employers must use QNFT for full-facepiece, negative-pressure respirators. In the proposal, employers would have been required to perform either QNFT or QLFT on all tight-fitting respirator facepieces, including those used for positive-pressure devices. The final rule also adds a new paragraph (h)(5)(iii) that requires employers to ensure that employees perform a fit check of the respirator facepiece before each entry into a BD-contaminated atmosphere.

OSHA received many comments on the proposed fit test requirements for BD. The IISRP stated that OSHA should not require QNFT at exposure levels above 20 ppm (i.e., an APF of 10), because it is scientifically unnecessary and much more expensive than QLFT. (Ex. 34–4) In the preamble to the BD proposal (55 FR 32793), OSHA referred to the Agency's proposed revision to 29 CFR 1910.134, which in turn discussed evidence indicating that QLFT was not reliable in achieving APFs higher than 10. (55 FR at 32793) OSHA's standards for cadmium (29 CFR 1910.27) and asbestos (29 CFR 1910.1001) require QNFT of full facepiece respirators used at APFs higher than 10. Although the Agency will make a final determination on the effectiveness of QLFT for achieving APFs higher than 10 as part of its revision of 29 CFR 1910.134, OSHA is not aware of any data or evidence presented in the BD rulemaking that suggest that OSHA should depart from the position expressed in the proposal. Therefore, the final rule for BD will require QNFT when negative-pressure respirators are to be used in atmospheres containing more than 10 ppm BD.

When tight fitting respirators are used, OSHA requires respirator fit testing because proper fit is critical to the performance of tight fitting negative pressure, air-purifying respirators. With tight fitting air-purifying respirators, a negative pressure is created within the facepiece of a properly fitted respirator when the wearer inhales. A poorly fitted respirator allows contaminated workplace air to enter the facepiece through gaps and leaks in the seal between the face and the facepiece instead of passing through the sorbent material.

The fit testing of positive pressure respirators, both half masks and full facepieces, was part of the respirator fit testing provisions in the proposal (paragraph (g)(5)(i)), based on a concern that employees may ''overbreathe'' while wearing the respirator, thus creating a temporary negative pressure within the facepiece and increasing the likelihood for leakage. Tom Nelson, testifying for CMA, questioned this requirement since the requirement had never appeared in previous OSHA standards. (Ex. 112) Mr. Nelson also claimed that requiring fit testing of positive-pressure respirators due to the potential for ''overbreathing'' was unwarranted for BD since this was likely to occur only at extremely high work rates. (Ex. 112) In addition, Mr. Nelson stated that, if OSHA does require fit testing of positive pressure respirators, then it should adopt the ANSI approach.

OSHA has previously required fit testing for positive pressure respirators in the recent cadmium standard, 29 CFR 1910.1027(g)(4) (ii), (iii), and (iv). However, OSHA is currently conducting a comprehensive evaluation of the need to require fit testing of positive-pressure facepieces as part of its rulemaking to revise 29 CFR 1910.134. Until this

evaluation is complete and OSHA has made a final determination, OSHA is not including the proposed requirement to fit test positive-pressure devices in the final rule for BD.

Some commenters objected to the requirement contained in Appendix E that employers conduct at least three separate quantitative fit tests to obtain a fit factor for a respirator, questioning the basis for the requirement and arguing that it was too costly. (Exs. 32–3, 32–28, 112, 118–6) For example, John Hale of Respirator Support Services provided the following comment in his pre-hearing submission:

> On what technical basis does OSHA impose this requirement? It is widely accepted among the health and safety professionals * * * that there is no more confidence gained from three fit test results than from one. Indeed, it would take many more than three to provide any level of statistical confidence in the actual value arrived at for a fit factor. The burden of time and expense imposed by this requirement is completely unjustified.* * * (and) there is no benefit to the respirator wearer. (Ex. 32–3)

As with other respirator issues raised in the BD record, OSHA is currently revising its required protocols for fit testing as part of the revision of 29 CFR 1910.134. At this time, OSHA has modified Appendix E in the final rule for BD to require a single test when QNFT is performed, pending OSHA's final determination for the revised 29 CFR 1910.134 standard.

Several commenters stated that the BD standard fit testing requirements did not allow the use of the Portacount fit testing device since there is no protocol for that method contained in Appendix E. (Ex. 32–3; 32–4; 32–8; 32–11; 32–27; 32–28; 112; 118–16) In 1988 OSHA issued a compliance memorandum classifying the use of the Portacount fit test as a de minimis violation for those OSHA standards that contain a mandatory appendix listing quantitative fit test protocols and instrumentation. The validation of fit testing methods such as the Portacount and appropriate protocols for such methods are to be addressed fully in the fit testing section of the 29 CFR 1910.134 respiratory protection standard revision. Shell Oil Company, in a pre-hearing submission to the BD record stated:

> In a new standard, it would seem reasonable for OSHA to recognize the Portacount system. It is improper for OSHA arbitrarily to exclude a proven fit-test system from a standard, but to encourage a technical violation by advising industry that it would consider Portacount [a de minimis violation] * * * (Ex. 32–27, p. 3)

CMA asked that OSHA allow use of ''any QNFT equipment such as the Portacount that can reliably measure a test challenge.'' (Ex. 32–28, p. 131)

TSI, Inc. (Ex. 32–11, Att. 1–3) submitted three technical papers to the BD record reporting the results of studies comparing the ''Portacount,'' condensation nuclei counting (CNC) respirator fit-test method with the aerosol/photometer method. The first, published in the Journal of the International Society for Respiratory Protection, described a U.S. Army study comparing fit factors determined by CNC and the more traditional corn oil aerosol/photometer determinations. Initial tests did not employ human subjects, but rather they used a mask/headform assembly enclosed in a plastic hood. Numerous conditions of heat and humidity were tested repeatedly.

The correlation coefficient was calculated to determine the strength of the relationship between measurements made in applying the two methods.[11] The correlation coefficients calculated in this study ranged from 0.953 to 0.996.

The Army study also fit-tested human subjects using both methods. Subjects were tested by each method sequentially and the pass-fail agreement/disagreements determined for 100 comparison tests. Agreement exceeded 95%. The author concluded that ''(CNC) was a suitable alternative to conventional photo-meter quantitative fit testing systems.'' (Ex. 32–11, Att. 1, p. 8)

The second study, performed at Shell Oil Company, described sequential fit tests of approximately 50 test subjects at each of two chemical plants. (Ex. 32–11, Att. 2) Again Portacount/CNC methodology was compared with the corn oil aerosol/photometric method. This researcher also compared fit test outcomes as pass-fail agreement/disagreement. The differences in the results obtained from the Portacount/CNC method and aerosol/photometric method shoed less than a 10% discordance and were not statistically distinguishable. The author concluded that ''the Portacount would appear to be an acceptable system for quantitative fit testing.'' (Ex. 32–11, Att. 2, p. 6)

The final submission was a paper by Rose et al. that appeared in the Journal of Applied Occupational and Environmental Hygiene in 1990. (Ex. 32–11, Att. 3) Again, sequential fit-factor measurements using both the aerosol/photometer test system and CNC (Portacount) methods were compared. They were tested at the same fitting of the respirator for each subject. The study involved 24 test subjects. It was found that fit factors determined by photometer were lower than the CNC determinations in 14 of 24 pairs. However, the correlation coefficient was over 0.85, indicating that the two sets of measurements were highly correlated. Other statistical tests were applied and no differences between the two methods were demonstrated. When pairwise comparisons of pass-fail agreement/disagreements were made, the authors concluded ''there was only one discordant pair in the 48 comparisons at the two critical fit factors.'' In reviewing the then-current literature, Rose et al. noted that several other studies had shown good agreement between the results of the 2 fit factor measurement methods also.

These findings affirm OSHA's earlier determination based on a study by Lawrence Livermore National Laboratory (as described in the above-mentioned compliance directive) that the CNC/Portacount method of fit factor determination is acceptable. Rather than continue to consider use of the CNC/Portacount method as a de minimis violation, OSHA is in this final rule accepting its use for fit testing for BD exposure and has included instructions for performing this fit test in Appendix E. These instructions are essentially the same as those of the manufacturer.

In Appendix E of the proposal, the QNFT protocol in section C(4)(xi) required that half masks and full facepiece respirators obtain a minimum fit factor of 100 during QNFT fit testing. John Hale stated that a minimum fit factor of 10 times the APF for that class of respirator is needed. (Ex. 32–3) James Kline of Wilson Safety Products pointed out that the preamble stated that a minimum fit factor of 100 for half masks and 500 for full facepieces should be obtained during fit testing, while Appendix E mentioned only a fit factor of 100. (Ex. 32–14) Mr. Kline recommended that the minimum fit factor should be ten times the applicable APF or the protection factor needed for the application, whichever is lower. NIOSH also recognized the difference in fit factor requirements between the preamble of the proposal and Appendix E and recommended a fit factor of 100 be used for quarter and half mask and that a fit factor of 500 be used for full facepieces. (Ex. 32–25) OSHA agrees that the language in the proposed Appendix E was in error, and has corrected it in the final rule to require that a minimum fit factor of 100 for half

[11] The correlation coefficient is the proportion of the total sum of the squares variation that is explained by the linear relationship. Thus, a correlation coefficient of zero indicates the two are not related, while a value close to 1 indicates a high positive correlation.

masks and 500 for full facepieces be obtained during QNFT testing.

Obtaining a proper fit for each employee may require that the employer provide two to three different sizes and types of masks so that an employee can select the most comfortable respirator that has a facepiece with the least leakage around the face seal. In past rulemaking efforts, OSHA has consistently found that this is a necessary requirement for fit testing of negative-pressure devices since the configuration of each manufacturer's facepiece varies, and it is highly unlikely that all employees will be comfortably fitted with the facepiece of a single manufacturer, even if different sizes are provided.

However, the requirement in Appendix E to use respirators from multiple manufacturers for the fit testing of positive-pressure respirators was questioned by CMA since, unlike the case for negative-pressure facepieces, most people can be adequately fitted with a single manufacturer's positive-pressure equipment. (Ex. 112) CMA was also concerned that, if employees were assigned different makes and models of positive-pressure facepieces, confusion would arise in the workplace with the use of different types of hoses specific to each manufacturer, increasing the likelihood that incompatible respirator hardware would be used, increasing risks to workers. However, as discussed above, OSHA is not now requiring fit testing of positive-pressure devices in the final rule for BD, deferring judgement until the issue is resolved in the rulemaking for 29 CFR 1910.134.

The CMA submission addressed two additional fit test issues, recommending that OSHA delete the protocol for the irritant smoke QLFT in Appendix E, due to health concerns, and that the grimace exercise be deleted from the QNFT protocols because it tends to yield an artificially low fit factor. (Ex. 32–28, Ex. 112) OSHA is evaluating both of these issues in the context of the rulemaking for 29 CFR 1910.134. At the present time, OSHA is retaining in Appendix E the irritant smoke QLFT, should employers wish to continue using it. Should OSHA determine upon promulgation of a final revision of 29 CFR 1910.134 that use of irritant smoke QLFT poses excessive risks to employees, OSHA will make appropriate changes to its final rule for BD.

Regarding the issue of the grimace test, this exercise is to determine whether the facepiece being tested will reseat itself on the face after the respirator seal is broken. In quantitative fit testing, the test instrument should show a rise in challenge agent concentration within the mask during the grimace exercise, followed by a drop once the respirator reseats itself. If the respirator fails to reseat, subsequent test exercises will show excessive leakage, resulting in a failed test. Since even a properly fitting mask may show increased penetration during the grimace exercise, the penetration observed during the exercise is not to be used in calculating the overall fit factor. OSHA has revised Appendix E in the final rule to clarify this aspect of determining fit factors for respirator facepieces.

The preamble to the proposal contained a discussion of the need to perform a facepiece fit check prior to entry into a BD exposed work area. (55 FR 32736 at 32793) The purpose of performing such a negative pressure or positive pressure fit check is to meet the objective of demonstrating that a proper facepiece seal is being obtained each time the respirator is donned. Appendix E, Section II contains descriptions of the recommended positive and negative fit check methods. This test can be either a positive pressure fit check, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure fit check, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Not all tight fitting respirators can be fit checked by using one or the other of these methods, since the wearer must be able to block off either the inlet or exhalation valves. Where the fit cannot be checked using one of the above methods, the wearer shall use the fit check method recommended by the manufacturer of the respirator being used. Language has been added to the respirator fit testing section of the final BD standard at paragraph (h)(5)(iii) that contains this requirement.

I. Personal Protective Equipment

This paragraph, which in the proposed rule was included in the Respiratory Protection paragraph, has been separated into a separate paragraph to facilitate compliance. Paragraph (i)(6) (paragraph (g)(6) of the proposed rule) requires that personal protective equipment must be worn where appropriate to prevent eye contact and limit dermal exposure to liquefied BD and solutions containing BD. Furthermore, it must be provided by the employer at no cost to the employee and the employer shall ensure its use where appropriate. OSHA believes that this performance oriented approach affords employers the flexibility to provide in a given situation only the protective clothing and equipment necessary to protect employees without specifying the exact nature of protective equipment to be used. This paragraph is sufficiently performance-oriented to allow the employer adequate flexibility to provide only the personal protective equipment necessary to protect employees in each particular work operation from the BD exposure encountered. Therefore, compliance can be tailored to fit the hazards posed on a day-to-day basis.

OSHA further notes that the generic requirements for Personal Protective Equipment (PPE) (Part 1910, Subpart I) apply for BD except where a specific provisions of the BD standard would provide otherwise.

J. Emergency Situations

Under paragraph (b) of this section, OSHA defines an emergency situation to be any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

Paragraph (j) requires that employers develop new written plans for emergency situations or modify an existing plan to contain applicable elements of 29 CFR 1910.38, Employee Emergency Plans and Fire Prevention Plans, and of 29 CFR 1910.120, Hazardous Waste Operations and Emergency Responses and how the cause of the emergency is to addressed.

Both the above-mentioned standards require written plans for emergency responses and set out their content and use; however, it is noted that paragraph (q)(1) of 1910.120 states the following:

> An emergency response plan shall be developed and implemented to handle anticipated emergencies prior to the commencement of emergency response operations. The plan shall be in writing and available for inspection and copying by employees, their representatives and OSHA personnel. Employers who will evacuate their employees from the danger area when an emergency occurs, and who do not permit any of their employees to assist in handling the emergency, are exempt from the requirements of this paragraph is they provide an emergency action plan in accordance with (29 CFR) 1910.38(a) of this part.

Thus, only one of the two standards, either 1910.38 or 1910.120, would likely apply in a single facility. OSHA believes that it is likely that smaller facilities will comply with the provisions of 29 CFR 1910.38, while employers whose facilities are large enough to have specific emergency response personnel available will comply with 29 CFR 1910.120.

OSHA recognizes that all sudden releases of BD do not constitute an emergency. For example, the accidental breaking of a sampling syringe containing a minute amount of BD would not normally constitute an emergency. On the other hand, failure of a valve on a reaction vessel, a flange, or a safety relief valve would likely constitute an emergency. OSHA believes that compliance with these requirements will ensure that affected employees are effectively protected during a BD emergency.

In the limited reopening of the BD record in March 1996, OSHA stated that it proposed to define ''Emergency'' as:

> * * * any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an unexpected significant release of BD.

The agency said that it was considering limiting the emergency releases to those that are uncontrolled, so that the last phrase of the definition would read: ''* * * that may or does result in an uncontrolled significant release of BD.'' It then asked whether this addition adequately clarifies what situations OSHA considers to be emergencies, and whether the term ''significant release'' gives adequate guidance to employers as to how much BD must be released in order to constitute an emergency?

Some comment was received on this issue and it is discussed in the paragraph dealing with the definition of the term emergency situation in the definition section (b) of the Summary and Explanation.

OSHA has chosen to use the term uncontrolled occurrence because it is more descriptive and is consistent with the Hazard Communication Standard (29 CFR 1910.1200) and Hazardous Waste Operations and Emergency Response Standard (29 CFR 1920.120).

In the proposed rule, OSHA included provisions for respiratory use and for alerting employees during emergencies. These have been omitted from this section as redundant. Paragraph (j)(1)(iv) sets out the requirement for respirator use during emergencies. Paragraph (k)(4)(ii) sets out medical screening requirements for those exposed to significant releases of BD.

K. Medical Screening and Surveillance

Where appropriate, medical screening and surveillance programs are required by section 6(b)(7) of the OSH Act to be included in OSHA health standards to aid in determining whether the health of workers is adversely affected by exposure to toxic substances. The relationship between medical screening and medical surveillance was clarified in posthearing comments by Dr. William Halperin, NIOSH. (Ex. 90, p.4) According to Dr. Halperin:

> The term ''medical'' surveillance is often used to encompass two distinct activities: (1) Medical screening: the search for early disease and (2) medical surveillance: the ongoing collection, analysis and dissemination of health related information that can be applied to the promotion of health and the prevention of adverse health effects (Ex. 90, p. 4).

Paragraph (k) of this rule clarifies OSHA's intention to include both activities in a program to identify and prevent BD-related disease.[12]

Health hazards that have been shown to be associated with occupational exposure to BD include leukemia, non-Hodgkins lymphoma, and anemia. Additionally, adverse reproductive and developmental outcomes have been observed in toxicologic studies of male and female mice. The medical screening and surveillance program specified in paragraph (k) has the following goals:

1. To prevent occupational diseases related to BD exposure;
2. To detect and treat BD-related disease before a worker would routinely seek medical care; and
3. To provide information on the adequacy of the PELs for BD.

Although most of the medical screening and surveillance provisions remain the same as in the proposal, several changes have been made. These changes include:

(1) Physical examinations are required once every three years, rather than annually;

(2) An annual health questionnaire for workers exposed to BD has been added;

(3) An annual complete blood count including differential and platelet count (CBC) is required;

(4) Medical evaluation of employees required to wear respirators, including assessment of cardiopulmonary function, is no longer required in this rule, and employers are referred to 29 CFR 1910.134;

(5) Employees with past BD exposures that meet specific criteria must be offered continued participation in medical screening and surveillance programs;

(6) Activities pertaining to medical screening and medical surveillance have been more clearly delineated; and

(7) Responsibility for the program has been expanded to include other licensed health care professionals, as well as physicians.

[12] Nothing in this standards changes the meaning of the term ''medical surveillance'' as it has been used in previous standards, such as the asbestos standards, 29 CFR 1910.1001 and 1926.110.

Paragraph (k)(1) specifies the circumstances under which employers must provide medical screening and surveillance for employees exposed to BD. Under paragraph (k)(1)(i) this program must be offered to each employee with exposure to BD at concentrations at or above the action level on at least 30 days a year. Additionally, it must be made available to those employees who have or may have exposure to BD at or above the PELs on at least 10 days per year.

This provision remains the same as that contained in the proposed rule. An alternative set of criteria for employee coverage was suggested in the joint labor-management agreement submitted to OSHA by the USWA and the IISRP. (Exs. 118–12; 119) This agreement would have raised the threshold of employee exposure to BD concentrations at or above the action level for at least 60 days per year, and at or above the PELs for at least 30 days per year. OSHA's review of the record did not produce evidence of controversy for the trigger levels as originally proposed. In fact, Shell Oil Company provided written comments which stated in part,

> This is a reasonable definition of who should be covered, with a time factor (30 days a year) for exposures at or above the action level * * * and a shorter time factor (10 days a year) for exposures at or above the PEL * * * or STEL * * * (Ex. 32–27)

Additionally, designation of trigger levels for medical screening and surveillance at or above the action level for 30 days and at or above the PELs for 10 days per year is consistent with past OSHA policy. For example, in the rulemaking for occupational exposure to coke oven emissions OSHA determined that a specific time period is the most effective and administratively feasible method to adopt in order to exclude workers with very limited exposures, e.g., temporary assignments during vacation periods. (41 FR 46777) At the same time, OSHA was concerned that the selected time period be sufficiently inclusive, and chose a cut-off point of 30 days. (41 FR 46777) The rulemaking for occupational exposure to inorganic arsenic followed the same policy. (43 FR 19620) Subsequently, the health standard for occupational exposure to benzene and the proposed rule for methylene chloride used the 30/10 triggers for inclusion in the medical surveillance program. (29 CFR 1910.1028; 56 FR 57036)

This overall approach to employee selection for coverage by the medical screening and surveillance program is based, in part, on the theory that cancers

associated with BD exposure are likely to be dose-related. Thus, employees exposed for only a few days a year may be at lower risk of developing BD-related disease. This approach allows employers to concentrate valuable medical screening and surveillance resources on higher risk employees.

Another change in the coverage of the medical screening and surveillance program is the elimination of coverage based only on required respirator use. The proposal specified that each employee whose exposure to BD requires the use of a respirator, regardless of the duration of exposure, be covered by the program. In the final rule, employees using respirators will be part of the medical screening program if they are over the action level or PELs for the amount of time stated in the medical screening provisions (on least 30 or more days for the action level and on 10 or more days for the PELs). This change is consistent with the recommendations contained in the labor-management agreement, and with OSHA's intention to clearly delineate medical screening requirements for employees with chemical specific exposures and those who must wear respirators, irrespective of the specific hazard. (Ex. 118–12; 29 CFR 1910.134) OSHA believes that the medical screening requirements for respirator users must be consistent with the provisions contained in 29 CFR 1910.134. Support for this approach was received from several industry representatives. (Exs. 118–11; 118–13; 118–14)

The proposed rule also included a provision for medical evaluation of cardiopulmonary function for all employees whose exposures require them to use respirators. This evaluation was supported by Dr. Philip Landrigan of the Mount Sinai Medical Center. He stated that,

> * * * the cardiorespiratory testing for people that are going to be wearing respirators is very much indicated, that wearing a respirator increases the work of breathing. It is important to know that a person has sufficient cardiorespiratory capacity to be able safely and healthfully to be able to work with the respirator on. (Tr.1/15/91, p. 200)

However OSHA received several comments, including ones from Shell, CMA, and Dr. James A. Saunders, that disagreed with this provision. (Exs. 32–27; 112; Tr. 1/18/91, p. 1213–1214) According to CMA,

> All employees who wear respirators should not receive an evaluation of cardiopulmonary function. As in the benzene standard, a pulmonary function test should be performed every three years on employees who wear respirators for at least 30 days per year. The cardiopulmonary function of these employees should also be evaluated but no specific test should be required except as directed by the examining physician. (Ex. 112, pp. 127–128)

The testimony of Dr. Saunders, who testified on behalf of the CMA BD panel, supported the CMA position on this issue. (Tr. 1/18/91, pp. 1213–1214) Shell offered the following opinion,

> This is *not* a reasonable definition of who should be evaluated. * * * To promulgate slightly different requirements for respirator user evaluation in different individual chemical exposure standards only creates confusion and nonuniformity. OSHA needs to finalize a respirator standard rather than putting different details in each standard. * * * (Ex. 32–27, attachment II, p. 3)

In the final rule, OSHA has clarified its position on medical screening and surveillance for employees whose exposure to BD requires them to use a respirator. Determinations regarding an employee's physical ability to perform the work and use the equipment should be made pursuant to 29 CFR 1910.134. Accordingly, paragraph (k)(4)(iii) has been added to refer employers to the standard on respiratory protection, and the requirement for evaluation of cardiopulmonary function has been deleted from this standard. Comments that support these changes have also been received from labor and industry representatives in response to the limited reopening of the rulemaking record. (Exs. 118–11; 118–13; 118–14; 118–16)

The concept for paragraph (k)(1)(ii) was recommended in the labor-management agreement submitted to OSHA by the USWA and the IISRP. It requires that employers continue medical screening and surveillance for employees after they have transferred to a job without potential exposure to BD when their work histories meet specified criteria. (Ex. 118–12) These criteria are: (1) Exposure at or above the 8-hour TWA limit or STEL on 30 or more days a year for 10 or more years; (2) exposure at or above the Action level on 60 days a year for 10 or more years; or (3) exposure above 10 ppm for 30 days in any past year. (Ex. 118–12) This would also include employees who transfer to low exposure BD jobs, provided that their work histories meet the specified criteria. OSHA welcomes this new provision to the final rule because of the additional protection it affords to workers with a history of occupational exposure to BD. The relatively short latency periods associated with BD-related diseases, which range from 4–9 years to 15–20 years, provide supporting rationale for this provision.

