

Federal Register

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- FOR: Any person who uses the Federal Register and Code of Federal Regulations.
- WHO: Sponsored by the Office of the Federal Register.
- WHAT: Free public briefings (approximately 3 hours) to present:
 1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
 2. The relationship between the Federal Register and Code of Federal Regulations.
 3. The important elements of typical Federal Register documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

[Two Sessions]

- WHEN: May 14, 1996 at 9:00 am
May 21, 1996 at 9:00 am
- WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street, NW., Washington, DC (3 blocks north of Union Station Metro)
- RESERVATIONS: 202-523-4538



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Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 17

Regulations Governing the Financing of Commercial Sales of Agricultural Commodities

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends regulations applicable to the financing of the sale and exportation of agricultural commodities pursuant to title I of the Agricultural Trade Development and Assistance Act of 1954, as amended (Pub. L. 480).

The amendment deletes one document from the list of those documents currently required to be submitted by the commodity supplier to the banking institution to support a request for payment; and deletes the contracting and documentary requirements for commodities which have not been shipped under the program for a number of years.

The purpose of these changes is to reduce the documentation required for payment to commodity suppliers and to simplify and shorten the regulations.

EFFECTIVE DATE: May 23, 1996. See **SUPPLEMENTARY INFORMATION** for compliance requirements.

FOR FURTHER INFORMATION CONTACT: Connie B. Delaplane, Director, Public Law 480 Operations Division, Export Credits, Foreign Agricultural Service, U.S. Department of Agriculture, Room 4549, South Building, 14th and Independence, SW., Washington, DC 20250-1033. Telephone: (202) 720-3664.

SUPPLEMENTARY INFORMATION: This final rule is issued in conformance with Executive Order 12866. It has been determined to be significant for the

purposes of E.O. 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

This final rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act. The General Sales Manager has certified that this rule will not have a significant economic impact on a substantial number of small entities. There will be no significant economic impact from this final rule on small or large entities. A copy of this final rule has been submitted to the General Counsel, Small Business Administration.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with state and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983).

Executive Order 12778

This final rule has been reviewed under the Executive Order 12778, Civil Justice Reform. The final rule would have preemptive effect with respect to any state or local laws, regulations, or policies which conflict with such provisions or which otherwise impede their full implementation. The final rule would not have retroactive effect. The rule does not require that administrative remedies be exhausted before suit may be filed.

Background

The Secretary of Agriculture implements title I of the Agricultural Trade Development and Assistance Act of 1954, as amended (Pub. L. 480). This function is delegated to the General Sales Manager, Foreign Agricultural Service. On August 22, 1995, the Foreign Agricultural Service (FAS) published a proposed rule (60 FR 43566) to amend the regulations governing the financing of the sale and exportation of agricultural commodities made available under title I, Public Law 480.

Discussion of Comments

Only one comment was received, fully supporting the proposed changes to the regulations: (1) Removing from the regulations information regarding a number of inactive commodities and (2)

Eliminating one document currently required to be submitted by commodity suppliers seeking payment.

Effective Date

The provisions of this rule shall apply to contracts entered into under purchase authorizations issued on or after May 23, 1996.

Paperwork Reduction Act

This final rule does not contain any information collection requirements that require OMB approval under the provisions of the Paperwork Reduction Act.

List of Subjects in 7 CFR Part 17

Agricultural commodities, Exports, Finance; Maritime carriers.

Accordingly, 7 CFR Part 17, Subpart A, is amended as follows:

1. The authority citation for Part 17 continues to read as follows:

Authority: 7 U.S.C. 1701-1705, 1736a, 1736c, 5676; E.O. 12220, 45 FR 44245.

§ 17.2 [Amended]

2. Section 17.2 is amended by removing the last sentence of the definition of "Form CCC-106" in paragraph (b).

3. Section 17.14 is amended by removing the word "(white)" from the first sentence of paragraph (d)(1); revising the last sentence of paragraph (d)(1) and all of paragraph (d)(2)(i) to read as follows; and removing the word "(yellow)" from paragraph (d)(2)(ii), as follows:

§ 17.14 Ocean transportation.

* * * * *

(d) *Advice of vessel approval.* * * *

(1) *For cotton.* * * * If CCC finances any part of the ocean freight when cotton is shipped on an f.a.s. basis, a signed original copy of this form will be issued to the ocean carrier.

(2) *For commodities other than cotton.* * * *

(i) For shipments to be made on an f.o.b. or f.a.s. basis, when CCC finances any part of the cost of ocean freight, the original of Form CCC-106-2 will be issued to the ocean carrier.

* * * * *

§ 17.18 [Amended]

4. Section 17.18 is amended by adding the phrase "for c. & f. or c.i.f. sales" at the end of paragraph (c)(8)(ii).

§ 17.20 [Amended]

5. Section 17.20 is amended by changing the reference to "sections (V) and (W)" to read "sections (D) and (E)" in paragraph (a)(9)(i).