Objections to this provision were made by Texas Petrochemicals Corporation and Hampshire Chemical Corporation on the grounds of unreliable past exposure measurements and recordkeeping. (Exs. 118–6; 118–8) The Air Transport Association objected to this provision on the grounds that including ''employees whose past exposure was over a period of 10 years seems extreme.'' (Ex. 118–18B) Instead, they suggested a ''period of 5 or 3 years'' as a selection criterion. In response to these concerns, OSHA believes that the epidemiologic evidence suggests that these workers may be at increased risk of BD-related disease. This provision narrows the coverage of previously exposed workers to those with the greatest risk. It is OSHA's opinion that this approach errs on the side of caution for this group of workers. Support for this requirement, together with the provisions of paragraph (k)(1)(i), was offered by CMA in their statement that, ''this eligibility standard is appropriate for the medical surveillance program and will effectively protect employees most at risk.'' (Ex. 118–13) OSHA is of the opinion that, when taken in conjunction with the entire labor-management agreement, the requirement to include employees with historical BD exposure will be protective for high risk employees and provide valuable data for the medical surveillance portion of this section, paragraph (k)(8)(i).

Paragraph (k)(1)(iii) requires that coverage in the medical screening and surveillance program must be extended to each employee exposed to BD following an emergency situation regardless of the airborne concentrations of BD normally present in the workplace. Where very large amounts of BD are maintained in a sealed system, routine exposure may be essentially zero. However, system failure might result in catastrophic exposures. Thus, employers who have identified operations where there is potential for an emergency involving BD must take the necessary action to implement an emergency plan, as required in 29 CFR 1910.38. Additionally, employers must ensure that emergency medical care is available to exposed employees, and that such care is rendered by physicians or other licensed health care professionals with knowledge of the acute and chronic toxicity of BD.

Paragraph (k)(2) addresses program administration. Specifically, this provision requires that the medical screening and surveillance program be provided without cost to the employee, without loss of pay, and at a reasonable time and place. It is OSHA's opinion

that this provision is necessary to encourage employee participation. This same requirement was contained in the proposal. Furthermore, it is consistent with other OSHA health standards as well as with provisions contained in the OSH Act.

Additionally, paragraph (k)(2)(ii) requires that all physical examinations, medical procedures, and health questionnaires be administered by a ''physician or other licensed health care professional,'' defined as an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this section. The proposal required that all medical procedures be performed by or under the supervision of a licensed physician.

However, OSHA has long been considering the issue of whether and how to specify the particular professionals who are to perform medical surveillance in all of its standards. The Agency has determined that other professionals who are licensed under state laws to provide medical screening and surveillance services would also be appropriate providers of such services for the purposes of the BD standard. The Agency recognizes that the personnel able to provide the required medical screening and surveillance may vary from state-to-state depending on the state's licensing laws. Under the final rule, an employer, after becoming familiar with state laws delineating scope of practice for various licensed health care professionals, has the flexibility to retain the services of a range of qualified licensed health care professionals, thus potentially reducing cost and inconvenience for employers, and easing compliance burdens.

In the future, OSHA may attempt, with the cooperation of interested stakeholders, to specify which health care professionals are the most appropriate to perform each of a variety of diagnostic, therapeutic, medical management and other services. The more generic approach contained in this standard does, however, signal OSHA's belief that employees should have access to, and that employers should retain, when feasible, those professionals with the greatest level of expertise in discriminating between medical problems associated with occupational or environmental exposures and those associated with organic conditions unrelated to exposure. While the limited numbers of occupational physicians and occupational health nurses available to perform these services is increasing, such expertise does not necessarily correlate with any particular credential.

The final program administration requirement, paragraph (k)(2)(iii), is for all laboratory tests to be conducted by an accredited laboratory. This provision is consistent with other health standards, including benzene (29 CFR 1910.1028), bloodborne pathogens (29 CFR 1910. 1030), and lead (29 CFR 1910.1025). Furthermore, OSHA believes that this requirement is a necessary element for quality control in the medical screening and surveillance program.

The required frequency of medical screening activities is shown in paragraph (k)(3). For each employee covered under paragraphs (k)(1)(i)-(ii), a health questionnaire and CBC are required every year. Additionally, physical examinations must be provided at specified intervals: (1) An initial physical examination if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure; (2) a preplacement examination before assumption of duties by the employee in a job with BD exposure; (3) every three years after the initial or preplacement physical examination; (4) at the discretion of the physician or other licensed health care professional; (5) a termination of exposure examination at the time of employee reassignment to an area where exposure to BD is below the Action level, if the employee's past exposure history does not meet the criteria of paragraph (k)(1)(ii) for continued participation in the program, and if twelve months or more have elapsed since the last physical examination; and (6) at termination of employment, if twelve months or more have elapsed since the last physical examination.

There are several differences between the proposed and final rules regarding the type and frequency of medical screening activities. First, the initial physical examination provided under this section must be provided only ''if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure.'' This addition to the proposal language was made to prevent unnecessary extra physical examinations when the medical screening and surveillance portion of the final rule becomes effective. It is OSHA's opinion that, if an employee has received a physical examination as part of a medical screening program for BD within the past year, a repeated physical examination conducted just to coincide with the promulgation of this rule would be unnecessary and costly to the employer and burdensome for the employee. However, evaluation of the data for the entire group of BD exposed workers would still need to be done to comply with the surveillance portion of this paragraph.

Second, the requirement for preplacement evaluations has been changed from ''before the time of initial assignment of the employee'' to ''before assumption of duties by the employee.'' This change reflects comments received from Shell, which stated,

> * * * before the time of initial assignment of the employee is not effective. OSHA should make clear that what is meant is at the time of initial assignment or transfer into a job meeting the entry criteria, and preferable before assumption of duties in such an assignment. (Ex. 32–27, attachment II, p. 4)

OSHA agrees that this wording more clearly reflects the intention behind this requirement for preplacement examinations. Such examinations are intended to evaluate an employee's ability to work in a safe and healthful manner in a specific work environment. Additionally, they establish a baseline of information against which future health status changes can be compared.

Third, the frequency of physical examinations has been changed from once a year to every three years following the initial or preplacement examination. Several comments were received that addressed the frequency of these examinations. For example, CMA offered the opinion that, ''requiring a complete physical examination each year is unreasonable and excessively burdensome.'' (Ex. 112, p. 131) Dr. Saunders, testifying on behalf of the CMA BD panel, also objected to annual physical examinations, stating that they are ''unreasonable and wasteful of limited medical resources.'' (Tr. 1/18/91, p. 1210) OSHA agrees that an annual physical examination is not the most effective medical screening activity to detect BD-related disease, and thus has changed this requirement. However, OSHA does not agree with CMA that physical examinations should only be provided ''where warranted by symptoms of adverse health effects that might be related to butadiene exposure.'' (Ex. 112, p. 127) Such an approach would ignore principles of medical screening and surveillance, i.e., early identification of disease before medical care would routinely be sought. Most recently, support has been expressed by both labor and industry representatives for this frequency schedule. (Exs. 118–12; 118–13)

Fourth, under the final rule employees covered by the medical screening and surveillance program must be offered an annual health questionnaire and a CBC. It is OSHA's opinion that these medical evaluation activities will be effective in detecting signs and symptoms of BD-related disease that occur in the interval between physical examinations. Furthermore, they allow for greater efficiency of medical resource utilization. Support for this approach to medical screening has been shown in the labor-management agreement submitted to OSHA. (Ex. 118–12; 118–13)

Fifth, to allow for the application of professional judgement in the care of employees exposed to BD, physical examinations are to be provided at the discretion of the physician or other licensed health care professional reviewing the annual health questionnaire and blood test results. This provision not only creates a mechanism for immediate response to abnormal questionnaire responses or laboratory results, but provides flexibility by eliminating the requirement for unnecessary physical examinations and requiring physical examinations when they are indicated.

The sixth difference between the NPRM and the final rule pertaining to the frequency of physical examinations concerns those that occur at termination of employment or at the time of employee reassignment to an area where exposure to BD is below the action level, if the employee has not been exposed over the action level or the PELs for the requisite period of time and if twelve months or more have elapsed since the last physical examination. The NPRM required a termination physical examination ''if three months or more have elapsed since (the) last annual medical examination.'' The final rule extends this time interval to a lapse of one year or more.

The frequency of medical evaluations for employees exposed to BD following an emergency situation is specified in paragraph (k)(3)(ii). Medical screening in this situation is required to be conducted as quickly as possible, but no later than 48 hours after the event. This requirement is supported in part by the labor-management agreement that recommended these medical evaluations to ''be performed as quickly as possible.'' (Ex. 118–12, p.16) OSHA has added the stipulation ''but not later than 48 hours after the exposure'' to ensure that a baseline CBC is obtained within that time period. An accurate CBC baseline reading is vital for comparison with subsequent CBC values in order to detect significant deviations from normal.

Finally, paragraph (k)(3)(iii) addresses medical evaluations for employees who must wear a respirator by referring employers to 29 CFR 1910.134. This change from the NPRM is consistent with comments received from Shell,

> * * * Respirator user medical evaluation should have some uniformity, regardless of the exposure. To promulgate slightly different requirements for respirator user evaluation in different individual chemical exposure standards only creates confusion and nonuniformity. OSHA needs to finalize a respirator standard rather than putting different details in each standard. * * * (Ex. 32–27, attachment II, p. 3)

This approach further clarifies OSHA's intention to distinguish between health-related issues of employees who wear respirators and those who are exposed to BD. Support for the separation of these issues was provided by both labor and industry representatives. (Ex. 118–12; 118–13; 118–11; 118–14; 119)

Paragraph (k)(4) covers the required content of medical screening. One of the required components is a comprehensive occupational and health history that is updated annually. This history must place particular emphasis on the hematopoietic and reticuloendothelial systems, including exposure to chemicals, in addition to BD, that may have an adverse effect on these systems, the presence of signs and symptoms that might be related to disorders of these systems, and any other information determined by the physician or other licensed health care professional to be necessary. OSHA has restated the intended focus of the occupational and health history to more clearly reflect current knowledge of BD epidemiology. While OSHA is not specifying the format of the questionnaire, samples provided in Appendix F indicate the minimum information that must be obtained through the use of any questionnaire to comply with the requirements of this paragraph.

A complete occupational and health history is one part of a thorough medical evaluation. More specifically, however, for workers who are exposed to BD this history has several focused goals. First, the initial history may identify workers who are potentially at increased risk of adverse health effects from exposure to BD. For example, as suggested by Dr. William Halperin of NIOSH on cross examination, ''[i]t may be reasonable to advise workers with a previous history of leukemia or lymphoma to avoid exposure to [BD] * * *'' (Tr. 1/17/91, p. 705) Personal risk factors, such as existing hematologic abnormalities, that also place a worker at increased risk of BD-related disease, may also be identified through the health history. Additionally, predisposition to lymphomas is associated with immune deficiency syndromes.

Second, the initial and updated occupational and health history will have a training effect on workers by educating them about the potential adverse health effects from exposure to BD. Over time OSHA believes that informed workers will be more likely to seek medial attention for signs and symptoms that may be associated with BD exposure. Third, the initial history will provide a critical baseline of health status against which any changes can be compared. Finally, the health questionnaire might also suggest to the physician or other licensed health care professional additional medical tests or procedures that would be prudent to offer to the employee.

Another required component of medical screening for BD is a complete physical examination, with special emphasis on the spleen, liver, lymph nodes and skin. The physical examination for BD exposed employees provides an opportunity for direct observation and palpation of target organs such as the lymph nodes, liver, and spleen. Specifically, the physician or other licensed health care professional would be looking for signs of lymphadenopathy (enlarged lymph nodes), splenomegaly (enlarged spleen), or hepatomegaly (enlarged liver). Although lymphadenopathy is not specific for either lymphoma or leukemia, the physical examination provides an opportunity to detect this finding before symptoms develop. This rationale was rejected by Dr. Saunders in his testimony. (Tr. 1/18/91, p. 1211–1212) However, according to Dr. Halperin of NIOSH, ''[s]ome individuals may benefit by receiving treatment at this earlier point in the course of their disease.'' (Ex. 90, p. 5) Dr. Dennis D. Weisenburger, an expert witness for OSHA, also offered testimony that supported this basis for periodic physical examination of BD exposed employees. (Tr. 1/16/91, pp. 275–276)

The final required medical screening activity is a complete blood count (CBC). A CBC consists of a white blood cell (WBC) count, hematocrit, hemoglobin, differential WBC count, platelet count, red blood cell (RBC) count, and WBC and RBC morphology. (Ex. 23–55) It is an important component of the medical screening program because acute leukemia may, in some cases, be diagnosed with the aid of a CBC prior to the onset of symptoms. Additionally, the CBC is an effective test

for the detection of anemia, which may result from BD exposure. (Tr. 1/17/91, p. 784)

Animal evidence suggests that BD affects the bone marrow, resulting in anemia. In mice, inhalation of BD at 1,250 ppm resulted in a decrease in circulating erythrocytes, total hemoglobin and hematocrit, an increase in mean corpuscular volume, and leukopenia (a decrease in the WBC count), due mainly to a decrease in segmented neutrophils. (Ex. 23–12) These findings are consistent with a diagnosis of macrocytic megaloblastic anemia, suggesting that a CBC with a leukocyte count might yield information on overexposure to BD.

Additionally, changes in hemoglobin level, thrombocyte (platelet) count, and leukocyte count occur in the presence of leukemia. However, the detection of leukemia at a pre-clinical phase, i.e., prior to onset of symptoms, may not lead to improved treatment outcomes. The value of early disease detection, in this case, is that it provides an opportunity to terminate further potential exposure to BD. An employee who already has hematologic abnormalities due to leukemia should avoid exposure to BD and any other chemicals that could accelerate or worsen cytopenias and blood cell dysfunction.

Abnormality in blood counts is found in only 37 percent of patients with bone marrow infiltration. The correlation between peripheral blood counts and marrow involvement by lymphoma is poor. However, examination of the peripheral smear in patients with non-Hodgkins lymphoma may yield evidence of malignant cells in about 15 percent of patients. (Ex. 23–52, p. 1,357)

A CBC would also be a valuable screening tool for disorders other than leukemia and lymphoma. According to testimony offered by OSHA's expert witness Dr. Dennis D. Weisenburger,

> * * * the occurrence of other diseases of the blood and blood forming organs should also be critically examined in workers with BD exposure, particularly blood cytopenias, bone marrow failure, aplastic anemia, and the myelodysplastic (pre-leukemic) syndromes, which have also been associated with other chemical agents. (Ex. 39, p. 11)

Because the latency period for development of lymphohematopoietic disorders and cancers is relatively short, e.g., death from leukemia may occur in as little as 3–4 years after initial exposure, a CBC performed annually is reasonable and prudent. (Ex. 39, p. 9)

The combination of an annual CBC and a physical examination every three years balances both the need to diagnose leukemias (CBC) and lymphomas (physical examination) at an early stage, and the limited number of cases likely to be identified through the screening program. OSHA believes that waiting for sentinel cases to be identified would place other employees at risk of chronic BD-related illnesses, such as leukemias and lymphomas. The more quickly such illnesses are recognized, the sooner workplace modifications may be instituted to protect the health of other employees. An annual CBC, in addition to a health questionnaire, is an efficient means of using medical screening resources to detect early leukemia or anemia in individuals, while simultaneously providing data that can be used to protect the whole population of exposed employees. A medical screening strategy that includes an annual CBC and health questionnaire with physical examinations provided every three years has received support from both labor and industry representatives. (Exs. 118–12; 118–13)

To allow for individual differences among covered employees, as well as professional judgement, provision is made for inclusion of any other test which the examining physician or other licensed health care professional deems necessary. This requirement is provided to ensure that adequate flexibility is incorporated into the standard, so that any occupational diseases due to BD exposure are adequately diagnosed and treated. Furthermore, this provision is consistent with previously promulgated health standards.

Medical screening requirements for employees exposed to BD in an emergency situation focus on the acute effects of BD exposure. These effects include: Irritation of the eyes, nose, throat, lungs, or skin; blurred vision; coughing; drowsiness; nausea; and headache. At a minimum, the required medical screening components include: A CBC within 48 hours of the exposure and then monthly for three months; and a physical examination if the employee reports symptoms related to any of the acute effects. Employee participation in the medical screening and surveillance program, subsequent to a BD exposure from an emergency situation, need not continue for the duration of employment. This limitation on employee inclusion after emergency exposure is supported in comments received from Shell. (Ex. 32–27, Att. II, pp. 3–4) However, to accommodate management of individual cases, continued employee participation in the medical screening and surveillance program, beyond the minimum requirements, is left to the discretion of the physician or other health care professional.

Additionally, the time frame for the collection of the blood specimen has been extended from immediately after the emergency to ''within 48 hours of the exposure and then monthly for three months.'' Again, support for this approach was provided by Shell,

> ''Immediately'' after every emergency may not be possible or even reasonable. We suggest ''as soon as possible'' after a *significant exposure* from an emergency event and at least within 48 hours. * * * (Ex. 32–27, attachment II, p.4)

Further support for this medical screening strategy following an emergency situation was provided by Dr. William Halperin, NIOSH,

> The life span of a red blood cell is approximately 120 days. Thus, the results of a medical examination shortly after a high exposure may be normal despite severely compromised blood-producing capacity. If an exposure is high enough to warrant a medical examination, then it would be reasonable to obtain a baseline hematologic examination at the time of exposure, followed by reexaminations at 30, 60, and 90 days. (Ex. 90)

A physical examination is required only if the employee reports symptoms related to the acute effects after exposure to BD in an emergency situation. Comments submitted by Shell support the idea that not every exposure in an emergency situation necessitates a physical examination. (Ex. 32–27, attachment II, p. 4) It is OSHA's opinion that this approach provides flexibility, as suggested by Dr. Saunders. (Tr. 1/18/91, p. 1214–1213) Contrary to the suggestion by CMA, it does not leave the need and frequency for medical examinations following an emergency situation completely to the judgement of the physician. (Ex. 112, p. 128) Thus, OSHA believes the final rule adopts a moderate, yet protective, approach for medical evaluation requirements for employees exposed to BD in an emergency situation.

Paragraph (k)(5) addresses additional medical evaluations and referrals. Whenever the results of medical screening indicate abnormalities of the hematopoietic or reticuloendothelial systems, for which a non-occupational cause is not readily apparent to the health care professional, the employee shall be referred to an appropriate specialist, e.g., hematologist, for further evaluation. The content of the evaluation is left to the professional judgement of the specialist to whom the employee is referred. This provision is essential to ensure that employees receive prompt diagnosis at the earliest stage possible, when treatment is most likely to be effective.

In the NPRM, the paragraph on additional examinations and referrals contained a provision for the content of the medical examinations or consultations to include, ''evaluation of fertility and other tests, if requested by the employee and deemed appropriate by the physician.'' (55 FR 32736 at 32806) After evaluation of all factors presented in the rulemaking, the Agency has deleted the provision for fertility testing from the final rule. However, given the observations in experimental animals, the medical screening and surveillance program provided by the employer should address the potential reproductive and developmental problems of workers exposed to BD. (The reader is referred to the Health Effects section of this preamble.) The sample health questionnaires provided in Appendix F include examples of questions that address reproductive and developmental health concerns.

Information that the employer must provide to the examining physician or other licensed health care provider is listed in paragraph (k)(6). Specifically, that information includes: (1) A copy of the BD standard; (2) a description of the employee's duties as they relate to BD exposure; (3) the employee's actual or representative BD exposure level; (4) a description of required pertinent personal protective equipment; and (5) information from previous employment-related medical evaluations which the physician or other licensed health care professional may not otherwise have available. The purpose of this requirement is to provide information necessary for the physician or other licensed health care professional to make an informed determination regarding whether the employee may be at increased risk from exposure to BD.

Paragraph (k)(7) requires employers to ensure that the physician or other licensed health care professional produces a written opinion of the evaluation results and provides a copy to the employer and employee within 15 business days of the medical evaluation. OSHA rejected Shell's suggestion of extending the time frame for provision of the written opinion to the employee from 15 to 30 days. (Ex. 32–27) In OSHA's opinion 30 days is too long to wait to inform employees of the results of the medical evaluation. However, OSHA agrees with the recommendation made in the labor-management agreement to specify ''business days.'' (Ex. 118–12, p.18) It is OSHA's opinion that this recommendation does not adversely impact the health of employees in the medical screening and surveillance program and, yet, it provides a more practical time frame for the communication of this information.

The written opinion must contain the results of the medical evaluation that are pertinent to BD exposure, an opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to BD, and any recommended limitations on the employee's exposure to BD. This opinion must be developed with consideration given to a comparison of all available medical evaluation results for occupational exposure to BD. OSHA recommends that the physician or other licensed health care professional use a flow sheet to chart temporal changes in the CBC. The occurrence of temporal changes in the CBC indices, even if the actual results remain within normal limits, should be considered when evaluating risk of material impairment to health, as well as the overall medical opinion.

Additionally, the written opinion must include a statement that the employee has been informed of the medical evaluation results and any conditions resulting from BD exposure that require further explanation or treatment. This written opinion shall not contain any information that is not related to the employee's ability to work with BD. In rendering this opinion, the physician or other licensed health care professional must rely on the results obtained from the medical evaluation. This provision does not negate the ethical obligation of the physician or other health care professional to transmit any other adverse findings directly to the employee.

Medical surveillance requirements are specified in paragraph (k)(8). This provision requires the employer to ensure periodic review of information obtained from the medical screening program activities to determine whether the health of the employee population of that employer is adversely affected by exposure to BD. This requirement is meant to clarify OSHA's longstanding policy that individual data collected during medical screening activities should be examined in the aggregate, with personal identifiers removed, so that population trends or patterns can be observed and appropriately managed. This medical surveillance provision does not require employers to conduct epidemiologic or any other type of research studies, although such studies are certainly not precluded.

It is OSHA's opinion that this information review will provide employers with supplemental evidence of the effectiveness of their exposure control strategies. The employer's obligations regarding medical surveillance may be limited to a determination that all medical evaluation results are within normal limits and temporal changes in these results have not occurred. However, should a pattern of abnormal findings be identified, the employer may have an opportunity for primary prevention of BD-related disease. Information learned from medical surveillance activities must be disseminated to employees covered by the medical screening and surveillance program provision, as defined in paragraph (k)(1).

L. Hazard Communication

The requirements for hazard communication have been moved from proposed paragraph (j), redesignated and promulgated as paragraph (l) of the final rule. The paragraph addressing hazard communication in the final BD rule is consistent with the requirements of OSHA's Hazard Communication Standard (HCS). The HCS requires all employers to provide information concerning the hazards of workplace chemicals to their employees. The transmittal of hazard information to employees is to be accomplished by such means as container labeling and other forms of warning, material safety data sheets, and employee training.

Signs and Labels

Since the HCS is ''intended to address comprehensively the issue of evaluating the potential hazard of chemicals and communicating information concerning hazards and appropriate protective measures to employees,'' OSHA is including paragraph (l)(1) only to reference HCS requirements for labels and material safety data sheets. Employers who have already met their longstanding requirements to comply with the HCS will have no additional duties with regard to labels and MSDSs under the BD rule.

The warning sign and labels for BD which OSHA proposed in 1990 have been deleted from the final rule in response to the recommendation of various commenters, including the labor/industry group, who suggested that no requirements were needed beyond those already listed in the HCS. (Tr. 1/18/91, p. 1169; Tr. 1/22/91, pp. 1348–1249; Ex. 112, 32–17, 32–19, 32–22, 32–27, 108, 118–12A) Therefore, the final rule now references the HCS.

Employee Information and Training

OSHA is also referencing the HCS for employee information and training, but is specifying additional provisions applicable when employee exposures

are likely to exceed the action level or STEL. Paragraph (l)(2) reiterates that training must be afforded employees in accordance with the HCS and contains various provisions which apply when exposure limits are exceeded. The first of these is the requirement that a training program be instituted and that employee participation in it be assured by the employer (paragraph (l)(2)(i)).

OSHA believes that training is not a passive process. The information provided employees in training requires their comprehension of the material and subsequent use of what they have learned while performing their duties in the workplace. There are many different ways to accomplish training effectively, but it cannot be a mechanical transfer of information such as giving someone a written document. OSHA's voluntary guidelines, which are found in OSHA publication No. 2252, are available to provide employers with additional guidance in setting up and implementing an appropriate employee training program. An effective training program is a critical component of any safety and health program in the workplace. Workers who are fully informed and engaged in the protective measures established by the employer will play a significant role in the prevention of adverse health effects. Ineffective training will not serve the purpose of making workers full participants in the program, and the likelihood of a successful program for safety and health in the absence of an effectively-trained workforce is remote.

OSHA expects that employers will ensure that the information and training is effective. Although not specifically required in the standard, any good training program should include an evaluation component to help ensure effectiveness. The voluntary training guidelines previously recommended can provide additional guidance in this respect.

Paragraph (l)(2)(ii) requires employers to provide the required information and training prior to or at the time of initial assignment to work with BD. This paragraph also requires that such training be repeated annually when employees are exposed over the action level or STEL ((l)(2)(iii)). OSHA notes that annual training for workers exposed above an action level is also required in other standards e.g., benzene (29 CFR 1910.1028), asbestos (29 CFR 1910.1001), cadmium (29 CFR 1910.1027), formaldehyde (29 CFR 1910.1048).

CMA requested that OSHA correct the final rule to require annual training only when the employee is assigned to a job where the potential exposure is above the action level or STEL. OSHA has included this provision in paragraph (l)(2)(iii). (Ex. 112, p. 116) OSHA notes, however that all employees potentially exposed to BD must receive training at least once as provided by the HCS. Those employees whose tasks place them at risk of higher exposure (above the action level or STEL) need training at least annually to review the nature of the hazards of BD exposure and the methods to be used to minimize exposure and to maintain a continuing awareness of the potential dangers associated with exposure.

In its submission, CMA also requested that OSHA specify in the final rule that where the BD standard does not apply because objective data are used to exempt a material or process from the standard, the hazard communication requirements would come from the HCS. (Ex. 112, p. 178) OSHA does not believe this is necessary and that it might lead to greater confusion. Clearly, exemption from the BD standard does not imply exemption from the HCS.

OSHA notes that materials containing less than 0.1% BD are exempt from the BD standard unless there is evidence which indicates that the action level or STEL can reasonably be expected to be exceeded during the job. On the other hand, the HCS contains no exemption from employee information and training provisions for materials containing less than 0.1% of a carcinogen (BD).

Paragraph (l)(2)(iv) indicates that employers must ensure that the information and training is presented in a manner that is understandable to employees, and lists topics which must be included in the training program.

The labor/industry agreement recommended deletion of the proposed requirement that: ''The training program shall be conducted in a manner that the employee is able to understand.'' (Ex. 118–12A) No explanation for this suggestion was offered in submissions to the record. OSHA believes that it is essential that training be understood by the employee. Thus, OSHA has not deleted the requirement from the standard.

Paragraph (l)(2)(iv) also addresses the items upon which employees are to be trained and includes training regarding specific measures employees can take to protect themselves from the effects of BD exposure. Paragraphs (l)(2)(iv)(A) through (F) set forth the basic topics to be covered during the requisite training program. CMA asked that OSHA delete most of this list of training topics. (Ex. 112, p. 177) CMA felt that the HCS provisions were adequate. However, the labor/industry group did not make a similar recommendation, and the final rule contains basic guidance to employers establishing an employee training program as to what subjects must be included. OSHA believes that these requirements build upon the HCS and provide BD-specific information needed by the employee to reduce exposure to BD, and therefore prevent adverse health effects from occurring.

Upon recommendation of the labor/industry group, OSHA has consolidated some of the training topics and made them more concise and clearer. (Ex. 118–12A) The labor/industry group recommended deletion of proposed paragraph (k)(4)(iii)(D), which stated that the training must cover

> The measure employees can take to protect themselves from exposure to BD, including a review of their habits, such as smoking and personal hygiene; and specific procedures the employer has implemented to protect employees from exposure to BD, such as appropriate work practices, emergency procedures, and personal protective equipment. (55 FR 32736 at 32807)

OSHA agrees that most of this material is to be covered under the other topics listed in the final rule, but has determined that the training must include information regarding what employees themselves can do to assist in protecting themselves from exposure to BD. Additionally, as recommended in the labor/industry agreement, reference to personal habits and hygiene has been deleted. (Ex. 118–12A) OSHA has concluded that there is little data regarding the relationship of personal habits to the hazards associated with BD exposure to justify the inclusion of this provision in the final rule. Therefore this subject is not included among those required in the training program.

Paragraph (l)(3)(i) requires the employer to give copies of the BD standard in its entirety, including all appendices, to employees. In response to the labor/industry group recommendation, OSHA has included in the provision that the standard must also be provided by the employer to persons designated as employee representative(s). (Ex. 118–12A) Further, the copy must be provided at no cost to the employee.

In paragraph (l)(3)(ii) OSHA has indicated that the Assistant Secretary or the Director may access all materials relating to employee information and training in the workplace. This would be done in conjunction with an inspection to ascertain compliance with the rule, or in the event of a NIOSH health hazard evaluation. Review of the available materials regarding information and training will help evaluate whether the program has been properly conducted, as well as ascertain

what could be improved if employees do not appear to be effectively trained. As in previous paragraph (l)(3)(i), and at the suggestion of the labor/industry group, designated employee representatives are to be provided all materials relating to information and training. (Ex. 118–12A) This will be useful to them in helping to assure that their members are benefitting from all the protection the BD standard affords.

The training provisions of this final rule are performance-oriented because employees may be exposed to BD in a variety of circumstances. Thus, the standard lists the topics of information to be transmitted to the employees, but does not specify the ways in which it is to be transmitted.

M. Recordkeeping

Section 8(c)(3) of the Act provides for the promulgation of ''regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6.'' All employers with BD in their workplace must do initial monitoring or reasonably rely on objective data that show that workplace exposures to BD are at or below the action level. Paragraph (m)(1) of the final rule requires employers who are relying on objective data (under paragraph (d)(2)) to avoid the initial monitoring requirements of the final rule, to maintain records that show the basis for their reliance and the reasoning used in reaching the conclusion that such monitoring is not necessary.

The objective data must provide the same degree of assurance that employees are not being significantly exposed to butadiene as monitoring would. Thus, such data should include information about the materials, product, activity, or process tested and found to qualify for exemptions; the source (e.g., manufacturer, testing laboratory, research study) of the objective data; the protocol used to obtain the results; a description of the product(s), materials(s), activities, or processes to which the relied upon data applies and an explanation of why such data are worthy of being relied upon; and any other data the employer believes are relevant to the exemption. This documentation is intended to demonstrate the appropriateness of the employer's reliance on objective data in lieu of the initial monitoring of employee exposure to BD.

The Agency has made a determination that significant employee exposures to BD should be closely monitored. Therefore it is appropriate to require the employer to carefully document and keep records of the data that are being relied upon in lieu of actual monitoring.

At the suggestion of the labor/industry group and for consistency with other provisions of the standard, the word ''streams'' has been included in paragraph (m)(1), since it is part of the exemptions in paragraph (a)(2) of this section.[13] (Ex. 118–12A)

Paragraph (m)(1)(iii) requires the employer to keep records of the objective data relied upon for as long as the employer continues to rely on such data.

Paragraph (m)(2) requires that employers keep records of all exposure monitoring required by the final rule. The provisions in this paragraph are consistent with those of 29 CFR 1910.1020, OSHA's Access to Employee Exposure and Medical Records standard. Paragraph (m)(2) specifies what information related to employee exposure monitoring must be kept. For example, it requires retention of information on the sampling and analytical methods, as well as information about the employee(s) sampled and their use of protective equipment. At the recommendation of the labor/industry group, records must also be maintained on written corrective action to be taken when monitoring indicates exposures over the PEL. (Ex. 118–12A) In addition, OSHA has also included a requirement that the schedule for completing the corrective action also be maintained.

A new paragraph, (m)(3), has been added to the final rule, which requires that records of respirator fit tests be maintained by the employer until the next fit test is administered to the employee. In the proposal, this provision was included in the mandatory appendix for respirator fit testing. OSHA believes that it will be more convenient for those using the standard to have all recordkeeping provisions together in the standard. Therefore recordkeeping provisions from other parts of the standard are being moved to paragraph (m) of the final rule.

Paragraph (m)(4) requires that the employer keep accurate medical records for each employee subject to medical screening and surveillance under the standard. Section 8(c) of the Act authorizes the promulgation of regulations requiring an employer to keep necessary and appropriate records regarding activities to permit the enforcement of the Act or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this context, requiring employers to maintain both medical and exposure measurement records is necessary and appropriate, and paragraph (m)(3) simply details what information must be kept.

Paragraph (m)(5)(i) states that all records required to be maintained by the standard must be made available to the Assistant Secretary and Director of NIOSH for examination and copying if such records are requested in writing. Access to these records is necessary for compliance monitoring. These records also contain information that the agencies may need to carry out other statutory responsibilities.

Paragraph (m)(5)(ii) provides that employees, former employees, and their designated representatives have access upon request to all exposure and medical records required by the standard. This provision is consistent with 29 CFR 1910.1020 (e). Section 8(c)(3) and other provisions of the Act make clear that employees and their representatives are expected to have an active and meaningful role in workplace safety and health. Employees and their representatives need information about employee exposures to toxic substances and their potential effects on health and safety if they are to benefit fully from these statutorily created rights.

OSHA's generic rule (29 CFR 1910.1020) permitting access to employee exposure and medical records was issued on May 23, 1980. (45 FR 35212) This rule applies to records created pursuant to specific standards and to records that are voluntarily created by employers. OSHA retains unrestricted access to medical and exposure records, but the Agency's access to personally identifiable records is subject to the Agency's rules of practice and procedure concerning OSHA access to employee medical records, which are codified at 29 CFR 1913.10.

Paragraph (m)(6) of the final rule addresses transfer of records. Under paragraph (m)(6)(i), when an employer ceases to do business, the employer must transfer records required by this section to the successor employer, who shall receive and maintain such records. If there is no successor employer, the employer shall notify the Director of NIOSH at least three months prior to anticipated disposal of the records, and shall transmit the records to the Director, if so requested. Under paragraph (m)(6)(ii), the employer is required to transfer medical and exposure records in accordance with

[13] Paragraph (m)(1)(i) now reads in pertinent part: ''Where the processing, use, or handling of products *or streams* made from or containing BD * * *

requirements set forth in 29 CFR 1910.1020(h).

The Agency believes it is necessary to keep certain records for extended periods of time because of the long latency periods commonly observed for the induction of cancer caused by exposures to carcinogens. Cancer often is not detected until 20 or more years after onset of exposure. The extended record retention period required by 29 CFR 1910.1020 therefore is needed for two purposes. First, possession of past and present exposure data and medical records aids in the diagnosis of workers' disease and determination of work-relatedness. In addition, retaining records for extended periods make possible future review to determine the effectiveness and adequacy of OSHA's final rules.

The time periods required for retention of exposure records and medical records are thirty years and the period of employment plus thirty years, respectively. These retention requirements are consistent with those in the OSHA exposure and medical records access standard.

N. Dates

This paragraph establishes the effective date of the final rule for butadiene and sets out start-up dates for various provisions of the standard. The final rule becomes effective 90 days following publication in the Federal Register. This period enables employers to familiarize themselves with the final rule. In addition, individual provisions, where appropriate, have delayed start-up dates. In addition, the Agency has established delayed start-up dates for several provisions of the final rule, based on evidence submitted to the record demonstrating that compliance with some provisions may require longer times than compliance with other provisions. These dates are based on the record in this rulemaking and on the Agency's experience with other standards concerning the amount of time required for employers to perform initial employee monitoring, institute medical surveillance programs, implement emergency procedures, etc.

The effective date, in conjunction with the start-up dates, will allow sufficient time for employers to achieve compliance with the substantive requirements of the final rule.

Paragraph (n)(2)(i) requires that initial monitoring shall be completed within sixty days of the effective date of the standard or within 60 days of the introduction of BD into the workplace. In the proposed rule, this paragraph was designated as paragraph (d)(2)(ii); it has been moved to paragraph (n) in the final rule to consolidate all effective date information in one section.

Dow Chemical Company objected to the 60 day start-up date for initial monitoring as being inadequate to set up such a program. (Ex. 118–16) OSHA believes that 60 days after the effective date of the standard is sufficient time to carry out initial monitoring. OSHA believes that much of the required monitoring may have already been performed by employers.

Final rule paragraph (n)(2)(iii) requires that the feasible engineering controls required by paragraph (f)(1) be implemented within two years after the effective date of the standard. This represents an extension of 12 months beyond that proposed for engineering controls. In testimony, the CMA Panel Chair, Dr. Norman Morrow, said that it was necessary to extend the one year start-up date to two years because of the time needed to identify those areas needing control, to determine the appropriate control measure to use, and to procure and install the equipment. (Tr. 1/18/91, p. 1168)

Other submissions contained similar requests for extension of the period to comply with controls. (Ex. 28–32; 112) OSHA agrees that additional time may be needed to come into full compliance and thus the final rule permits a full 24 months for compliance with the engineering controls provision of the final rule. During the period in which employers are implementing these controls, additional respirator use may be required to comply with the new exposure limits.

Paragraph (n)(2)(iii) also has a start-up date of within three years of the effective date of the standard to implement the exposure goal program (paragraph (g)). This is the length of time agreed upon by the labor/industry group who developed the provisions for the exposure goal program and submitted them to OSHA. (Ex. 118–12A) OSHA believes that this will provide ample time for employers to install or otherwise comply with the provisions in the program.

Final rule paragraph (n)(2)(ii), which covers start-up dates for paragraphs (c) through (m), including those for feasible work practice controls but not for the engineering controls specified in the paragraph (f)(1), requires that employers attain compliance within 180 days of the effective date of the BD standard. This provision is identical to proposed paragraph (n)(2)(i).

The rest of the provisions of the standard must be implemented within 180 days of the effective date.

O. Appendices

Six appendices have been included at the end of this standard. Appendices A, B, C, D, and F are included primarily for purposes of information and compliance assistance and should not be construed as establishing a mandatory requirement not otherwise imposed by the standard, or as detracting from an obligation which the standard does impose. However, the protocols for respiratory fit testing in Appendix E are binding.

The appendices have been updated from the proposal to reflect the final rule. Additionally, a number of technical and typographical corrections have been made in them. Appendix A contains information briefly describing the properties of BD and its hazards, and describes in general terms the provisions of the standard. Further, it contains the procedures to be used during emergencies, fires, and other situations in which there is potential for BD exposure.

Appendix B describes more fully the chemical and physical properties of BD and gives procedures to use when leaks or spills occur. Correct disposal is also outlined. Additional information is given on ways to safely handle BD.

Appendix C provides medical screening and surveillance guidelines for BD. The appendix describes the effects of BD exposure on the body and gives an overview of the medical screening and surveillance provisions of the standard. In general terms, it provides the physician or other licensed healthcare professional with an outline of the requirements of the rule.

Appendix D contains the sampling method developed and validated by the OSHA laboratory for use with BD. This is a non-mandatory appendix—the use of other measurement methods is allowed when accuracy levels required in the standard are met. Paragraph (d)(6) states that monitoring shall be accurate, at a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of BD at or above the 1 ppm TWA limit and to within plus or minus 35 percent for airborne concentrations of BD at or above the action level of 0.5 ppm and below the 1 ppm TWA limit. In addition, paragraph (m)(2)(ii)(C) requires that the exposure measurement record include sampling and analytical methods used and evidence of their accuracy.

Supplementary data used by the OSHA laboratory in developing the analytical method were included in the proposal, but have been deleted from the final rule. (55 FR 32736 at 32814.)

Basically, the OSHA method is a charcoal tube (CT)-gas chromatography (GC)-mass spectrometry (MS) (CT–GC–MS) method. It involves the use of charcoal tubes and sampling pumps, followed by analysis of the samples by gas chromatography and a confirmation of GC peak by MS when it is necessary. The charcoal is coated with 4-tert-butylcatechol to inhibit the polymerization of BD, in order to increase the stability of the sample. (Ex. 118–9) Since BD often is present in a complex mixture which may make it difficult to adequately evaluate due to interferences, MS is used in GC–MS combination to identify the GC chemical peak and to make sure that there is no interferences and to identify any interferences that occur.

OSHA agrees with API that no single CT–GC–MS method can be used as a ''cookbook'' for all situations. (Ex. 118–11) The American Petroleum Institute (API) developed a method to ''resolve interferences for complex mixtures found in the petroleum industry'' in 1991 and refined the method in 1996. (Exs. 108 and 118–11) The API method uses a long length of capillary column with different configurations for a greater separation ability from other isomers/interferences found in the petroleum industry. API asked OSHA's acceptance of the API BD monitoring method. (Ex. 118–11) OSHA believes that the API method, as well as other methods which may be developed that accurately measure BD levels in the breathing zone of exposed workers, are acceptable.

Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers must assure that the evaluation of employee exposure is performed by a technically qualified person.

Appendix E is the only mandatory appendix to the BD rule. This appendix has been revised somewhat from the proposal throughout, primarily for clarity. However, it now contains a protocol for using ambient aerosol condensation nuclei counter (CNC) quantitative fit testing, which was not included in the proposal.

Appendix F contains sample questionnaires for use in medical screening and surveillance. The appendix contains two sample questionnaires, one for the initial medical evaluation and the other for the annual updating of the medical evaluations. These are included to provide medical personnel information to assist them in complying with the standard.

Authority and Signature

This document was prepared under the direction of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210

Pursuant to sections 4, 6(b), 8(c) and 8(g) of the Occupational Safety and Health Action (29 U.S.C. 653, 655, 657), section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); the Secretary of Labor's Order No. 1–90 (55 FR 9033); and 29 CFR part 1911; 29 CFR parts 1910, 1915 and 1926 are amended as set forth below.

List of Subjects in 29 CFR Parts 1910, 1915 and 1926

1,3–Butadiene, Cancer, Chemicals, Health risk-assessment, Occupational safety and health.

Signed at Washington, DC, this 24th day of October 1996.

Joseph A. Dear,

Assistant Secretary of Labor.

PART 1910—[AMENDED]

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

Subpart B—[Amended]

1. The authority citation for subpart B of Part 1910 is revised to read as follows:

Authority: Secs. 4, 6 and 8 of the Occupational Safety and Health Act, 29 U.S.C. 653, 655; 657; Walsh-Healey Act, 41 U.S.C. 35 *et seq;* Service Contract Act of 1965, 41 U.S.C. 351 *et seq;* sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act), 40 U.S.C. 333; sec. 41, Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 941; National Foundation of Arts and Humanities Act, 20 U.S.C. 951 et seq.; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059); 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable; and 29 CFR part 1911.

2. A new paragraph (l) is added to § 1910.19 to read as follows:

§ 1910.19 Special provisions for air contaminants.

* * * * *

(l) 1,3-Butadiene (BD): Section 1910.1051 shall apply to the exposure of every employee to BD in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or § 1910.16, in lieu of any different standard on exposure to BD which would otherwise be applicable by virtue of those sections.

Subpart Z—Toxic and Hazardous Substances—[Amended]

3. The authority citation for subpart Z of part 1910 continues to read as follows:

Authority: Secs. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), of 1–90 (55 FR 9033) as applicable; and 29 CFR part 1911.

Section 1910.1000, Tables Z–1, Z–2, and Z–3 also issued under 5 U.S.C. 553. Section 1910.1000, Tables Z–1, Z–2, and Z–3 not issued under 29 CFR Part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and 1,3-butadiene listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and 5 U.S.C. 553.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR 1911; also issued under 5 U.S.C. 553.

Section 1910.1200 also issued under 5 U.S.C. 553.

§ 1910.1000 [Amended]

4. The entry in Table Z–1 of § 1910.1000, ''Butadiene (1,3-Butadiene)'' is amended as follows: remove the ''1000'' and ''2200'' from the columns entitled ppm(a)[1] and mg/m[3] (b)[1] respectively, add ''1 ppm/5 ppm STEL'' in the ppm (a)[1] column; and add the following to the butadiene entry ''; See 29 CFR 1910.1051; 29 CFR 1910.19(l)'' so that the entry reads as follows: ''Butadiene (1,3-Butadiene); See 29 CFR 1910.1051; 29 CFR 1910.19(l).''

5. A new 1910.1051 is added to read as follows:

§ 1910.1051 1,3-Butadiene.

(a) *Scope and application.* (1) This section applies to all occupational exposures to 1,3-Butadiene (BD), Chemical Abstracts Service Registry No. 106–99–0, except as provided in paragraph (a)(2) of this section.

(2)(i) Except for the recordkeeping provisions in paragraph (m)(1) of this section, this section does not apply to the processing, use, or handling of products containing BD or to other work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate the work operation or the product or the group of products or operations to which it belongs may not reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release or in any plausible accident.

(ii) This section also does not apply to work operations, products or streams where the only exposure to BD is from liquid mixtures containing 0.1% or less of BD by volume or the vapors released from such liquids, unless objective data become available that show that airborne concentrations generated by such mixtures can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release.

(iii) Except for labeling requirements and requirements for emergency response, this section does not apply to the storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid.

(3) Where products or processes containing BD are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (m)(1) of this section.

(b) *Definitions:* For the purpose of this section, the following definitions shall apply:

Action level means a concentration of airborne BD of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically designated by the employer, whose duties require entrance into a regulated area, or a person entering such an area as a designated representative of employees to exercise the right to observe monitoring and measuring procedures under paragraph (d)(8) of this section, or a person designated under the Act or regulations issued under the Act to enter a regulated area.

1,3–Butadiene means an organic compound with chemical formula CH_2=CH–CH=CH_2 that has a molecular weight of approximately 54.15 gm/mole.

Business day means any Monday through Friday, except those days designated as federal, state, local or company specific holidays.

Complete Blood Count (CBC) means laboratory tests performed on whole blood specimens and includes the following: White blood cell count (WBC), hematocrit (Hct), red blood cell count (RBC), hemoglobin (Hgb), differential count of white blood cells, red blood cell morphology, red blood cell indices, and platelet count.

Day means any part of a calendar day.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency situation means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

Employee exposure means exposure of a worker to airborne concentrations of BD which would occur if the employee were not using respiratory protective equipment.

Objective data means monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.

Permissible Exposure Limits, PELs means either the 8 hour Time Weighted Average (8-hr TWA) exposure or the Short-Term Exposure Limit (STEL).

Physician or other licensed health care professional is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide one or more of the specific health care services required by paragraph (k) of this section.

Regulated area means any area where airborne concentrations of BD exceed or can reasonably be expected to exceed the 8-hour time weighted average (8-hr TWA) exposure of 1 ppm or the short-term exposure limit (STEL) of 5 ppm for 15 minutes.

This section means this 1,3-butadiene standard.

(c) *Permissible exposure limits (PELs).*—(1) *Time-weighted average (TWA) limit.* The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of one (1) part BD per million parts of air (ppm) measured as an eight (8)-hour time-weighted average.

(2) *Short-term exposure limit (STEL).* The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of five parts of BD per million parts of air (5 ppm) as determined over a sampling period of fifteen (15) minutes.

(d) *Exposure monitoring*—(1) *General.* (i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift and for each job classification in each work area.

(iii) Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the STEL for each shift and for each job classification in each work area.

(iv) Except for the initial monitoring required under paragraph (d)(2) of this section, where the employer can document that exposure levels are equivalent for similar operations on different work shifts, the employer need only determine representative employee exposure for that operation from the shift during which the highest exposure is expected.

(2) *Initial monitoring.* (i) Each employer who has a workplace or work operation covered by this section, shall perform initial monitoring to determine accurately the airborne concentrations of BD to which employees may be exposed, or shall rely on objective data pursuant to paragraph (a)(2)(i) of this section to fulfill this requirement.

(ii) Where the employer has monitored within two years prior to the effective date of this section and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section, provided that the conditions under which the initial monitoring was conducted have not changed in a manner that may result in new or additional exposures.

(3) *Periodic monitoring and its frequency.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be at or above the action level but at or below both the 8-hour TWA limit and the STEL, the employer shall repeat the representative monitoring required by paragraph (d)(1) of this section every twelve months.

(ii) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the 8-hour TWA limit, the employer shall repeat the representative monitoring required by paragraph (d)(1)(ii) of this section at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

(iii) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the STEL, the employer shall repeat the

representative monitoring required by paragraph (d)(1)(iii) of this section at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

(iv) The employer may alter the monitoring schedule from every six months to annually for any required representative monitoring for which two consecutive measurements taken at least 7 days apart indicate that employee exposure has decreased to or below the 8-hour TWA, but is at or above the action level.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be below the action level and at or below the STEL, the employer may discontinue the monitoring for employees whose exposures are represented by the initial monitoring.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level and at or below the STEL, the employer may discontinue the monitoring for those employees who are represented by such monitoring.

(5) *Additional monitoring.* (i) The employer shall institute the exposure monitoring required under paragraph (d) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to BD or when the employer has any reason to suspect that a change may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the 8-hr TWA limit or above the STEL, the employer shall monitor [using leak source, such as direct reading instruments, area or personal monitoring], after the cleanup of the spill or repair of the leak, rupture or other breakdown, to ensure that exposures have returned to the level that existed prior to the incident.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, at a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of BD at or above the 1 ppm TWA limit and to within plus or minus 35 percent for airborne concentrations of BD at or above the action level of 0.5 ppm and below the 1 ppm TWA limit.

(7) *Employee notification of monitoring results.* (i) The employer shall, within 5 business days after the receipt of the results of any monitoring performed under this section, notify the affected employees of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The employer shall, within 15 business days after receipt of any monitoring performed under this section indicating the 8-hour TWA or STEL has been exceeded, provide the affected employees, in writing, with information on the corrective action being taken by the employer to reduce employee exposure to or below the 8-hour TWA or STEL and the schedule for completion of this action.

(8) *Observation of monitoring.*—(i) *Employee observation.* The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to BD conducted in accordance with paragraph (d) of this section.

(ii) *Observation procedures.* When observation of the monitoring of employee exposure to BD requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer at no cost with protective clothing and equipment, and shall ensure that the observer uses this equipment and complies with all other applicable safety and health procedures.

(e) *Regulated areas.* (1) The employer shall establish a regulated area wherever occupational exposures to airborne concentrations of BD exceed or can reasonably be expected to exceed the permissible exposure limits, either the 8-hr TWA or the STEL.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated from the rest of the workplace in any manner that minimizes the number of employees exposed to BD within the regulated area.

(4) An employer at a multi-employer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite whose employees may have access to these areas.

(f) *Methods of compliance.*—(1) *Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the PELs, except to the extent that the employer can establish that these controls are not feasible or where paragraph (h)(1)(i) of this section applies.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the 8-hour TWA or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (h) of this section.

(2) *Compliance plan.* (i) Where any exposures are over the PELs, the employer shall establish and implement a written plan to reduce employee exposure to or below the PELs primarily by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section. No compliance plan is required if all exposures are under the PELs.

(ii) The written compliance plan shall include a schedule for the development and implementation of the engineering controls and work practice controls including periodic leak detection surveys.

(iii) Copies of the compliance plan required in paragraph (f)(2) of this section shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(g) *Exposure Goal Program.* (1) For those operations and job classifications where employee exposures are greater than the action level, in addition to compliance with the PELs, the employer shall have an exposure goal program that is intended to limit employee exposures to below the action level during normal operations.

(2) Written plans for the exposure goal program shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives.

(3) Such plans shall be updated as necessary to reflect significant changes in the status of the exposure goal program.

(4) Respirator use is not required in the exposure goal program.

(5) The exposure goal program shall include the following items unless the employer can demonstrate that the item is not feasible, will have no significant effect in reducing employee exposures, or is not necessary to achieve exposures below the action level:

(i) A leak prevention, detection, and repair program.

(ii) A program for maintaining the effectiveness of local exhaust ventilation systems.

(iii) The use of pump exposure control technology such as, but not limited to, mechanical double-sealed or seal-less pumps.

(iv) Gauging devices designed to limit employee exposure, such as magnetic gauges on rail cars.

(v) Unloading devices designed to limit employee exposure, such as a vapor return system.

(vi) A program to maintain BD concentration below the action level in control rooms by use of engineering controls.

(h) *Respiratory protection.*—(1) *General.* The employer shall provide respirators that comply with the requirements of this paragraph, at no cost to each affected employee, and ensure that each affected employee uses such respirator where required by this section. Respirators shall be used in the following circumstances:

(i) During the time interval necessary to install or implement feasible engineering and work practice controls;

(ii) In non-routine work operations which are performed infrequently and in which exposures are limited in duration.

(iii) In work situations where feasible engineering controls and work practice controls are not yet sufficient to reduce exposures to or below the PELs; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required, the employer shall select and provide the appropriate respirator as specified in Table 1 in paragraph (h)(5)(ii) of this section, and ensure its use.

(ii) The employer shall select respirators from among those approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 42 CFR Part 84, ''Respiratory Protective Devices.'' Air purifying respirators shall have filter element(s) approved by NIOSH for organic vapors or BD.

(iii) If an employee whose job requires the use of a respirator cannot use a negative pressure respirator, the employee must be provided with a respirator having less breathing resistance, such as a powered air-purifying respirator or supplied air respirator, if the employee is able to use it and if it will provide adequate protection.

(3) *Respirator program.* Where respiratory protection is required, the employer shall institute a respirator program in accordance with 29 CFR 1910.134.

(4) *Respirator use.* (i) Where air-purifying respirators are used, the employer shall replace the air purifying filter element(s) according to the replacement life interval set for the class of respirator listed in Table 1 in paragraph (h)(5) of this section and at the beginning of each work shift.

(ii) In lieu of the replacement intervals listed in Table 1, the employer may replace cartridges or canisters at 90% of the expiration of service life, provided the employer can demonstrate that employees will be adequately protected. BD breakthrough data relied upon by the employer must derive from tests conducted under worst case conditions of humidity, temperature, and air flow rate through the filter element. The employer shall describe the data supporting the cartridge/canister change schedule and the basis for reliance on the data in the employer's respirator program.

(iii) A label shall be attached to the filter element(s) to indicate the date and time it is first installed on the respirator. If an employee detects the odor of BD, the employer shall replace the air-purifying element(s) immediately.

(iv) If a NIOSH-approved end of service life indicator (ESLI) for BD becomes available for an air-purifying filter element, the element may be used until such time as the indicator shows no further useful service life or until replaced at the beginning of the next work shift, whichever comes first. If an employee detects the odor of BD, the employer shall replace the air-purifying element(s) immediately.

(v) The employer shall permit employees who wear respirators to leave the regulated area to wash their faces and respirator facepieces as necessary in order to prevent skin irritation associated with respirator use or to change the filter elements of air-purifying respirators whenever they detect a change in breathing resistance or whenever the odor of BD is detected.

(5) *Respirator fit testing.* (i) The employer shall perform either qualitative fit testing (QLFT) or quantitative fit testing (QNFT), as required in Appendix E to this section, at the time of initial fitting and at least annually thereafter for employees who wear tight-fitting negative pressure respirators. Fit testing shall be used to select a respirator facepiece which exhibits minimum leakage and provides the required protection as prescribed in Table 1 in paragraph (h)(5)(ii) of this section.

(ii) For each employee wearing a tight-fitting full facepiece negative pressure respirator who is exposed to airborne concentrations of BD that exceed 10 times the TWA PEL (10 ppm), the employer shall perform quantitative fit testing as required in Appendix E to this section, at the time of initial fitting and at least annually thereafter.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE BD

Concentration of airborne BD (ppm) or condition of use	Minimum required respirator
Less than or equal to 5 ppm (5 times PEL).	(a) Air-purifying half mask or full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 4 hours.
Less than or equal to 10 ppm (10 times PEL).	(a) Air-purifying half mask or full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 3 hours.
Less than or equal to 25 ppm (25 times PEL).	(a) Air-purifying full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 2 hours. (b) Any powered air-purifying respirator equipped with approved BD or organic vapor cartridges. PAPR cartridges shall be replaced every 2 hours. (c) Continuous flow supplied air respirator equipped with a hood or helmet.
Less than or equal to 50 ppm (50 times PEL).	(a) Air-purifying full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every (1) hour. (b) Powered air-purifying respirator equipped with a tight-fitting facepiece and an approved BD or organic vapor cartridges. PAPR cartridges shall be replaced every (1) hour.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE BD—Continued

Concentration of airborne BD (ppm) or condition of use	Minimum required respirator
Less than or equal to 1,000 ppm (1,000 times PEL).	(a) Supplied air respirator equipped with a half mask of full facepiece and operated in a pressure demand or other positive pressure mode.
Greater than 1000 ppm	(a) Self-contained breathing unknown concentration, or apparatus equipped with a firefighting full facepiece and operated in a pressure demand or other positive pressure mode. (b) Any supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.
Escape from IDLH conditions	(a) Any positive pressure self-contained breathing apparatus with an appropriate service life. (b) A air-purifying full facepiece respirator equipped with a front or back mounted BD or organic vapor canister.

Notes: Respirators approved for use in higher concentrations are permitted to be used in lower concentrations. Full facepiece is required when eye irritation is anticipated.

(iii) The employer shall ensure that employees wearing tight fitting respirators perform a facepiece seal fit check to ensure that a proper facepiece seal is obtained prior to entry into a BD atmosphere. The recommended positive or negative pressure fit check procedures listed in Appendix E to this section or the respirator manufacturer's recommended fit check procedure shall be used.

(i) *Protective clothing and equipment.* Where appropriate to prevent eye contact and limit dermal exposure to BD, the employer shall provide protective clothing and equipment at no cost to the employee and shall ensure its use. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(j) *Emergency situations. Written plan.* A written plan for emergency situations shall be developed, or an existing plan shall be modified, to contain the applicable elements specified in 29 CFR 1910.38, ''Employee Emergency Plans and Fire Prevention Plans,'' and in 29 CFR 1910.120 ''Hazardous Waste Operations and Emergency Responses,'' for each workplace where there is a possibility of an emergency.

(k) *Medical screening and surveillance.*—(1) *Employees covered.* The employer shall institute a medical screening and surveillance program as specified in this paragraph for:

(i) Each employee with exposure to BD at concentrations at or above the action level on 30 or more days or for employees who have or may have exposure to BD at or above the PELs on 10 or more days a year;

(ii) Employers (including successor owners) shall continue to provide medical screening and surveillance for employees, even after transfer to a non-BD exposed job and regardless of when the employee is transferred, whose work histories suggest exposure to BD:

(A) At or above the PELs on 30 or more days a year for 10 or more years;

(B) At or above the action level on 60 or more days a year for 10 or more years; or

(C) Above 10 ppm on 30 or more days in any past year; and

(iii) Each employee exposed to BD following an emergency situation.

(2) *Program administration.* (i) The employer shall ensure that the health questionnaire, physical examination and medical procedures are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(ii) Physical examinations, health questionnaires, and medical procedures shall be performed or administered by a physician or other licensed health care professional.

(iii) Laboratory tests shall be conducted by an accredited laboratory.

(3) *Frequency of medical screening activities.* The employer shall make medical screening available on the following schedule:

(i) For each employee covered under paragraphs (j)(1) (i)–(ii) of this section, a health questionnaire and complete blood count with differential and platelet count (CBC) every year, and a physical examination as specified below:

(A) An initial physical examination that meets the requirements of this rule, if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure;

(B) Before assumption of duties by the employee in a job with BD exposure;

(C) Every 3 years after the initial physical examination;

(D) At the discretion of the physician or other licensed health care professional reviewing the annual health questionnaire and CBC;

(E) At the time of employee reassignment to an area where exposure to BD is below the action level, if the employee's past exposure history does not meet the criteria of paragraph (j)(1)(ii) of this section for continued coverage in the screening and surveillance program, and if twelve months or more have elapsed since the last physical examination; and

(F) At termination of employment if twelve months or more have elapsed since the last physical examination.

(ii) Following an emergency situation, medical screening shall be conducted as quickly as possible, but not later than 48 hours after the exposure.

(iii) For each employee who must wear a respirator, physical ability to perform the work and use the respirator must be determined as required by 29 CFR 1910.134.

(4) *Content of medical screening.* (i) Medical screening for employees covered by paragraphs (j)(1) (i)–(ii) of this section shall include:

(A) A baseline health questionnaire that includes a comprehensive occupational and health history and is updated annually. Particular emphasis shall be placed on the hematopoietic and reticuloendothelial systems, including exposure to chemicals, in addition to BD, that may have an adverse effect on these systems, the presence of signs and symptoms that might be related to disorders of these systems, and any other information determined by the examining physician or other licensed health care professional to be necessary to evaluate whether the employee is at increased risk of material impairment of health from BD exposure. Health questionnaires shall consist of the sample forms in Appendix C to this section, or be equivalent to those samples;

(B) A complete physical examination, with special emphasis on the liver, spleen, lymph nodes, and skin;

(C) A CBC; and

(D) Any other test which the examining physician or other licensed health care professional deems necessary to evaluate whether the

employee may be at increased risk from exposure to BD.

(ii) Medical screening for employees exposed to BD in an emergency situation shall focus on the acute effects of BD exposure and at a minimum include: A CBC within 48 hours of the exposure and then monthly for three months; and a physical examination if the employee reports irritation of the eyes, nose throat, lungs, or skin, blurred vision, coughing, drowsiness, nausea, or headache. Continued employee participation in the medical screening and surveillance program, beyond these minimum requirements, shall be at the discretion of the physician or other licensed health care professional.

(5) *Additional medical evaluations and referrals.* (i) Where the results of medical screening indicate abnormalities of the hematopoietic or reticuloendothelial systems, for which a non-occupational cause is not readily apparent, the examining physician or other licensed health care professional shall refer the employee to an appropriate specialist for further evaluation and shall make available to the specialist the results of the medical screening.

(ii) The specialist to whom the employee is referred under this paragraph shall determine the appropriate content for the medical evaluation, e.g., examinations, diagnostic tests and procedures, etc.

(6) *Information provided to the physician or other licensed health care professional.* The employer shall provide the following information to the examining physician or other licensed health care professional involved in the evaluation:

(i) A copy of this section including its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's BD exposure;

(iii) The employee's actual or representative BD exposure level during employment tenure, including exposure incurred in an emergency situation;

(iv) A description of pertinent personal protective equipment used or to be used; and

(v) Information, when available, from previous employment-related medical evaluations of the affected employee which is not otherwise available to the physician or other licensed health care professional or the specialist.

(7) *The written medical opinion.* (i) For each medical evaluation required by this section, the employer shall ensure that the physician or other licensed health care professional produces a written opinion and provides a copy to the employer and the employee within 15 business days of the evaluation. The written opinion shall be limited to the following information:

(A) The occupationally pertinent results of the medical evaluation;

(B) A medical opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to BD;

(C) Any recommended limitations upon the employee's exposure to BD; and

(D) A statement that the employee has been informed of the results of the medical evaluation and any medical conditions resulting from BD exposure that require further explanation or treatment.

(ii) The written medical opinion provided to the employer shall not reveal specific records, findings, and diagnoses that have no bearing on the employee's ability to work with BD.

Note: However, this provision does not negate the ethical obligation of the physician or other licensed health care professional to transmit any other adverse findings directly to the employee.

(8) *Medical surveillance.* (i) The employer shall ensure that information obtained from the medical screening program activities is aggregated (with all personal identifiers removed) and periodically reviewed, to ascertain whether the health of the employee population of that employer is adversely affected by exposure to BD.

(ii) Information learned from medical surveillance activities must be disseminated to covered employees, as defined in paragraph (k)(1) of this section, in a manner that ensures the confidentiality of individual medical information.

(l) *Communication of BD hazards to employees.*—(1) *Hazard communication.* The employer shall communicate the hazards associated with BD exposure in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, and 29 CFR 1926.59.

(2) *Employee information and training.* (i) The employer shall provide all employees exposed to BD with information and training in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, and 29 CFR 1926.59.

(ii) The employer shall institute a training program for all employees who are potentially exposed to BD at or above the action level or the STEL, ensure employee participation in the program and maintain a record of the contents of such program.

(iii) Training shall be provided prior to or at the time of initial assignment to a job potentially involving exposure to BD at or above the action level or STEL and at least annually thereafter.

(iv) The training program shall be conducted in a manner that the employee is able to understand. The employee shall ensure that each employee exposed to BD over the action level or STEL is informed of the following:

(A) The health hazards associated with BD exposure, and the purpose and a description of the medical screening and surveillance program required by this section;

(B) The quantity, location, manner of use, release, and storage of BD and the specific operations that could result in exposure to BD, especially exposures above the PEL or STEL;

(C) The engineering controls and work practices associated with the employee's job assignment, and emergency procedures and personal protective equipment;

(D) The measures employees can take to protect themselves from exposure to BD.

(E) The contents of this standard and its appendices, and

(F) The right of each employee exposed to BD at or above the action level or STEL to obtain:

(*1*) medical examinations as required by paragraph (j) of this section at no cost to the employee;

(*2*) the employee's medical records required to be maintained by paragraph (m)(4) of this section; and

(*3*) all air monitoring results representing the employee's exposure to BD and required to be kept by paragraph (m)(2) of this section.

(3) *Access to information and training materials.* (i) The employer shall make a copy of this standard and its appendices readily available without cost to all affected employees and their designated representatives and shall provide a copy if requested.

(ii) The employer shall provide to the Assistant Secretary or the Director, or the designated employee representatives, upon request, all materials relating to the employee information and the training program.

(m) *Recordkeeping.*—(1) *Objective data for exemption from initial monitoring.* (i) Where the processing, use, or handling of products or streams made from or containing BD are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial

monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain a record of the objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product or activity qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and analysis of the material for the release of BD;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) *Exposure measurements.* (i) The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to BD as prescribed in paragraph (d) of this section.

(ii) The record shall include at least the following information:

(A) The date of measurement;

(B) The operation involving exposure to BD which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of protective devices worn, if any; and

(F) Name, social security number and exposure of the employees whose exposures are represented.

(G) The written corrective action and the schedule for completion of this action required by paragraph (d)(7)(ii) of this section.

(iii) The employer shall maintain this record for at least 30 years in accordance with 29 CFR 1910.20.

(3) *Respirator Fit-test.* (i) The employer shall establish a record of the fit tests administered to an employee including:

(A) The name of the employee,

(B) Type of respirator,

(C) Brand and size of respirator,

(D) Date of test, and

(E) Where QNFT is used, the fit factor, strip chart recording or other recording of the results of the test.

(ii) Fit test records shall be maintained for respirator users until the next fit test is administered.

(4) *Medical screening and surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical screening and surveillance under this section.

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physician's or other licensed health care professional's written opinions as described in paragraph (k)(7) of this section;

(C) A copy of the information provided to the physician or other licensed health care professional as required by paragraphs (k)(7)(ii)–(iv) of this section.

(iii) Medical screening and surveillance records shall be maintained for each employee for the duration of employment plus 30 years, in accordance with 29 CFR 1910.20.

(5) *Availability.* (i) The employer, upon written request, shall make all records required to be maintained by this section available for examination and copying to the Assistant Secretary and the Director.

(ii) Access to records required to be maintained by paragraphs (l)(1)–(3) of this section shall be granted in accordance with 29 CFR 1910.20(e).

(6) *Transfer of records.* (i) Whenever the employer ceases to do business, the employer shall transfer records required by this section to the successor employer. The successor employer shall receive and maintain these records. If there is no successor employer, the employer shall notify the Director, at least three (3) months prior to disposal, and transmit them to the Director if requested by the Director within that period.

(ii) The employer shall transfer medical and exposure records as set forth in 29 CFR 1910.20(h).

(n) *Dates.*—(1) *Effective date.* This section shall become effective ninety (90) days after the date of publication in the Federal Register.

(2) *Start-up dates.* (i) The initial monitoring required under paragraph (d)(2) of this section shall be completed within sixty (60) days of the effective date of this standard or the introduction of BD into the workplace.

(ii) The requirements of paragraphs (c) through (m) of this section, including feasible work practice controls but not including engineering controls specified in paragraph (f)(1) of this section, shall be complied with within one-hundred and eighty (180) days after the effective date of this section.

(iii) Engineering controls specified by paragraph (f)(1) of this section shall be implemented within two (2) years after the effective date of this section, and the exposure goal program specified in paragraph (g) of this section shall be implemented within three (3) years after the effective date of this section.

(o) *Appendices.* (1) Appendix E to this section is mandatory.

(2) Appendices A, B, C, D, and F to this section are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

Appendix A. Substance Safety Data Sheet For 1,3-Butadiene (Non-Mandatory)

I. Substance Identification

A. Substance: 1,3-Butadiene (CH_2=CH-CH=CH_2).

B. Synonyms: 1,3-Butadiene (BD); butadiene; biethylene; bi-vinyl; divinyl; butadiene-1,3; buta-1,3-diene; erythrene; NCI–C50602; CAS–106–99–0.

C. BD can be found as a gas or liquid.

D. BD is used in production of styrene-butadiene rubber and polybutadiene rubber for the tire industry. Other uses include copolymer latexes for carpet backing and paper coating, as well as resins and polymers for pipes and automobile and appliance parts. It is also used as an intermediate in the production of such chemicals as fungicides.

E. Appearance and odor: BD is a colorless, non-corrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure.

F. Permissible exposure: Exposure may not exceed 1 part BD per million parts of air averaged over the 8-hour workday, nor may short-term exposure exceed 5 parts of BD per million parts of air averaged over any 15-minute period in the 8-hour workday.

II. Health Hazard Data

A. BD can affect the body if the gas is inhaled or if the liquid form, which is very cold (cryogenic), comes in contact with the eyes or skin.

B. Effects of overexposure: Breathing very high levels of BD for a short time can cause central nervous system effects, blurred vision, nausea, fatigue, headache, decreased blood pressure and pulse rate, and unconsciousness. There are no recorded cases of accidental exposures at high levels that have caused death in humans, but this could occur. Breathing lower levels of BD may cause irritation of the eyes, nose, and throat. Skin contact with liquefied BD can cause irritation and frostbite.

C. Long-term (chronic) exposure: BD has been found to be a potent carcinogen in rodents, inducing neoplastic lesions at multiple target sites in mice and rats. A recent study of BD-exposed workers showed that exposed workers have an increased risk of developing leukemia. The risk of leukemia increases with increased exposure to BD. OSHA has concluded that there is strong evidence that workplace exposure to BD poses an increased risk of death from cancers of the lymphohematopoietic system.

D. Reporting signs and symptoms: You should inform your supervisor if you develop any of these signs or symptoms and suspect that they are caused by exposure to BD.

III. Emergency First Aid Procedures

In the event of an emergency, follow the emergency plan and procedures designated for your work area. If you have been trained

in first aid procedures, provide the necessary first aid measures. If necessary, call for additional assistance from co-workers and emergency medical personnel.

A. Eye and Skin Exposures: If there is a potential that liquefied BD can come in contact with eye or skin, face shields and skin protective equipment must be provided and used. If liquefied BD comes in contact with the eye, immediately flush the eyes with large amounts of water, occasionally lifting the lower and the upper lids. Flush repeatedly. Get medical attention immediately. Contact lenses should not be worn when working with this chemical. In the event of skin contact, which can cause frostbite, remove any contaminated clothing and flush the affected area repeatedly with large amounts of tepid water.

B. Breathing: If a person breathes in large amounts of BD, move the exposed person to fresh air at once. If breathing has stopped, begin cardiopulmonary resuscitation (CPR) if you have been trained in this procedure. Keep the affected person warm and at rest. Get medical attention immediately.

C. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, call for help and begin emergency rescue procedures. Use extreme caution so that you do not become a casualty. Understand the plant's emergency rescue procedures and know the locations of rescue equipment before the need arises.

IV. Respirators and Protective Clothing

A. Respirators: Good industrial hygiene practices recommend that engineering and work practice controls be used to reduce environmental concentrations to the permissible exposure level. However, there are some exceptions where respirators may be used to control exposure. Respirators may be used when engineering and work practice controls are not technically feasible, when such controls are in the process of being installed, or when these controls fail and need to be supplemented or during brief, non-routine, intermittent exposure. Respirators may also be used in situations involving non-routine work operations which are performed infrequently and in which exposures are limited in duration, and in emergency situations. In some instances cartridge respirator use is allowed, but only with strict time constraints. For example, at exposure below 5 ppm BD, a cartridge (or canister) respirator, either full or half face, may be used, but the cartridge must be replaced at least every 4 hours, and it must be replaced every 3 hours when the exposure is between 5 and 10 ppm. If the use of respirators is necessary, the only respirators permitted are those that have been approved by the National Institute for Occupational Safety and Health (NIOSH). In addition to respirator selection, a complete respiratory protection program must be instituted which includes regular training, maintenance, fit testing, inspection, cleaning, and evaluation of respirators. If you can smell BD while wearing a respirator, proceed immediately to fresh air, and change cartridge (or canister) before re-entering an area where there is BD exposure. If you experience difficulty in breathing while wearing a respirator, tell your supervisor.

B. Protective Clothing: Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen by contact with liquefied BD (or a vessel containing liquid BD).

Employees should be provided with and required to use splash-proof safety goggles where liquefied BD may contact the eyes.

V. Precautions for Safe Use, Handling, and Storage

A. Fire and Explosion Hazards: BD is a flammable gas and can easily form explosive mixtures in air. It has a lower explosive limit of 2%, and an upper explosive limit of 11.5%. It has an autoignition temperature of 420° C (788° F). Its vapor is heavier than air (vapor density, 1.9) and may travel a considerable distance to a source of ignition and flash back. Usually it contains inhibitors to prevent self-polymerization (which is accompanied by evolution of heat) and to prevent formation of explosive peroxides. At elevated temperatures, such as in fire conditions, polymerization may take place. If the polymerization takes place in a container, there is a possibility of violent rupture of the container.

B. Hazard: Slightly toxic. Slight respiratory irritant. Direct contact of liquefied BD on skin may cause freeze burns and frostbite.

C. Storage: Protect against physical damage to BD containers. Outside or detached storage of BD containers is preferred. Inside storage should be in a cool, dry, well-ventilated, noncombustible location, away from all possible sources of ignition. Store cylinders vertically and do not stack. Do not store with oxidizing material.

D. Usual Shipping Containers: Liquefied BD is contained in steel pressure apparatus.

E. Electrical Equipment: Electrical installations in Class I hazardous locations, as defined in Article 500 of the National Electrical Code, should be in accordance with Article 501 of the Code. If explosion-proof electrical equipment is necessary, it shall be suitable for use in Group B. Group D equipment may be used if such equipment is isolated in accordance with Section 501–5(a) by sealing all conduit ½- inch size or larger. See Venting of Deflagrations (NFPA No. 68, 1994), National Electrical Code (NFPA No. 70, 1996), Static Electricity (NFPA No. 77, 1993), Lightning Protection Systems (NFPA No. 780, 1995), and Fire Hazard Properties of Flammable Liquids, Gases and Volatile Solids (NFPA No. 325, 1994).

F. Fire Fighting: Stop flow of gas. Use water to keep fire-exposed containers cool. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

G. Spill and Leak: Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until clean-up has been completed. If BD is spilled or leaked, the following steps should be taken:

1. Eliminate all ignition sources.
2. Ventilate area of spill or leak.
3. If in liquid form, for small quantities, allow to evaporate in a safe manner.
4. Stop or control the leak if this can be done without risk. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place and repair the leak or allow the cylinder to empty.

H. Disposal: This substance, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR part 261). It is listed as hazardous waste number D001 due to its ignitability. The transportation, storage, treatment, and disposal of this waste material must be conducted in compliance with 40 CFR parts 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Check state and local regulation of any additional requirements as these may be more restrictive than federal laws and regulation.

I. You should not keep food, beverages, or smoking materials in areas where there is BD exposure, nor should you eat or drink in such areas.

J. Ask your supervisor where BD is used in your work area and ask for any additional plant safety and health rules.

VI. Medical Requirements

Your employer is required to offer you the opportunity to participate in a medical screening and surveillance program if you are exposed to BD at concentrations exceeding the action level (0.5 ppm BD as an 8-hour TWA) on 30 days or more a year, or at or above the 8 hr TWA (1 ppm) or STEL (5 ppm for 15 minutes) on 10 days or more a year. Exposure for any part of a day counts. If you have had exposure to BD in the past, but have been transferred to another job, you may still be eligible to participate in the medical screening and surveillance program. The OSHA rule specifies the past exposures that would qualify you for participation in the program. These past exposure are work histories that suggest the following: (1) That you have been exposed at or above the PELs on 30 days a year for 10 or more years; (2) that you have been exposed at or above the action level on 60 days a year for 10 or more years; or (3) that you have been exposed above 10 ppm on 30 days in any past year. Additionally, if you are exposed to BD in an emergency situation, you are eligible for a medical examination within 48 hours. The basic medical screening program includes a health questionnaire, physical examination, and blood test. These medical evaluations must be offered to you at a reasonable time and place, and without cost or loss of pay.

VII. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to BD and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with,

and must wear, the protective clothing and equipment.

VIII. Access to Information

A. Each year, your employer is required to inform you of the information contained in this appendix. In addition, your employer must instruct you in the proper work practices for using BD, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to BD. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits and of the schedule to implement these actions.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least thirty (30) years.

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

Appendix B. Substance Technical Guidelines for 1,3-Butadiene (Non-Mandatory)

I. Physical and Chemical Data

A. Substance identification:

1. Synonyms: 1,3-Butadiene (BD); butadiene; biethylene; bivinyl; divinyl; butadiene-1,3; buta-1,3-diene; erythrene; NCI-C50620; CAS–106–99–0.

2. Formula: CH_2=CH-CH=CH_2.

3. Molecular weight: 54.1.

B. Physical data:

1. Boiling point (760 mm Hg): −4.7 °C (23.5 °F).

2. Specific gravity (water=1): 0.62 at 20 °C (68 °F).

3. Vapor density (air=1 at boiling point of BD): 1.87.

4. Vapor pressure at 20 °C (68 °F): 910 mm Hg.

5. Solubility in water, g/100 g water at 20 °C (68 °F): 0.05.

6. Appearance and odor: Colorless, flammable gas with a mildly aromatic odor. Liquefied BD is a colorless liquid with a mildly aromatic odor.

II. Fire, Explosion, and Reactivity Hazard Data

A. Fire:

1. Flash point: −76 °C (−105 °F) for take out; liquefied BD; Not applicable to BD gas.

2. Stability: A stabilizer is added to the monomer to inhibit formation of polymer during storage. Forms explosive peroxides in air in absence of inhibitor.

3. Flammable limits in air, percent by volume: Lower: 2.0; Upper: 11.5.

4. Extinguishing media: Carbon dioxide for small fires, polymer or alcohol foams for large fires.

5. Special fire fighting procedures: Fight fire from protected location or maximum possible distance. Stop flow of gas before extinguishing fire. Use water spray to keep fire-exposed cylinders cool.

6. Unusual fire and explosion hazards: BD vapors are heavier than air and may travel to a source of ignition and flash back. Closed containers may rupture violently when heated.

7. For purposes of compliance with the requirements of 29 CFR 1910.106, BD is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.

8. For purposes of compliance with 29 CFR 1910.155, BD is classified as a Class B fire hazard.

9. For purposes of compliance with 29 CFR 1910.307, locations classified as hazardous due to the presence of BD shall be Class I.

B. Reactivity:

1. Conditions contributing to instability: Heat. Peroxides are formed when inhibitor concentration is not maintained at proper level. At elevated temperatures, such as in fire conditions, polymerization may take place.

2. Incompatibilities: Contact with strong oxidizing agents may cause fires and explosions. The contacting of crude BD (not BD monomer) with copper and copper alloys may cause formations of explosive copper compounds.

3. Hazardous decomposition products: Toxic gases (such as carbon monoxide) may be released in a fire involving BD.

4. Special precautions: BD will attack some forms of plastics, rubber, and coatings. BD in storage should be checked for proper inhibitor content, for self-polymerization, and for formation of peroxides when in contact with air and iron. Piping carrying BD may become plugged by formation of rubbery polymer.

C. Warning Properties:

1. Odor Threshold: An odor threshold of 0.45 ppm has been reported in The American Industrial Hygiene Association (AIHA) Report, *Odor Thresholds for Chemicals with Established Occupational Health Standards.* (Ex. 32–28C)

2. Eye Irritation Level: Workers exposed to vapors of BD (concentration or purity unspecified) have complained of irritation of eyes, nasal passages, throat, and lungs. Dogs and rabbits exposed experimentally to as much as 6700 ppm for 7½ hours a day for 8 months have developed no histologically demonstrable abnormality of the eyes.

3. Evaluation of Warning Properties: Since the mean odor threshold is about half of the 1 ppm PEL, and more than 10-fold below the 5 ppm STEL, most wearers of air purifying respirators should still be able to detect breakthrough before a significant overexposure to BD occurs.

III. Spill, Leak, and Disposal Procedures

A. Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until cleanup has been completed. If BD is spilled or leaked, the following steps should be taken:

1. Eliminate all ignition sources.

2. Ventilate areas of spill or leak.

3. If in liquid form, for small quantities, allow to evaporate in a safe manner.

4. Stop or control the leak if this can be done without risk. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place and repair the leak or allow the cylinder to empty.

B. Disposal: This substance, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR part 261). It is listed by the EPA as hazardous waste number D001 due to its ignitability. The transportation, storage, treatment, and disposal of this waste material must be conducted in compliance with 40 CFR parts 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Check state and local regulations for any additional requirements because these may be more restrictive than federal laws and regulations.

IV. Monitoring and Measurement Procedures

A. Exposure above the Permissible Exposure Limit (8-hr TWA) or Short-Term Exposure Limit (STEL):

1. 8-hr TWA exposure evaluation: Measurements taken for the purpose of determining employee exposure under this standard are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. STEL exposure evaluation: Measurements must represent 15 minute exposures associated with operations most likely to exceed the STEL in each job and on each shift.

3. Monitoring frequencies: Table 1 gives various exposure scenarios and their required monitoring frequencies, as required by the final standard for occupational exposure to butadiene.

TABLE 1.—FIVE EXPOSURE SCENARIOS AND THEIR ASSOCIATED MONITORING FREQUENCIES

Action level	8-hr TWA	STEL	Required monitoring activity
−*	−	−	No 8-hr TWA or STEL monitoring required.
+*	−	−	No STEL monitoring required. Monitor 8-hr TWA annually.
+	+	−	No STEL monitoring required. Periodic monitoring 8-hr TWA, in accordance with (d)(3)(ii).**
+	+	+	Periodic monitoring 8-hr TWA, in accordance with (d)(3)(ii)**. Periodic monitoring STEL, in accordance with (d)(3)(iii).

TABLE 1.—FIVE EXPOSURE SCENARIOS AND THEIR ASSOCIATED MONITORING FREQUENCIES—Continued

Action level	8-hr TWA	STEL	Required monitoring activity
+	–	+	Periodic monitoring STEL, in accordance with (d)(3)(iii). Monitor 8-hr TWA, annually.

*Exposure Scenario, Limit Exceeded: + = Yes, – = No.

**The employer may decrease the frequency of exposure monitoring to annually when at least 2 consecutive measurements taken at least 7 days apart show exposures to be below the 8 hr TWA, but at or above the action level.

4. Monitoring techniques: Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with BD. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his or her unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of BD at or above 1 ppm, and to plus or minus 35 percent for concentrations below 1 ppm.

V. Personal Protective Equipment

A. Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen from contact with liquid BD.

B. Any clothing which becomes wet with liquid BD should be removed immediately and not re-worn until the butadiene has evaporated.

C. Employees should be provided with and required to use splash proof safety goggles where liquid BD may contact the eyes.

VI. Housekeeping and Hygiene Facilities

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

A. The workplace should be kept clean, orderly, and in a sanitary condition.

B. Adequate washing facilities with hot and cold water are to be provided and maintained in a sanitary condition.

VII. Additional Precautions

A. Store BD in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B. Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded.

C. Do not incinerate BD cartridges, tanks or other containers.

D. Employers must advise employees of all areas and operations where exposure to BD might occur.

Appendix C. Medical Screening and Surveillance for 1,3-Butadiene (Non-Mandatory)

I. Basis for Medical Screening and Surveillance Requirements

A. Route of Entry Inhalation

B. Toxicology

Inhalation of BD has been linked to an increased risk of cancer, damage to the reproductive organs, and fetotoxicity. Butadiene can be converted via oxidation to epoxybutene and diepoxybutane, two genotoxic metabolites that may play a role in the expression of BD's toxic effects.

BD has been tested for carcinogenicity in mice and rats. Both species responded to BD exposure by developing cancer at multiple primary organ sites. Early deaths in mice were caused by malignant lymphomas, primarily lymphocytic type, originating in the thymus.

Mice exposed to BD have developed ovarian or testicular atrophy. Sperm head morphology tests also revealed abnormal sperm in mice exposed to BD; lethal mutations were found in a dominant lethal test. In light of these results in animals, the possibility that BD may adversely affect the reproductive systems of male and female workers must be considered.

Additionally, anemia has been observed in animals exposed to butadiene. In some cases, this anemia appeared to be a primary response to exposure; in other cases, it may have been secondary to a neoplastic response.

C. Epidemiology

Epidemiologic evidence demonstrates that BD exposure poses an increased risk of leukemia. Mild alterations of hematologic parameters have also been observed in synthetic rubber workers exposed to BD.

II. Potential Adverse Health Effects

A. Acute

Skin contact with liquid BD causes characteristic burns or frostbite. BD is gaseous form can irritate the eyes, nasal passages, throat, and lungs. Blurred vision, coughing, and drowsiness may also occur. Effects are mild at 2,000 ppm and pronounced at 8,000 ppm for exposures occurring over the full workshift.

At very high concentrations in air, BD is an anesthetic, causing narcosis, respiratory paralysis, unconsciousness, and death. Such concentrations are unlikely, however, except in an extreme emergency because BD poses an explosion hazard at these levels.

B. Chronic

The principal adverse health effects of concern are BD-induced lymphoma, leukemia and potential reproductive toxicity. Anemia and other changes in the peripheral blood cells may be indicators of excessive exposure to BD.

C. Reproductive

Workers may be concerned about the possibility that their BD exposure may be affecting their ability to procreate a healthy child. For workers with high exposures to BD, especially those who have experienced difficulties in conceiving, miscarriages, or stillbirths, appropriate medical and laboratory evaluation of fertility may be necessary to determine if BD is having any adverse effect on the reproductive system or on the health of the fetus.

III. Medical Screening Components At-A–Glance

A. Health Questionnaire

The most important goal of the health questionnaire is to elicit information from the worker regarding potential signs or symptoms generally related to leukemia or other blood abnormalities. Therefore, physicians or other licensed health care professionals should be aware of the presenting symptoms and signs of lymphohematopoietic disorders and cancers, as well as the procedures necessary to confirm or exclude such diagnoses. Additionally, the health questionnaire will assist with the identification of workers at greatest risk of developing leukemia or adverse reproductive effects from their exposures to BD.

Workers with a history of reproductive difficulties or a personal or family history of immune deficiency syndromes, blood dyscrasias, lymphoma, or leukemia, and those who are or have been exposed to medicinal drugs or chemicals known to affect the hematopoietic or lymphatic systems may be at higher risk from their exposure to BD. After the initial administration, the health questionnaire must be updated annually.

B. Complete Blood Count (CBC)

The medical screening and surveillance program requires an annual CBC, with differential and platelet count, to be provided for each employee with BD exposure. This test is to be performed on a blood sample obtained by phlebotomy of the venous system or, if technically feasible, from a fingerstick sample of capillary blood. The sample is to be analyzed by an accredited laboratory.

Abnormalities in a CBC may be due to a number of different etiologies. The concern for workers exposed to BD includes, but is not limited to, timely identification of lymphohematopoietic cancers, such as leukemia and non-Hodgkin's lymphoma. Abnormalities of portions of the CBC are identified by comparing an individual's results to those of an established range of normal values for males and females. A substantial change in any individual employee's CBC may also be viewed as ''abnormal'' for that individual even if all measurements fall within the population-based range of normal values. It is suggested that a flowsheet for laboratory values be included in each employee's medical record so that comparisons and trends in annual CBCs can be easily made.

A determination of the clinical significance of an abnormal CBC shall be the responsibility of the examining physician, other licensed health care professional, or medical specialist to whom the employee is referred. Ideally, an abnormal CBC should be compared to previous CBC measurements for the same employee, when available. Clinical common sense may dictate that a CBC value

that is very slightly outside the normal range does not warrant medical concern. A CBC abnormality may also be the result of a temporary physical stressor, such as a transient viral illness, blood donation, or menorrhagia, or laboratory error. In these cases, the CBC should be repeated in a timely fashion, i.e., within 6 weeks, to verify that return to the normal range has occurred. A clinically significant abnormal CBC should result in removal of the employee from further exposure to BD. Transfer of the employee to other work duties in a BD-free environment would be the preferred recommendation.

C. Physical Examination

The medical screening and surveillance program requires an initial physical examination for workers exposed to BD; this examination is repeated once every three years. The initial physical examination should assess each worker's baseline general health and rule out clinical signs of medical conditions that may be caused by or aggravated by occupational BD exposure. The physical examination should be directed at identification of signs of lymphohematopoietic disorders, including lymph node enlargement, splenomegaly, and hepatomegaly.

Repeated physical examinations should update objective clinical findings that could be indicative of interim development of a lymphohematopoietic disorder, such as lymphoma, leukemia, or other blood abnormality. Physical examinations may also be provided on an as needed basis in order to follow up on a positive answer on the health questionnaire, or in response to an abnormal CBC. Physical examination of workers who will no longer be working in jobs with BD exposure are intended to rule out lymphohematopoietic disorders.

The need for physical examinations for workers concerned about adverse reproductive effects from their exposure to BD should be identified by the physician or other licensed health care professional and provided accordingly. For these workers, such consultations and examinations may relate to developmental toxicity and reproductive capacity.

Physical examination of workers acutely exposed to significant levels of BD should be especially directed at the respiratory system, eyes, sinuses, skin, nervous system, and any region associated with particular complaints. If the worker has received a severe acute exposure, hospitalization may be required to assure proper medical management. Since this type of exposure may place workers at greater risk of blood abnormalities, a CBC must be obtained within 48 hours and repeated at one, two, and three months.

Appendix D: Sampling and Analytical Method for 1,3-Butadiene (Non-Mandatory)

OSHA Method No.: 56.

Matrix: Air.

Target concentration: 1 ppm (2.21 mg/m^3)

Procedure: Air samples are collected by drawing known volumes of air through sampling tubes containing charcoal adsorbent which has been coated with 4-tert-butylcatechol. The samples are desorbed with carbon disulfide and then analyzed by gas chromatography using a flame ionization detector.

Recommended sampling rate and air volume: 0.05 L/min and 3 L.

Detection limit of the overall procedure: 90 ppb (200 ug/m^3) (based on 3 L air volume).

Reliable quantitation limit: 155 ppb (343 ug/m^3) (based on 3 L air volume).

Standard error of estimate at the target concentration: 6.5%.

Special requirements: The sampling tubes must be coated with 4-tert-butylcatechol. Collected samples should be stored in a freezer.

Status of method: A sampling and analytical method has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah 84165.

1. Background

This work was undertaken to develop a sampling and analytical procedure for BD at 1 ppm. The current method recommended by OSHA for collecting BD uses activated coconut shell charcoal as the sampling medium (Ref. 5.2). This method was found to be inadequate for use at low BD levels because of sample instability.

The stability of samples has been significantly improved through the use of a specially cleaned charcoal which is coated with 4-tert-butylcatechol (TBC). TBC is a polymerization inhibitor for BD (Ref. 5.3).

1.1.1 Toxic effects

Symptoms of human exposure to BD include irritation of the eyes, nose and throat. It can also cause coughing, drowsiness and fatigue. Dermatitis and frostbite can result from skin exposure to liquid BD. (Ref. 5.1)

NIOSH recommends that BD be handled in the workplace as a potential occupational carcinogen. This recommendation is based on two inhalation studies that resulted in cancers at multiple sites in rats and in mice. BD has also demonstrated mutagenic activity in the presence of a liver microsomal activating system. It has also been reported to have adverse reproductive effects. (Ref. 5.1)

1.1.2. Potential workplace exposure

About 90% of the annual production of BD is used to manufacture styrene-butadiene rubber and Polybutadiene rubber. Other uses include: Polychloroprene rubber, acrylonitrile butadiene-stryene resins, nylon intermediates, styrene-butadiene latexes, butadiene polymers, thermoplastic elastomers, nitrile resins, methyl methacrylate-butadiene styrene resins and chemical intermediates. (Ref. 5.1)

1.1.3. Physical properties (Ref. 5.1)

CAS No.: 106–99–0
Molecular weight: 54.1
Appearance: Colorless gas
Boiling point: −4.41 °C (760 mm Hg)
Freezing point: −108.9 °C
Vapor pressure: 2 atm @ 15.3 °C; 5 atm @ 47 °C
Explosive limits: 2 to 11.5% (by volume in air)
Odor threshold: 0.45 ppm
Structural formula: $H_2C{:}CHCH{:}CH_2$

Synonyms: BD; biethylene; bivinyl; butadiene; divinyl; buta-1,3-diene; alpha-gamma-butadiene; erythrene; NCI–C50602; pyrrolylene; vinylethylene.

1.2. Limit defining parameters

The analyte air concentrations listed throughout this method are based on an air volume of 3 L and a desorption volume of 1 mL. Air concentrations listed in ppm are referenced to 25 °C and 760 mm Hg.

1.2.1. Detection limit of the analytical procedure

The detection limit of the analytical procedure was 304 pg per injection. This was the amount of BD which gave a response relative to the interferences present in a standard.

1.2.2. Detection limit of the overall procedure

The detection limit of the overall procedure was 0.60 µg per sample (90 ppb or 200 µg/m^3). This amount was determined graphically. It was the amount of analyte which, when spiked on the sampling device, would allow recovery approximately equal to the detection limit of the analytical procedure.

1.2.3. Reliable quantitation limit

The reliable quantitation limit was 1.03 µg per sample (155 ppb or 343 µg/m^3). This was the smallest amount of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision (±1.96 SD) of ±25% or better.

1.2.4. Sensitivity [1]

The sensitivity of the analytical procedure over a concentration range representing 0.6 to 2 times the target concentration, based on the recommended air volume, was 387 area units per µg/mL. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5. Recovery

The recovery of BD from samples used in storage tests remained above 77% when the samples were stored at ambient temperature and above 94% when the samples were stored at refrigerated temperature. These values were determined from regression lines which were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6. Precision (analytical method only)

The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.6 to 2 times the target concentration was 0.011.

1.2.7. Precision (overall procedure)

The precision at the 95% confidence level for the refrigerated temperature storage test

[1] The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operation parameters.

was ±12.7%. This value includes an additional ±5% for sampling error. The overall procedure must provide results at the target concentrations that are ±25% at the 95% confidence level.

1.2.8. Reproducibility

Samples collected from a controlled test atmosphere and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The average recovery was 97.2% and the standard deviation was 6.2%.

2. Sampling procedure

2.1. Apparatus

2.1.1. Samples are collected by use of a personal sampling pump that can be calibrated to within ±5% of the recommended 0.05 L/min sampling rate with the sampling tube in line.

2.1.2. Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane-treated glass and is about 5-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The opening in the tapered end of the sampling tube is at least one-half the ID of the tube (2 mm). The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with 2 sections of pretreated charcoal which has been coated with TBC. The tube is packed with a 50-mg backup section, located nearest the tapered end, and with a 100-mg sampling section of charcoal. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7/32 inch OD plastic end caps. Instructions for the pretreatment and coating of the charcoal are presented in Section 4.1 of this method.

2.2. Reagents

None required.

2.3. Technique

2.3.1. Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2. Attach the sampling tube to the pump using a section of flexible plastic tubing such that the larger front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3. After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps. Wrap the tube lengthwise.

2.3.4. Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5. List any potential interferences on the sample data sheet.

2.3.6. The samples require no special shipping precautions under normal conditions. The samples should be refrigerated if they are to be exposed to higher than normal ambient temperatures. If the samples are to be stored before they are shipped to the laboratory, they should be kept in a freezer. The samples should be placed in a freezer upon receipt at the laboratory.

2.4. Breakthrough

(Breakthrough was defined as the relative amount of analyte found on the backup section of the tube in relation to the total amount of analyte collected on the sampling tube. Five-percent breakthrough occurred after sampling a test atmosphere containing 2.0 ppm BD for 90 min at 0.05 L/min. At the end of this time 4.5 L of air had been sampled and 20.1 µg of the analyte was collected. The relative humidity of the sampled air was 80% at 23 °C.)

Breakthrough studies have shown that the recommended sampling procedure can be used at air concentrations higher than the target concentration. The sampling time, however, should be reduced to 45 min if both the expected BD level and the relative humidity of the sampled air are high.

2.5. Desorption efficiency

The average desorption efficiency for BD from TBC coated charcoal over the range from 0.6 to 2 times the target concentration was 96.4%. The efficiency was essentially constant over the range studied.

2.6. Recommended air volume and sampling rate

2.6.1. The recommended air volume is 3L.

2.6.2. The recommended sampling rate is 0.05 L/min for 1 hour.

2.7. Interferences

There are no known interferences to the sampling method.

2.8. Safety precautions

2.8.1. Attach the sampling equipment to the worker in such a manner that it will not interfere with work performance or safety.

2.8.2. Follow all safety practices that apply to the work area being sampled.

3. Analytical procedure

3.1. Apparatus

3.1.1. A gas chromatograph (GC), equipped with a flame ionization detector (FID).[2]

3.1.2. A GC column capable of resolving the analytes from any interference.[3]

3.1.3. Vials, glass 2-mL with Teflon-lined caps.

3.1.4. Disposable Pasteur-type pipets, volumetric flasks, pipets and syringes for preparing samples and standards, making dilutions and performing injections.

3.2. Reagents

3.2.1. Carbon disulfide.[4]

The benzene contaminant that was present in the carbon disulfide was used as an internal standard (ISTD) in this evaluation.

3.2.2. Nitrogen, hydrogen and air, GC grade.

3.2.3. BD of known high purity.[5]

3.3. Standard preparation

3.3.1. Prepare standards by diluting known volumes of BD gas with carbon disulfide. This can be accomplished by injecting the appropriate volume of BD into the headspace above the 1-mL of carbon disulfide contained in sealed 2-mL vial. Shake the vial after the needle is removed from the septum.[6]

3.3.2. The mass of BD gas used to prepare standards can be determined by use of the following equations:

$MV=(760/BP)(273+t)/(273)(22.41)$

Where:

MV=ambient molar volume
BP=ambient barometric pressure
T=ambient temperature
µg/µL=54.09/MV
µg/standard=(µg/µL)(µL) BD used to prepare the standard

3.4. Sample preparation

3.4.1. Transfer the 100-mg section of the sampling tube to a 2-mL vial. Place the 50-mg section in a separate vial. If the glass wool plugs contain a significant amount of charcoal, place them with the appropriate sampling tube section.

3.4.2. Add 1-mL of carbon disulfide to each vial.

3.4.3. Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand vigorously several times during the desorption period.

3.4.4. If it is not possible to analyze the samples within 4 hours, separate the carbon disulfide from the charcoal, using a disposable Pasteur-type pipet, following the one hour. This separation will improve the stability of desorbed samples.

3.4.5. Save the used sampling tubes to be cleaned and repacked with fresh adsorbent.

3.5. Analysis

3.5.1. GC Conditions
Column temperature: 95 °C
Injector temperature: 180 °C
Detector temperature: 275 °C
Carrier gas flow rate: 30 mL/min
Injection volume: 0.80 µL
GC column: 20-ft x 1/8-in OD stainless steel GC column containing 20%
FFAP on 80/100 Chromabsorb W–AW–DMCS.

3.5.2. Chromatogram. See Section 4.2.

3.5.3. Use a suitable method, such as electronic or peak heights, to measure detector response.

[2] A Hewlett-Packard Model 5840A GC was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

[3] A 20-ft x 1/8-inch OD stainless steel GC column containing 20% FFAP on 80/100 mesh Chromabsorb W–AW–DMCS was used for this evaluation.

[4] Fisher Scientific Company A.C.S. Reagent Grade solvent was used in this evaluation.

[5] Matheson Gas Products, CP Grade 1,3-butadiene was used in this study.

[6] A standard containing 7.71 µg/mL (at ambient temperature and pressure) was prepared by diluting 4 µL of the gas with 1-mL of carbon disulfide.

3.5.4. Prepare a calibration curve using several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report the results in µg/mL.

3.5.5. Bracket sample concentrations with standards.

3.6. Interferences (analytical)

3.6.1. Any compound with the same general retention time as the analyte and which also gives a detector response is a potential interference. Possible interferences should be reported by the industrial hygienist to the laboratory with submitted samples.

3.6.2. GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3. A useful means of structure designation is GC/MS. It is recommended that this procedure be used to confirm samples whenever possible.

3.7. Calculations

3.7.1. Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2. The concentration, in ug/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If any analyte is found on the backup section, this amount is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3. The BD air concentration can be expressed using the following equation:

$mg/m^3=(A)(B)/(C)(D)$

Where:

A=µg/mL from Section 3.7.2
B=volume
C=L of air sampled
D=efficiency

3.7.4. The following equation can be used to convert results in mg/m^3 to ppm:

$ppm=(mg/m^3)(24.46)/54.09$

Where:

mg/m^3=result from Section 3.7.3.
24.46=molar volume of an ideal gas at 760 mm Hg and 25°C.

3.8. Safety precautions (analytical)

3.8.1. Avoid skin contact and inhalation of all chemicals.

3.8.2. Restrict the use of all chemicals to a fume hood whenever possible.

3.8.3. Wear safety glasses and a lab coat in all laboratory areas.

4. Additional Information

4.1. A procedure to prepare specially cleaned charcoal coated with TBC

4.1.1. Apparatus.

4.1.1.1. Magnetic stirrer and stir bar.

4.1.1.2. Tube furnace capable of maintaining a temperature of 700°C and equipped with a quartz tube that can hold 30 g of charcoal.[8]

4.1.1.3. A means to purge nitrogen gas through the charcoal inside the quartz tube.

4.1.1.4. Water bath capable of maintaining a temperature of 60°C.

4.1.1.5. Miscellaneous laboratory equipment: One-liter vacuum flask, 1–L Erlenmeyer flask, 350–M1 Buchner funnel with a coarse fitted disc, 4-oz brown bottle, rubber stopper, Teflon tape etc.

4.1.2. Reagents

4.1.2.1. Phosphoric acid, 10% by weight, in water.[9]

4.1.2.2. 4-tert-Butylcatechol (TBC).[10]

4.1.2.3. Specially cleaned coconut shell charcoal, 20/40 mesh.[11]

4.1.2.4. Nitrogen gas, GC grade.

4.1.3. Procedure.

Weigh 30g of charcoal into a 500-mL Erlenmeyer flask. Add about 250 mL of 10% phosphoric acid to the flask and then swirl the mixture. Stir the mixture for 1 hour using a magnetic stirrer. Filter the mixture using a fitted Buchner funnel. Wash the charcoal several times with 250-mL portions of deionized water to remove all traces of the acid. Transfer the washed charcoal to the tube furnace quartz tube. Place the quartz tube in the furnace and then connect the nitrogen gas purge to the tube. Fire the charcoal to 700 °C. Maintain that temperature for at least 1 hour. After the charcoal has cooled to room temperature, transfer it to a tared beaker. Determine the weight of the charcoal and then add an amount of TBC which is 10% of the charcoal, by weight.

CAUTION-TBC is toxic and should only be handled in a fume hood while wearing gloves.

Carefully mix the contents of the beaker and then transfer the mixture to a 4-oz bottle. Stopper the bottle with a clean rubber stopper which has been wrapped with Teflon tape. Clamp the bottle in a water bath so that the water level is above the charcoal level. Gently heat the bath to 60 °C and then maintain that temperature for 1 hour. Cool the charcoal to room temperature and then transfer the coated charcoal to a suitable container.

The coated charcoal is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number.

4.2 Chromatograms

The chromatograms were obtained using the recommended analytical method. The chart speed was set at 1 cm/min for the first three min and then at 0.2 cm/min for the time remaining in the analysis.

The peak which elutes just before BD is a reaction product between an impurity on the charcoal and TBC. This peak is always present, but it is easily resolved from the analyte. The peak which elutes immediately before benzene is an oxidation product of TBC.

5. References

5.1. ''Current Intelligence Bulletin 41, 1,3-Butadiene'', U.S. Dept. of Health and Human Services, Public Health Service, Center for Disease Control, NIOSH.

5.2. ''NIOSH Manual of Analytical Methods'', 2nd ed; U.S. Dept. of Health Education and Welfare, National Institute for Occupational Safety and Health: Cincinnati, OH. 1977, Vol. 2, Method No. S91 DHEW (NIOSH) Publ. (US), No. 77–157–B.

5.3. Hawley, G.C., Ed. ''The Condensed Chemical Dictionary'', 8th ed.; Van Nostrand Rienhold Company: New York, 1971; 139.5.4. *Chem. Eng. News* (June 10, 1985), (63), 22–66.

Appendix E: Respirator Fit Testing Procedures (Mandatory)

A. The Employer Shall Conduct Fit Testing Using the Following Procedures

These provisions apply to both QLFT and QNFT

1. The test subject shall be allowed to pick the most comfortable respirator from a selection of respirators of various sizes and models.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose.
(b) Room for eye protection.
(c) Room to talk.
(d) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;
(b) Adequate strap tension, not overly tightened;

[8] A Lindberg Type 55035 Tube furnace was used in this evaluation.

[9] Baker Analyzed'' Reagent grade was diluted with water for use in this evaluation.

[10] The Aldrich Chemical Company 99% grade was used in this evaluation.

[11] Specially cleaned charcoal was obtained from Supelco, Inc. for use in this evaluation. The cleaning process used by Supelco is proprietary.

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks using procedures in Appendix A or those recommended by the respirator manufacturer. Before conducting the negative or positive pressure fit checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. Test Exercises. The test subject shall perform exercises, in the test environment, while wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with fit, in the manner described below:

(a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) Grimace. The test subject shall grimace by smiling or frowning. (Only for QNFT testing, not performed for QLFT)

(g) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) Normal breathing. Same as exercise (a).

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

(a) Odor threshold screening.

The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): ''The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.''

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl acetate fit test

(1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test

exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When the subject wearing the respirator passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self sealing bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 13 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. Irritant Fume Protocol

(a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) No form of test enclosure or hood for the test subject shall be used.

(c) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties.

(d) Break both ends of a ventilation smoke tube containing stannic chloride. Attach one end of the smoke tube to an aspirator squeeze bulb and cover the other end with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(d) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 13 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response (involuntary cough) shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable.

(1) Quantitative fit testing using a non-hazardous challenge aerosol (such as corn oil or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator.

(2) Quantitative fit testing using ambient aerosol as the challenge agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit.

(3) Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean, maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated aerosol quantitative fit testing protocol

Apparatus

(a) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil or sodium chloride) or gases or vapors as test aerosols shall be used for quantitative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate air (HEPA) filter supplied by the same manufacturer in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(d) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process based upon the length of the exposure and the exposure limit duration.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(g) The test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant to within a 10 percent variation for the duration of the test.

(I) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. Procedural Requirements

(a) When performing the initial positive or negative pressure fit check the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these fit checks.

(b) The use of an abbreviated screening QLFT test is optional and may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to use to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be over tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(I) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(2) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e. 8 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method. .

(ii) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(iii) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(iv) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_7 + 1/ff_8}$$

Where ff_1, ff_2, ff_3, etc. are the fit factors for exercise 1,2,3, etc. [Results of the grimace exercise (7) are not used in this calculation.]

(j) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(k) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced if there is any indication of breakthrough by a test agent.

2. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing

(Portacount™) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, model, and size in which your company requires and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer Dynatech Nevada also provides probe attachments (TSI sampling adapters) that permits fit testing in an employee's own respirator. A fit factor pass level of 100 is necessary for a half-mask respirator and a fit factor of at least 10 times greater than the assigned protection factor for any other negative pressure respirator. The Agency does not recommend the use of homemade sampling adapters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Portacount Fit Test Requirements.

(1) Check the respirator to make sure the respirator is fitted with a high efficiency filter and that the sampling probe and line are properly attached to the facepiece.

(2) Instruct the person to be tested to don the respirator several minutes before the fit test starts. This purges the particles inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual should have already been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendencies for the respirator to slip, Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the person wearing the respirator do a fit check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same type of respirator.

(5) Follow the instructions for operating the Portacount and proceed with the test.

(b) Portacount Test Exercises.

(1) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally for 1 minute.

(2) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution so as too not hyperventilate.

(3) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) *Moving head up and down.* Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute.

(6) *Grimace.* The test subject shall grimace by smiling or frowning for 15 seconds.

(7) *Bending Over.* The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(8) *Normal Breathing.* Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute.

After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

(c) Portacount Test Instrument.

(1) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) A record of the test needs to be kept on file assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

BILLING CODE 4510–26–P

APPENDIX F. MEDICAL QUESTIONNAIRES, (Non-mandatory)

1,3 -Butadiene (BD) Initial Health Questionnaire

DIRECTIONS:

You have been asked to answer the questions on this form because you work with BD (butadiene). These questions are about your work, medical history, and health concerns. Please do your best to answer all of the questions. If you need help, please tell the doctor or health care professional who reviews this form.

This form is a confidential medical record. Only information directly related to your health and safety on the job may be given to your employer. Personal health information will not be given to anyone without your consent.

Date:_____

Name:_____ _____ ___ SSN_____/____/_____
Last First MI

Job Title:_____

Company's Name:_____

Supervisor's Name:_____ Supervisor's Phone No.:( )_____-_____

Work History

1. Please list all jobs you have had in the past, starting with the job you have now and moving back in time to your first job. (For more space, write on the back of this page.)

Main Job Duty	Years	Company Name City, State	Chemicals
1			
2			
3			
4			
5			
6			
7			
8			

2. Please describe what you do during a typical work day. Be sure to tell about your work with BD.

_____

_____

_____

3. Please check any of these chemicals that you work with now or have worked with in the past:

benzene	___	carbon tetrachloride ("carbon tet")	___
glues	___	arsine	___
toluene	___	carbon disulfide	___
inks, dyes	___	lead	___
other solvents, grease cutters	___	cement	___
insecticides (like DDT, lindane, etc.)	___	petroleum products	___
paints, varnishes, thinners, strippers	___	nitrites	___
dusts	___		

4. Please check the protective clothing or equipment you use at the job you have now:

gloves	___
coveralls	___
respirator	___
dust mask	___
safety glasses, goggles	___

Please circle your answer of yes or no.

5. Does your protective clothing or equipment fit you properly? yes no

6. Have you ever made changes in your protective clothing or equipment to make it fit better? yes no

7. Have you been exposed to BD when you were not wearing protective clothing or equipment? yes no

8. Where do you eat, drink and/or smoke when you are at work? (Please check all that apply.)

Cafeteria/restaurant/snack bar	___
Break room/employee lounge	___
Smoking lounge	___
At my work station	___

Please circle your answer.

9. Have you been exposed to radiation (like x-rays or nuclear material) at the job you have now or at past jobs? yes no

10. Do you have any hobbies that expose you to dusts or chemicals (including paints, glues, etc.)? yes no

11. Do you have any second or side jobs? yes no

If yes, what are your duties there?_____

_____

_____

12. Where you in the military? yes no

If yes, what did you do in the military?_____

Family Health History

1. In the FAMILY MEMBER column, across from the disease name, write which family member, if any, had the disease.

DISEASE	FAMILY MEMBER
Cancer	
Lymphoma	
Sickle Cell Disease or Trait	
Immune Disease	
Leukemia	
Anemia	

2. Please fill in the following information about family health:

Relative	Alive?	Age at death?	Cause of death?
Father			
Mother			
Brother/Sister			
Brother/Sister			
Brother/Sister			

Personal Health History

Birth Date____/____/____ Age_____ Sex____ Height____ Weight_____

Please circle your answer.

1. Do you smoke any tobacco products? yes no

2. Have you ever had any kind of surgery or operation? yes no

If yes, what type of surgery:_____

3. Have you ever been in the hospital for any other reasons? yes no

If yes, please describe the reason:_____
_____
_____

4. Do you have any on-going or current medical problems or conditions? yes no

If yes, please describe:_____
_____
_____

5. Do you now have or have you ever had any of the following? Please check all that apply to you.

unexplained fever	___	bruising easily	___	still birth	___
anemia ("low blood")	___	lupus	___	eye redness	___
HIV/AIDS	___	weight loss	___	lumps you can feel	___
weakness	___	kidney problems	___	child with birth defect	___
sickle cell	___	enlarged lymph nodes	___	autoimmune disease	___
miscarriage	___	liver disease	___	overly tired	___
skin rash	___	cancer	___	lung problems	___
bloody stools	___	infertility	___	rheumatoid arthritis	___
leukemia/lymphoma	___	drinking problems	___	mononucleosis ("mono")	___
neck mass/swelling	___	thyroid problems	___	nagging cough	___
wheezing	___	night sweats	___		
yellowing of skin	___	chest pain	___		

Please circle your answer.

6. Do you have any symptoms or health problems that you think may be related to your work with BD? yes no

If yes, please describe:_____
_____

7. Have any of your co-workers had similar symptoms or problems?
yes no don't know

If yes, please describe:_____
_____

8. Do you notice any irritation of your eyes, nose, throat, lungs, or skin when working with BD? yes no

9. Do you notice any blurred vision, coughing, drowsiness, nausea or headache when working with BD? yes no

10. Do you take any medications (including birth control or over-the-counter)? yes no

If yes, please list:_____
_____

11. Are you allergic to any medication, food, or chemicals? yes no

If yes, please list:_____
_____

12. Do you have any health conditions not covered by this questionnaire that you think are affected by your work with BD? yes no

If yes, please explain:_____
_____

13. Did you understand all the questions? yes no

_____
Signature

1,3 -Butadiene (BD) Update Health Questionnaire

DIRECTIONS:

You have been asked to answer the questions on this form because you work with BD (butadiene). These questions ask about changes in your work, medical history, and health concerns since the last time you were evaluated. Please do your best to answer all of the questions. If you need help, please tell the doctor or health care professional who reviews this form.

This form is a confidential medical record. Only information directly related to your health and safety on the job may be given to your employer. Personal health information will not be given to anyone without your consent.

Date:_____

Name:_____ _____ ___ SSN____/___/_____
Last First MI

Job title:_____

Company's Name:_____

Supervisor's Name:_____ Supervisor's Phone No.( )____-_____

Present Work History

1. Please describe any NEW duties that you have at your job:_____
_____
_____
_____
_____

2 Please list any additional job titles you have:

_____ _____
_____ _____
_____ _____

Please circle your answer.

3. Are you exposed to any other chemicals in your work since the last time you were evaluated for exposure to BD? yes no

If yes, please list what they are:_____
_____

4. Does your personal protective equipment and clothing fit you properly? yes no

5. Have you made changes in this equipment or clothing to make it fit better? yes no

6. Have you been exposed to BD when you were not wearing protective equipment or clothing?
yes no

7. Are you exposed to any NEW chemicals at home or while working on hobbies?
yes no

If yes, please list what they are:_____
_____

8. Since your last BD health evaluation, have you started working any new second or side jobs?
yes no

If yes, what are your duties there?_____
_____
_____

Personal Health History

1. What is your current weight?_____ pounds

2. Have you been diagnosed with any new medical conditions or illness since your last evaluation?
yes no

If yes, please tell what they are:_____
_____

3. Since your last evaluation, have you been in the hospital for any illnesses, injuries, or surgery?
yes no

If yes, please describe: _____
_____
_____

4. Do you have any of the following? Please place a check for all that apply to you.

unexplained fever	____	bruising easily	____	still birth	____
anemia ("low blood")	____	lupus	____	eye redness	____
HIV/AIDS	____	weight loss	____	lumps you can feel	____
weakness	____	kidney problems	____	child with birth defect	____
sickle cell	____	enlarged lymph nodes	____	autoimmune disease	____
miscarriage	____	liver disease	____	overly tired	____
skin rash	____	cancer	____	lung problems	____
bloody rash	____	infertility	____	rheumatoid arthritis	____
leukemia/lymphoma	____	drinking problems	____	mononucleosis "mono"	____
neck mass/swelling	____	thyroid problems	____	nagging cough	____
wheezing	____	night sweats	____	yellowing of skin	____

chest pain ____

Please circle your answer.

5. Do you have any symptoms or health problems that you think may be related to your work with BD? yes no

If yes, please describe:_____
_____

6. Have any of your co-workers had similar symptoms or problems?
yes no don't know

If yes, please describe:_____
_____

7. Do you notice any irritation of your eyes, nose, throat, lungs, or skin when working with BD?
yes no

8. Do you notice any blurred vision, coughing, drowsiness, nausea, or headache when working with BD? yes no

9. Have you been taking any NEW medications (including birth control or over-the-counter)? yes no

If yes, please list:

_____ _____ _____

_____ _____ _____

10. Have you developed any NEW allergies to medications, foods, or chemicals?
yes no

If yes, please list:

_____ _____ _____

_____ _____ _____

11. Do you have any health conditions not covered by this questionnaire that you think are affected by your work with BD? yes no

If yes, please explain:_____
_____

12. Did you understand all the questions? yes no

_____
Signature

BILLING CODE 4510–26–C

PART 1915—[AMENDED]

Part 1915 of 29 CFR is hereby amended as follows:

1. The authority citation for 29 CFR part 1915 continues to read as follows:

Authority: Sec. 41, Longshore and Harbor Workers Compensation Act (33 U.S.C. 941); secs. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); sec. 4 of the Administrative Procedure Act (5 U.S.C. 553); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), or 1–90 (55 FR 9033), as applicable; 29 CFR part 1911.

§ 1915.1000 [Amended]

2. The entry in Table Z–1 of Section 1915.1000, for ''Butadiene (1,3–Butadiene)'' is amended as follows: remove the ''1000'' and ''2200'' from the columns entitled ppm [a]* and mg/m^3 [b]* respectively; add ''1 ppm/5 ppm STEL'' in the ppm [a]* column; and add the following to the butadiene entry: ''; See 29 CFR 1910.1051; 29 CFR 1910.19(l)'' so that the entry reads as follows: ''Butadiene (1,3–Butadiene); See 29 CFR 1910.1051; 29 CFR 1910.19(l).''

PART 1926—[AMENDED]

Part 1926 of 29 CFR is hereby amended as set forth below:

Subpart Z—[Amended]

1. The authority citation for Subpart Z of 29 CFR part 1926 is revised to read as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 333); secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059) 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable; 29 CFR part 1911.

Appendix A to § 1926.55 [Amended]

2. The entry in Appendix A to § 1926.55 for ''Butadiene (1,3–Butadiene)'' is amended as follows: remove the ''1000'' and ''2200'' from the columns entitled ppma and mg/m^3 [b] respectively; add ''1 ppm/5 ppm STEL'' in the ppm[a] column; and add the following to the butadiene entry; ''; See 29 CFR 1910.1051; 29 CFR 1910.19(l)'' so that the entry reads as follows: ''Butadiene (1,3–Butadiene); See 29 CFR 1910.1051; 29 CFR 1910.19(1).''

[FR Doc. 96–27791 Filed 11–1–96; 8:45 am]

BILLING CODE 4510–26–P

Federal Register

Monday
November 4, 1996

Part III

The President

Federal Register
Vol. 61, No. 214
Monday, November 4, 1996

Presidential Documents

Title 3—

The President

Presidential Determination No. 96–53 of September 26, 1996

Determination To Authorize the Furnishing of Emergency Military Assistance to Eritrea, Ethiopia, and Uganda Under Section 506(a)(1) of the Foreign Assistance Act

Memorandum for the Secretary of State [and] the Secretary of Defense

Pursuant to the authority vested in me by section 506(a)(1) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2318(a)(1) (''the Act''), I hereby determine that:

(1) an unforeseen emergency exists that requires immediate military assistance to Eritrea, Ethiopia, and Uganda; and

(2) the emergency requirement cannot be met under the authority of the Arms Export Control Act or under any other law except section 506 of the Act.

Therefore, I hereby authorize the furnishing of up to $10,000,000 in defense articles from the stocks of the Department of Defense, defense services of the Department of Defense and military education and training to assist the governments of Eritrea, Ethiopia, and Uganda.

The Secretary of State is authorized and directed to report this determination to the Congress and to arrange for its publication in the Federal Register.

THE WHITE HOUSE,
Washington, September 26, 1996.

[FR Doc. 96–28392
Filed 11–1–96; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 96–55 of September 30, 1996

Determination To Authorize the Furnishing of Non-Lethal Emergency Military Assistance to the States Participating in the Economic Community of West African States' Peacekeeping Force (ECOMOG) Under Section 506(a)(1) of the Foreign Assistance Act of 1961, as Amended

Memorandum for the Secretary of State [and] the Secretary of Defense

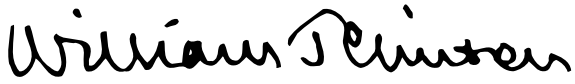
Pursuant to the authority vested in me by section 506(a)(1) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2318(a)(1) (''the Act''), I hereby determine that:

(1) an unforeseen emergency exists which requires immediate military assistance to states currently participating in, and to states which may in the future participate in, ECOMOG; and

(2) the emergency requirement cannot be met under the authority of the Arms Export Control Act or any other law except section 506 of the Act.

I therefore direct the drawdown from the inventory and resources of the Department of Defense of an aggregate value not to exceed $5 million in defense articles from the stocks of the Department of Defense, defense services of the Department of Defense and military education and training to provide assistance to the states currently participating (Nigeria, Ghana, Sierra Leone, Mali and Guinea), and for those states that may in the future participate, in ECOMOG to enhance ECOMOG's peacekeeping capabilities to bring about a peaceful solution to the crisis in Liberia.

The Secretary of State is authorized and directed to report this Determination to Congress and to arrange for its publication in the Federal Register.



THE WHITE HOUSE,
Washington, September 30, 1996.

[FR Doc. 96–28393
Filed 11–1–96; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 96–56 of September 30, 1996

Determination To Authorize the Drawdown of Commodities, Services, and Training From the Department of Defense for the Economic Community of West African States' Peacekeeping Force (ECOMOG) Under Section 552(c)(2) of the Foreign Assistance Act of 1961, as Amended

Memorandum for the Secretary of State [and] the Secretary of Defense

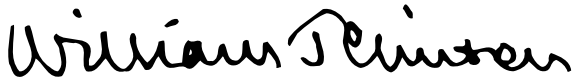
Pursuant to the authority vested in me by section 552(c)(2) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2348(c)(2) (''the Act''), I hereby determine that:

(1) as a result of an unforeseen emergency, the provision of assistance under Chapter 6 of Part II of the Act in amounts in excess of funds otherwise available for such assistance is important to the national interests of the United States; and

(2) such unforeseen emergency requires the immediate provision of assistance under Chapter 6 of Part II of the Act.

I therefore direct the drawdown from the inventory and resources of the Department of Defense of an aggregate value not to exceed $10 million in commodities and services to provide assistance to states currently participating (Nigeria, Ghana, Sierra Leone, Guinea, and Mali), and for those states that may in the future participate, in ECOMOG to enhance ECOMOG's peacekeeping capabilities to bring about a peaceful solution to the crisis in Liberia.

The Secretary of State is authorized and directed to report this determination to the Congress and to arrange for its publication in the Federal Register.



THE WHITE HOUSE,
Washington, September 30, 1996.

[FR Doc. 96–28394
Filed 11–1–96; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 96–57 of September 30, 1996

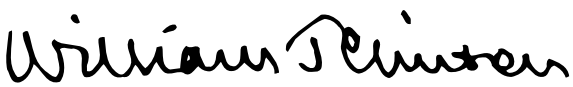
Drawdown of Articles, Services, and Military Education and Training from DOD To Provide Antinarcotics Assistance to Colombia, Venezuela, Peru, and the Countries of the Eastern Caribbean

Memorandum for the Secretary of State [and] the Secretary of Defense

Pursuant to the authority vested in me by section 506(a)(2) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2318(a)(2) (''the Act''), I hereby determine that it is in the national interest of the United States to draw down articles, services, and military education and training from the inventory and resources of the Department of Defense for the purpose of providing antinarcotics assistance to Colombia, Venezuela, Peru, and the countries of the Eastern Caribbean Regional Security System (RSS), which are: Antigua & Barbuda, Barbados, Dominica, Grenada, St. Kitts & Nevis, St. Lucia, and St. Vincent and the Grenadines.

Therefore, I direct the drawdown in FY 1996 authority of up to $75 million of articles, services, and military education and training from the Department of Defense for such countries for the purposes and under the authorities of Chapter 8 of Part I of the Act.

The Secretary of State is authorized and directed to report this determination to the Congress immediately and to arrange for its publication in the Federal Register.



THE WHITE HOUSE,
Washington, September 30, 1996.

[FR Doc. 96–28395
Filed 11–1–96; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 96–58 of September 30, 1996

Loan Guarantee to Israel Program

Memorandum for the Secretary of State

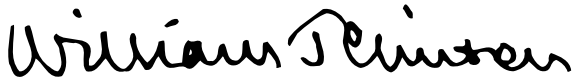
Pursuant to the authority vested in me by section 226(b) and section 614(a)(1) of the Foreign Assistance Act of 1961, as amended (''the Act''), 22 U.S.C. 2186(b) and 22 U.S.C. 2364(a)(1), respectively, I hereby determine that:

(1) $307 million of loan guarantee authority pursuant to section 226(a) and (b) of the Act for Fiscal Year 1997 is subject to the deduction requirements of section 226(d) of the Act; and

(2) it is important to the security interests of the United States that the aforementioned amount shall be reduced by $247 million without regard to the deduction requirement of section 226(d) of the Act or any other provision of law within the scope of section 614 of the Act;

Therefore, I hereby authorize that such $247 million in loan guarantee authority shall remain available pursuant to section 226(a) and (b) of the Act and that $60 million in loan guarantee authority shall be deducted pursuant to section 226(d) of the Act.

You are hereby authorized and directed to transmit this determination to the Congress and to arrange for its publication in the Federal Register.



THE WHITE HOUSE,
Washington, September 30, 1996.

[FR Doc. 96–28396
Filed 11–1–96; 8:45 am]
Billing code 4710–10–M

Presidential Documents

Presidential Determination No. 96–59 of September 30, 1996

Presidential Determination on FY 1997 Refugee Admissions Numbers and Authorizations of In-Country Refugee Status Pursuant to Sections 207 and 101(a)(42), Respectively, of the Immigration and Nationality Act, and Determination Pursuant to Section 2(b)(2) of the Migration and Refugee Assistance Act, as Amended

Memorandum for the Secretary of State

In accordance with section 207 of the Immigration and Nationality Act (''the Act'') (8 U.S.C. 1157), as amended, and after appropriate consultation with the Congress, I hereby make the following determinations and authorize the following actions:

The admission of up to 78,000 refugees to the United States during FY 1997 is justified by humanitarian concerns or is otherwise in the national interest; provided, however, that this number shall be understood as including persons admitted to the United States during FY 1997 with Federal refugee resettlement assistance under the Amerasian immigrant admissions program, as provided below.

The 78,000 funded admissions shall be allocated among refugees of special humanitarian concern to the United States as described in the documentation presented to the Congress during the consultations that preceded this determination and in accordance with the following regional allocations; provided, however, that the number allocated to the East Asia region shall include persons admitted to the United States during FY 1997 with Federal refugee resettlement assistance under section 584 of the Foreign Operations, Export Financing and Related Programs Appropriations Act of 1988, as contained in section 101(e) of Public Law 100–202 (Amerasian immigrants and their family members); provided further that the number allocated to the former Soviet Union shall include persons admitted who were nationals of the former Soviet Union, or in the case of persons having no nationality, who were habitual residents of the former Soviet Union, prior to September 2, 1991:

Africa	7,000
East Asia	10,000
Europe	48,000
Latin America/Caribbean	4,000
Near East/South Asia	4,000
Unallocated	5,000

The 5,000 unallocated federally funded numbers shall be allocated as needed. Unused admissions numbers allocated to a particular region within the 78,000 federally funded ceiling may be transferred to one or more other regions if there is an overriding need for greater numbers for the region or regions to which the numbers are being transferred. You are hereby authorized and directed to consult with the Judiciary Committees of the Congress prior to any such use of the unallocated numbers or reallocation of numbers from one region to another.

Pursuant to section 2(b)(2) of the Migration and Refugee Assistance Act of 1962, as amended, 22 U.S.C. 2601(b)(2), I hereby determine that assistance to or on behalf of persons applying for admission

to the United States as part of the overseas refugee admissions program will contribute to the foreign policy interests of the United States and designate such persons for this purpose.

An additional 10,000 refugee admissions numbers shall be made available during FY 1997 for the adjustment to permanent resident status under section 209(b) of the Immigration and Nationality Act (8 U.S.C. 1159(b)) of aliens who have been granted asylum in the United States under section 208 of the Act (8 U.S.C. 1158), as this is justified by humanitarian concerns or is otherwise in the national interest.

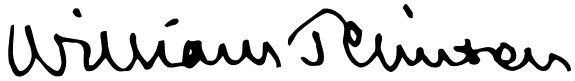
In accordance with section 101(a)(42)(B) of the Act (8 U.S.C. 1101(a)(42)) and after appropriate consultation with the Congress, I also specify that, for FY 1997, the following persons may, if otherwise qualified, be considered refugees for the purpose of admission to the United States within their countries of nationality or habitual residence:

a. Persons in Vietnam

b. Persons in Cuba

c. Persons in the former Soviet Union

You are authorized and directed to report this determination to the Congress immediately and to publish it in the Federal Register.



THE WHITE HOUSE,
Washington, September 30, 1996.

[FR Doc. 96–28397
Filed 11–1–96; 8:45 am]
Billing code 4710–10–M

Federal Register

Monday
November 4, 1996

Part IV

The President

Proclamation 6950—Veterans Day, 1996

Executive Order 13022—Administration of the Midway Islands

Federal Register
Vol. 61, No. 214
Monday, November 4, 1996

Presidential Documents

Title 3—

The President

Proclamation 6950 of October 31, 1996

Veterans Day, 1996

By the President of the United States of America

A Proclamation

This Veterans Day, Americans enjoy the fruits of peace, freedom, and prosperity in a world where too many must still struggle to live their lives free from conflict, violence, and repression.

As leaders in the fight for liberty, we have sought to advance the cause of freedom and democracy to people all over the world. The credit for our own freedom, as well as our continued security, belongs overwhelmingly to the men and women who have served in our Nation's Armed Forces—our veterans. Had they not been there yesterday, were they not with us today, our world would be far different.

Today we salute their service, honor their sacrifice, thank them for supporting this Nation in every hour of need. And we acknowledge that freedom's cost continues long after the guns fall silent. Many of our veterans bear the disabilities and scars of military service. The families of others—who never returned from their service—live always with a profound sense of loss. It is our duty to remember what our veterans have done and to uphold our commitments to them and their families.

As we mark the past achievements of our veterans, let us remember that they are a vital part of our present and future. Of the 40 million who have served in America's military since the Revolutionary War, 26.5 million are with us today—not distant historical footnotes, but as close as a father or mother, brother or sister, grandfather or grandmother, friend or neighbor.

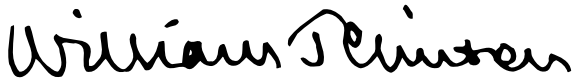
Their tradition of service extends beyond the battlefield and the barracks. Most veterans in civilian life continue devoting their energies to the service of their country and communities. They are civic-minded role models who challenge and inspire our young people. They are volunteers who work for neighbors in need. They represent what is best in the American spirit.

That is why we must help them make the transition from military to civilian careers and empower them with the opportunities to use their training, discipline, and motivation in good and rewarding jobs. We owe them as well a guarantee that we will continue to defend the American ideals for which they have served and sacrificed. As the strongest force for peace and freedom in the world, we recognize our responsibility to maintain a military capability second to none.

In respect and recognition of the contributions our service men and women have made in defense of America and to advance the cause of peace, the Congress has provided (5 U.S.C. 6103(a)) that November 11 of each year shall be set aside as a legal public holiday to recognize America's veterans.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim Monday, November 11, 1996, as Veterans Day. I urge all Americans to recognize the valor and sacrifice of our veterans through appropriate public ceremonies and private prayers. I call upon Federal, State, and local officials to display the flag of the United States and to encourage and participate in patriotic activities in their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirty-first day of October, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twenty-first.



[FR Doc. 96–28505
Filed 11–01–96; 11:04 am]
Billing code 3195–01–P

Presidential Documents

Executive Order 13022 of October 31, 1996

Administration of the Midway Islands

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 48 of the Hawaii Omnibus Act, Public Law 86-624, and section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. The Midway Islands, Hawaiian group, and their territorial seas, located approximately between the parallels of 28 degrees 5 minutes and 28 degrees 25 minutes North latitude and between the meridians of 177 degrees 10 minutes and 177 degrees 30 minutes West longitude, were placed under the jurisdiction and control of the Department of the Navy by the provisions of Executive Order 199-A of January 20, 1903, and Part II of Executive Order 11048 of September 4, 1962, and are hereby transferred to the jurisdiction and control of the Department of the Interior. The provisions of Executive Order 199-A of January 20, 1903, and the provisions of Executive Order 11048 of September 4, 1962, that pertain to the Midway Islands are hereby superseded.

Sec. 2. The Midway Islands Naval Defensive Sea Area and the Midway Islands Naval Airspace Reservation are hereby dissolved. The provisions of Executive Order 8682 of February 14, 1941, as amended by Executive Order 8729 of April 2, 1941, are hereby superseded.

Sec. 3. (a) The Secretary of the Interior, through the United States Fish and Wildlife Service, shall administer the Midway Islands as the Midway Atoll National Wildlife Refuge in a manner consistent with Executive Order 12996 of March 25, 1996, for the following purposes:

(1) maintaining and restoring natural biological diversity within the refuge;

(2) providing for the conservation and management of fish and wildlife and their habitats within the refuge;

(3) fulfilling the international treaty obligations of the United States with respect to fish and wildlife;

(4) providing opportunities for scientific research, environmental education, and compatible wildlife dependent recreational activities; and

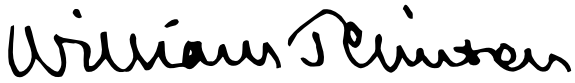
(5) in a manner compatible with refuge purposes, shall recognize and maintain the historic significance of the Midway Islands consistent with the policy stated in Executive Order 11593 of May 13, 1971.

(b) The Secretary of the Interior shall be responsible for the civil administration of the Midway Islands and all executive and legislative authority necessary for that administration, and all judicial authority respecting the Midway Islands other than the authority contained in 48 U.S.C. 644a.

Sec. 4. Any civil or criminal proceeding that is pending under the Midway Islands Code, 32 CFR Part 762, upon the date of this order, shall remain under the jurisdiction of the Secretary of the Navy. Actions arising after the date of this order are the responsibility of the Secretary of the Interior and shall be administered pursuant to regulations promulgated by the Secretary of the Interior.

Sec. 5. To the extent that any prior Executive order or proclamation is inconsistent with the provisions of this order, this order shall control.

Sec. 6. Nothing in this order shall be deemed to reduce, limit, or otherwise modify the authority or responsibility of the Attorney General of the United States to represent the legal interests of the United States in civil or criminal cases arising under the provisions of 48 U.S.C. 644a.



THE WHITE HOUSE,
October 31, 1996.

[FR Doc. 96–28509
Filed 11–01–96; 11:04 am]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 61, No. 214

Monday, November 4, 1996

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FEDERAL REGISTER PAGES AND DATES, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
6949 56397
6950 56873

Executive Orders:
199–A (Superseded in part by EO 13022) 56875
8682 (Superseded in part by EO 13022) 56875
8729 (Superseded in part by EO 13022) 56875
11048 (Superseded in part by EO 13022) 56875
11593 (See EO 13022) 56875
12996 (See EO 13022) 56875
13022 56875

Administrative Orders:
Presidential Determinations:
No. 96–53 of September 26, 1996 56859
No. 96–55 of September 30, 1996 56861
No. 96–56 of September 30, 1996 56863
No. 96–57 of September 30, 1996 56865
No. 96–58 of September 30, 1996 56857
No. 96–59 of September 30, 1996 56859

5 CFR

Ch. LVII 56399

7 CFR

301 56403

10 CFR

2 56623
13 56623

12 CFR

225 56404
263 56407

14 CFR

25 56408
71 ..... 56623, 56624
382 56409

Proposed Rules:
39 ..... 56640, 56642
71 ..... 56479, 56480, 56644
382 56481

15 CFR

902 56425

17 CFR

Proposed Rules:
300 56485

19 CFR

Proposed Rules:
10 56645
18 56645
114 56645

22 CFR

41 56438

24 CFR

3500 56624

26 CFR

Proposed Rules:
1 56647

29 CFR

1910 56746
1915 56746
1926 56746

30 CFR

Proposed Rules:
943 56648

37 CFR

1 56439
2 56439
5 56439
10 56439

38 CFR

2 56448
3 56626
36 56449
42 56449

Proposed Rules:
17 56486

39 CFR

233 56450

40 CFR

52 ..... 56461, 56470, 56472, 56474, 56627, 56629
70 056631
266 56631
300 56477

Proposed Rules:
52 ..... 56491, 56492, 56649,

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT TODAY

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Plant-related quarantine, domestic:
Karnal bunt disease--
Seed planting, regulated articles movement and risk levels; criteria; published 10-4-96
Viruses, serums, toxins, etc.:
Antibody products; published 10-4-96

ENVIRONMENTAL PROTECTION AGENCY
Clean Air Act:
State operating permits programs--
California; published 11-4-96

FEDERAL COMMUNICATIONS COMMISSION
Radio stations; table of assignments:
Arkansas; published 10-4-96
Missouri; published 9-30-96

HEALTH AND HUMAN SERVICES DEPARTMENT
Health Care Financing Administration
Medicare:
End stage renal disease--
Routine extended care services provided in swing-bed hospital; new payment methodology; published 10-3-96

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Civil rights:
Nondiscrimination and equal opportunity matters; hearing procedures consolidation; published 10-4-96
Residential antidisplacement and relocation assistance plans, one-for-one replacement requirements, and relocation benefits; Federal regulatory reform; published 10-3-96

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
de Havilland; published 9-30-96
Airbus; published 9-30-96
Boeing; published 9-30-96
Fokker; published 9-30-96
Jetstream; published 9-30-96

VETERANS AFFAIRS DEPARTMENT
Adjudication, pensions, compensation, dependency, etc.:
Marriage dissolution; birth of child; death of family member; evidence requirements; published 11-4-96
Adjudication; pensions, compensation, dependency, etc.:
Willful misconduct; removal of latin phrases and other unnecesary or redundant material; published 11-4-96

COMMENTS DUE NEXT WEEK

ADVISORY COUNCIL ON HISTORIC PRESERVATION
Historic Preservation, Advisory Council
Historic and cultural properties protection; comments due by 11-12-96; published 9-13-96

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Perishable Agricultural Commodities Act:
Retailers and grocery wholesalers; phase-out of license fee payments, etc.; comments due by 11-12-96; published 9-10-96

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Interstate transportation of animals and animal products (quarantine):
Brucellosis in cattle, bison, and swine--
Rapid automated presumptive test; comments due by 11-12-96; published 9-13-96
Plant-related quarantine, domestic:
Fire ant, imported; comments due by 11-14-96; published 10-15-96

AGRICULTURE DEPARTMENT
Federal Crop Insurance Corporation
Crop insurance regulations:
Cranberry crop; comments due by 11-12-96; published 9-13-96
Forage production crop; comments due by 11-12-96; published 9-13-96

AGRICULTURE DEPARTMENT
Food and Consumer Service
Food stamp program:
Quality control system; technical amendments; comments due by 11-12-96; published 9-10-96

ARMS CONTROL AND DISARMAMENT AGENCY
National Security Information; comments due by 11-15-96; published 10-10-96

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Bering Sea and Aleutian Islands and Gulf of Alaska groundfish; comments due by 11-12-96; published 9-27-96
Bering Sea and Aleutian Islands groundfish; comments due by 11-12-96; published 9-19-96
Northeast multispecies, Atlantic sea scallop, and American lobster; comments due by 11-11-96; published 9-20-96
Puerto Rico and U.S. Virgin Islands queen conch; comments due by 11-12-96; published 9-27-96

DEFENSE DEPARTMENT
Federal Acquisition Regulation (FAR):
Contracting by negotiation; Phase I rewrite; comments due by 11-12-96; published 9-12-96
Contractors and offerors; certification requirements removed; comments due by 11-12-96; published 9-12-96
Performance-based payments; comments due by 11-12-96; published 9-10-96
Simplified acquisition procedures; comments due by 11-12-96; published 9-13-96

EDUCATION DEPARTMENT
Federal regulatory review:
Vocational and adult education programs; comments due by 11-15-96; published 10-16-96

ENERGY DEPARTMENT
Property management:
Federal regulatory review; comments due by 11-12-96; published 9-11-96

ENVIRONMENTAL PROTECTION AGENCY
Air programs:
Fuel and fuel additives--
Guam; anti-dumping and detergent additization requirements for conventional gasoline; exemption petition; comments due by 11-15-96; published 10-16-96
Guam; anti-dumping and detergent additization requirements for conventional gasoline; exemption petition; comments due by 11-15-96; published 10-16-96
Air quality implementation plans; approval and promulgation; various States:
Alaska; comments due by 11-12-96; published 10-10-96
District of Columbia; comments due by 11-12-96; published 10-10-96
Maine; comments due by 11-14-96; published 10-15-96
New Jersey; comments due by 11-14-96; published 10-15-96
Pennsylvania; comments due by 11-12-96; published 10-10-96
Tennessee; comments due by 11-14-96; published 10-15-96
Utah; comments due by 11-12-96; published 10-10-96
Air quality implementation plans; √A√approval and promulgation; various States; air quality planning purposes; designation of areas:
Louisiana et al.; comments due by 11-14-96; published 10-15-96
Hazardous waste:
Identification and listing--
Exclusions; comments due by 11-14-96; published 10-2-96
Pesticide programs:
Risk/benefit information; reporting requirements; comments due by 11-12-96; published 10-25-96

FARM CREDIT ADMINISTRATION
Farm credit system:
Disclosure to shareholders and investors in

CFR CHECKLIST

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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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Title	Stock Number	Price	Revision Date
1, 2 (2 Reserved)	(869–028–00001–1)	$4.25	Feb. 1, 1996
3 (1995 Compilation and Parts 100 and 101)	(869–028–00002–9)	22.00	[1] Jan. 1, 1996
4	(869–028–00003–7)	5.50	Jan. 1, 1996
5 Parts:			
1–699	(869–028–00004–5)	26.00	Jan. 1, 1996
700–1199	(869–028–00005–3)	20.00	Jan. 1, 1996
1200–End, 6 (6 Reserved)	(869–028–00006–1)	25.00	Jan. 1, 1996
7 Parts:			
0–26	(869–028–00007–0)	22.00	Jan. 1, 1996
27–45	(869–028–00008–8)	11.00	Jan. 1, 1996
46–51	(869–028–00009–6)	13.00	Jan. 1, 1996
52	(869–028–00010–0)	5.00	Jan. 1, 1996
53–209	(869–028–00011–8)	17.00	Jan. 1, 1996
210–299	(869–028–00012–6)	35.00	Jan. 1, 1996
300–399	(869–028–00013–4)	17.00	Jan. 1, 1996
400–699	(869–028–00014–2)	22.00	Jan. 1, 1996
700–899	(869–028–00015–1)	25.00	Jan. 1, 1996
900–999	(869–028–00016–9)	30.00	Jan. 1, 1996
1000–1199	(869–028–00017–7)	35.00	Jan. 1, 1996
1200–1499	(869–028–00018–5)	29.00	Jan. 1, 1996
1500–1899	(869–028–00019–3)	41.00	Jan. 1, 1996
1900–1939	(869–028–00020–7)	16.00	Jan. 1, 1996
1940–1949	(869–028–00021–5)	31.00	Jan. 1, 1996
1950–1999	(869–028–00022–3)	39.00	Jan. 1, 1996
2000–End	(869–028–00023–1)	15.00	Jan. 1, 1996
8	(869–028–00024–0)	23.00	Jan. 1, 1996
9 Parts:			
1–199	(869–028–00025–8)	30.00	Jan. 1, 1996
200–End	(869–028–00026–6)	25.00	Jan. 1, 1996
10 Parts:			
0–50	(869–028–00027–4)	30.00	Jan. 1, 1996
51–199	(869–028–00028–2)	24.00	Jan. 1, 1996
200–399	(869–028–00029–1)	5.00	Jan. 1, 1996
400–499	(869–028–00030–4)	21.00	Jan. 1, 1996
500–End	(869–028–00031–2)	34.00	Jan. 1, 1996
11	(869–028–00032–1)	15.00	Jan. 1, 1996
12 Parts:			
1–199	(869–028–00033–9)	12.00	Jan. 1, 1996
200–219	(869–028–00034–7)	17.00	Jan. 1, 1996
220–299	(869–028–00035–5)	29.00	Jan. 1, 1996
300–499	(869–028–00036–3)	21.00	Jan. 1, 1996
500–599	(869–028–00037–1)	20.00	Jan. 1, 1996
600–End	(869–028–00038–0)	31.00	Jan. 1, 1996
13	(869–028–00039–8)	18.00	Mar. 1, 1996
14 Parts:			
1–59	(869–028–00040–1)	34.00	Jan. 1, 1996
60–139	(869–028–00041–0)	30.00	Jan. 1, 1996
140–199	(869–028–00042–8)	13.00	Jan. 1, 1996
200–1199	(869–028–00043–6)	23.00	Jan. 1, 1996
1200–End	(869–028–00044–4)	16.00	Jan. 1, 1996
15 Parts:			
0–299	(869–028–00045–2)	16.00	Jan. 1, 1996
300–799	(869–028–00046–1)	26.00	Jan. 1, 1996
800–End	(869–028–00047–9)	18.00	Jan. 1, 1996
16 Parts:			
0–149	(869–028–00048–7)	6.50	Jan. 1, 1996
150–999	(869–028–00049–5)	19.00	Jan. 1, 1996
1000–End	(869–028–00050–9)	26.00	Jan. 1, 1996
17 Parts:			
1–199	(869–028–00052–5)	21.00	Apr. 1, 1996
200–239	(869–028–00053–3)	25.00	Apr. 1, 1996
240–End	(869–028–00054–1)	31.00	Apr. 1, 1996
18 Parts:			
1–149	(869–028–00055–0)	17.00	Apr. 1, 1996
150–279	(869–028–00056–8)	12.00	Apr. 1, 1996
280–399	(869–028–00057–6)	13.00	Apr. 1, 1996
400–End	(869–028–00058–4)	11.00	Apr. 1, 1996
19 Parts:			
1–140	(869–028–00059–2)	26.00	Apr. 1, 1996
141–199	(869–028–00060–6)	23.00	Apr. 1, 1996
200–End	(869–028–00061–4)	12.00	Apr. 1, 1996
20 Parts:			
1–399	(869–028–00062–2)	20.00	Apr. 1, 1996
400–499	(869–028–00063–1)	35.00	Apr. 1, 1996
500–End	(869–028–00064–9)	32.00	Apr. 1, 1996
21 Parts:			
1–99	(869–028–00065–7)	16.00	Apr. 1, 1996
100–169	(869–028–00066–5)	22.00	Apr. 1, 1996
170–199	(869–028–00067–3)	29.00	Apr. 1, 1996
200–299	(869–028–00068–1)	7.00	Apr. 1, 1996
300–499	(869–028–00069–0)	50.00	Apr. 1, 1996
500–599	(869–028–00070–3)	28.00	Apr. 1, 1996
600–799	(869–028–00071–1)	8.50	Apr. 1, 1996
800–1299	(869–028–00072–0)	30.00	Apr. 1, 1996
1300–End	(869–028–00073–8)	14.00	Apr. 1, 1996
22 Parts:			
1–299	(869–028–00074–6)	36.00	Apr. 1, 1996
300–End	(869–028–00075–4)	24.00	Apr. 1, 1996
23	(869–028–00076–2)	21.00	Apr. 1, 1996
24 Parts:			
0–199	(869–028–00077–1)	30.00	May 1, 1996
200–219	(869–028–00078–9)	14.00	May 1, 1996
220–499	(869–028–00079–7)	13.00	May 1, 1996
500–699	(869–028–00080–1)	14.00	May 1, 1996
700–899	(869–028–00081–9)	13.00	May 1, 1996
900–1699	(869–028–00082–7)	21.00	May 1, 1996
1700–End	(869–028–00083–5)	14.00	May 1, 1996
25	(869–028–00084–3)	32.00	May 1, 1996
26 Parts:			
§§ 1.0-1–1.60	(869–028–00085–1)	21.00	Apr. 1, 1996
§§ 1.61–1.169	(869–028–00086–0)	34.00	Apr. 1, 1996
§§ 1.170–1.300	(869–028–00087–8)	24.00	Apr. 1, 1996
§§ 1.301–1.400	(869–028–00088–6)	17.00	Apr. 1, 1996
§§ 1.401–1.440	(869–028–00089–4)	31.00	Apr. 1, 1996
§§ 1.441-1.500	(869-028-00090-8)	22.00	Apr. 1, 1996
§§ 1.501–1.640	(869–028–00091–6)	21.00	Apr. 1, 1996
§§ 1.641–1.850	(869–028–00092–4)	25.00	Apr. 1, 1996
§§ 1.851–1.907	(869–028–00093–2)	26.00	Apr. 1, 1996
§§ 1.908–1.1000	(869–028–00094–1)	26.00	Apr. 1, 1996
§§ 1.1001–1.1400	(869–028–00095–9)	26.00	Apr. 1, 1996
§§ 1.1401–End	(869–028–00096–7)	35.00	Apr. 1, 1996
2–29	(869–028–00097–5)	28.00	Apr. 1, 1996
30–39	(869–028–00098–3)	20.00	Apr. 1, 1996
40–49	(869–028–00099–1)	13.00	Apr. 1, 1996
50–299	(869–028–00100–9)	14.00	Apr. 1, 1996
300–499	(869–028–00101–7)	25.00	Apr. 1, 1996

Title	Stock Number	Price	Revision Date
500–599	(869–028–00102–5)	6.00	[4] Apr. 1, 1990
600–End	(869–028–00103–3)	8.00	Apr. 1, 1996
27 Parts:			
1–199	(869–028–00104–1)	44.00	Apr. 1, 1996
200–End	(869–028–00105–0)	13.00	Apr. 1, 1996
28 Parts:			
1-42	(869–028–00106–8)	35.00	July 1, 1996
43-end	(869-028-00107-6)	30.00	July 1, 1996
29 Parts:			
0–99	(869–028–00108–4)	26.00	July 1, 1996
100–499	(869–028–00109–2)	12.00	July 1, 1996
500–899	(869–028–00110–6)	48.00	July 1, 1996
900–1899	(869–028–00111–4)	20.00	July 1, 1996
1900–1910 (§§ 1909 to 1910.999)	(869–028–00112–2)	43.00	July 1, 1996
1910 (§§ 1910.1000 to end)	(869–026–00115–4)	22.00	July 1, 1995
1911–1925	(869–028–00114–9)	19.00	July 1, 1996
1926	(869–028–00115–7)	30.00	July 1, 1996
1927–End	(869–026–00118–9)	36.00	July 1, 1995
30 Parts:			
1–199	(869–028–00117–3)	33.00	July 1, 1996
200–699	(869–028–00118–1)	26.00	July 1, 1996
700–End	(869–028–00119–0)	38.00	July 1, 1996
31 Parts:			
0–199	(869–028–00120–3)	20.00	July 1, 1996
200–End	(869–028–00121–1)	33.00	July 1, 1996
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–028–00122–0)	42.00	July 1, 1996
191–399	(869–028–00123–8)	50.00	July 1, 1996
400–629	(869–028–00124–6)	34.00	July 1, 1996
630–699	(869–028–00125–4)	14.00	[5] July 1, 1991
700–799	(869–028–00126–2)	28.00	July 1, 1996
800–End	(869–028–00127–1)	28.00	July 1, 1996
33 Parts:			
1–124	(869–026–00130–8)	20.00	July 1, 1995
125–199	(869–026–00131–6)	27.00	July 1, 1995
200–End	(869–028–00130–1)	32.00	July 1, 1996
34 Parts:			
1–299	(869–028–00131–9)	27.00	July 1, 1996
300–399	(869–028–00132–7)	27.00	July 1, 1996
400–End	(869–026–00135–9)	37.00	July 5, 1995
35	(869–028–00134–3)	15.00	July 1, 1996
36 Parts			
1–199	(869–028–00135–1)	20.00	July 1, 1996
200–End	(869–028–00136–0)	48.00	July 1, 1996
37	(869–028–00137–8)	24.00	July 1, 1996
38 Parts:			
0–17	(869–026–00140–5)	30.00	July 1, 1995
18–End	(869–028–00139–4)	38.00	July 1, 1996
39	(869–028–00140–8)	23.00	July 1, 1996
40 Parts:			
1–51	(869–028–00141–6)	50.00	July 1, 1996
*52	(869–028–00142–4)	51.00	July 1, 1996
*53–59	(869–028–00143–2)	14.00	July 1, 1996
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61–71	(869–028–00145–9)	47.00	July 1, 1996
72–85	(869–026–00148–1)	41.00	July 1, 1995
81–85	(869–028–00147–5)	31.00	July 1, 1996
86	(869–026–00149–9)	40.00	July 1, 1995
87-135	(869–028–00149–1)	35.00	July 1, 1996
136–149	(869–028–00150–5)	35.00	July 1, 1996
150–189	(869–026–00151–1)	25.00	July 1, 1995
190–259	(869–028–00152–1)	22.00	July 1, 1996
260–299	(869–026–00153–7)	40.00	July 1, 1995
*300–399	(869–028–00154–8)	28.00	July 1, 1996
400–424	(869–028–00155–6)	33.00	July 1, 1996
*425–699	(869–028–00156–4)	38.00	July 1, 1996
700–789	(869–028–00157–2)	33.00	July 1, 1996
790–End	(869–028–00158–7)	19.00	July 1, 1996
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
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1–100	(869–028–00159–9)	12.00	July 1, 1996
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201–End	(869–028–00162–9)	17.00	July 1, 1996
42 Parts:			
1–399	(869–026–00163–4)	26.00	Oct. 1, 1995
400–429	(869–026–00164–2)	26.00	Oct. 1, 1995
430–End	(869–026–00165–1)	39.00	Oct. 1, 1995
43 Parts:			
1–999	(869–026–00166–9)	23.00	Oct. 1, 1995
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4000–End	(869–026–00168–5)	15.00	Oct. 1, 1995
44	(869–026–00169–3)	24.00	Oct. 1, 1995
45 Parts:			
1–199	(869–022–00170–7)	22.00	Oct. 1, 1995
200–499	(869–026–00171–5)	14.00	Oct. 1, 1995
500–1199	(869–026–00172–3)	23.00	Oct. 1, 1995
1200–End	(869–026–00173–1)	26.00	Oct. 1, 1995
46 Parts:			
1–40	(869–026–00174–0)	21.00	Oct. 1, 1995
41–69	(869–026–00175–8)	17.00	Oct. 1, 1995
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166–199	(869–026–00180–4)	17.00	Oct. 1, 1995
200–499	(869–026–00181–2)	19.00	Oct. 1, 1995
500–End	(869–026–00182–1)	13.00	Oct. 1, 1995
47 Parts:			
0–19	(869–026–00183–9)	25.00	Oct. 1, 1995
20–39	(869–026–00184–7)	21.00	Oct. 1, 1995
40–69	(869–026–00185–5)	14.00	Oct. 1, 1995
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80–End	(869–026–00187–1)	30.00	Oct. 1, 1995
48 Chapters:			
1 (Parts 1–51)	(869–026–00188–0)	39.00	Oct. 1, 1995
1 (Parts 52–99)	(869–026–00189–8)	24.00	Oct. 1, 1995
2 (Parts 201–251)	(869–026–00190–1)	17.00	Oct. 1, 1995
2 (Parts 252–299)	(869–026–00191–0)	13.00	Oct. 1, 1995
3–6	(869–026–00192–8)	23.00	Oct. 1, 1995
7–14	(869–026–00193–6)	28.00	Oct. 1, 1995
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29–End	(869–026–00195–2)	19.00	Oct. 1, 1995
49 Parts:			
1–99	(869–026–00196–1)	25.00	Oct. 1, 1995
100–177	(869–026–00197–9)	34.00	Oct. 1, 1995
178–199	(869–026–00198–7)	22.00	Oct. 1, 1995
200–399	(869–026–00199–5)	30.00	Oct. 1, 1995
400–999	(869–026–00200–2)	40.00	Oct. 1, 1995
1000–1199	(869–026–00201–1)	18.00	Oct. 1, 1995
1200–End	(869–026–00202–9)	15.00	Oct. 1, 1995
50 Parts:			
1–199	(869–026–00203–7)	26.00	Oct. 1, 1995
200–599	(869–026–00204–5)	22.00	Oct. 1, 1995
600–End	(869–026–00205–3)	27.00	Oct. 1, 1995

Title	Stock Number	Price	Revision Date
CFR Index and Findings Aids	(869–028–00051–7)	35.00	Jan. 1, 1996
Complete 1996 CFR set		883.00	1996
Microfiche CFR Edition:			
Subscription (mailed as issued)		264.00	1996
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Complete set (one-time mailing)		264.00	1995
Complete set (one-time mailing)		244.00	1994

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1996. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1996. The CFR volume issued July 1, 1991, should be retained.