Appendices A and B [Amended]

6. Appendix A and Appendix B are amended by removing existing sections (D), (E), (G), (I), (J), (L), (M), (N), (O), (P), (Q), (R), (S), (T), and (U); redesignating existing section (K) as (G); redesignating existing section (V) as (D); and redesignating existing section (W) as (E).

7. Appendix B is amended by changing the reference to "section (K)(7)(b)" to read "section (G)(7)(b)" in newly redesignated paragraph (G)(1)(j) and by adding the phrase "for c. & f. or c.i.f. sales" at the end of the following paragraphs: (A)(1)(d) and (2)(d); (B)(4); (C)(1)(d) and (2)(d); newly redesignated (D)(4) and (E)(4); (F)(1)(d) and (2)(d); newly redesignated (G)(1)(d) and (2)(d); and (H)(1)(d) and (2)(d).

Signed at Washington, D.C. on February 22, 1996.

Christopher E. Goldthwait,

General Sales Manager, Foreign Agricultural Service and Vice President, Commodity Credit Corporation.

[FR Doc. 96-9899 Filed 4-22-96; 8:45 am]

BILLING CODE 3410-10-M

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. 95-NM-98-AD; Amendment 39-9571; AD 96-08-05]

Airworthiness Directives; Boeing Model 747-400 Series Airplanes Powered by General Electric CF6-80C2 or Pratt & Whitney PW4000 Series Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747-400 series airplanes, that requires modification of the engine fuel feed system. This amendment is prompted by reports indicating that the coupling nut on the fuel tube on the outboard strut (engine position 1) fractured. The actions specified by this AD are intended to prevent such fracturing of the coupling nut, which could result in release of fuel onto the engine cowling and a subsequent fire.

DATES: Effective May 23, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 23, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Tamra J. Elkins, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington; telephone (206) 227-2669; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Boeing Model 747-400 series airplanes was published in the Federal Register on December 12, 1995 (60 FR 63663). That action proposed to require modification of the engine fuel feed system.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposed rule.

The Air Transport Association (ATA) of America, on behalf of one of its members, requests that the proposed compliance time be extended from 18 months to 24 months to provide time for operators to procure replacement kits and to accomplish the proposed actions during a regularly scheduled maintenance ("C") check. The FAA concurs with the commenter's request. The FAA finds that extending the compliance time to 24 months will not compromise safety; will allow operators sufficient time to procure the necessary replacement kits (estimated by the manufacturer to take approximately nine months); and will allow the modification to be accomplished during a "C" check interval (15 months for most operators) at a main maintenance base where special equipment and trained personnel will be available if necessary.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the

adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

There are approximately 226 Model 747-400 series airplanes of the affected design in the worldwide fleet.

The FAA estimates that 34 airplanes of U.S. registry will be required by this AD to replace the strut fuel tubes and couplings at engine positions 1 and 4 in accordance with Boeing Alert Service Bulletin 747-28A2185. That replacement will take approximately 74 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$9,582 per airplane. Based on these figures, the cost impact of this required replacement on U.S. operators is estimated to be \$476,748, or \$14,022 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Currently, there are no Model 747-400 series airplanes on the U.S. Register that would be required by this AD to accomplish the installation specified in Boeing Service Bulletin 747-28-2146 [and required by paragraph (a)(2) of the final rule]. However, should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 162 work hours per airplane (81 work hours per engine; 2 engines per airplane) to accomplish the installation, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$9,582 per airplane. Based on these figures, the cost impact of this installation would be \$19,302 per airplane.

The regulations adopted herein will 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 final rule does 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) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

96-08-05 Boeing: Amendment 39-9571.
Docket 95-NM-98-AD.

Applicability: Model 747-400 series airplanes powered by General Electric CF6-80C2 or Pratt & Whitney PW4000 series engines; as identified in Boeing Alert Service Bulletin 747-28A2185, Revision 1, dated September 21, 1995, and Boeing Service Bulletin 747-28-2146, dated August 13, 1992; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (b) 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 as indicated, unless accomplished previously.

To prevent fracturing of the coupling nut, which could result in release of fuel onto the engine cowl and a subsequent fire, accomplish the following:

(a) Within 24 months after the effective date of this AD, accomplish the requirements of paragraph (a)(1) or (a)(2), as applicable.

(1) For Model 747-400 series airplanes identified in Boeing Alert Service Bulletin

747-28A2185, Revision 1, dated September 21, 1995: Replace the strut fuel tubes and couplings at engine numbers 1 and 4 with new redesigned (shrouded) couplings, in accordance with that alert service bulletin.

(2) For Model 747-400 series airplanes having variable numbers RT641 through RT650 inclusive, identified in Boeing Service Bulletin 747-28-2146, dated August 13, 1992: On engine positions 1 and 4 only, install new fuel lines, shrouded fuel line couplings (between the strut mid bulkhead and the wing front spar), and drain lines in accordance with that service bulletin.

(b) 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, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

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

(c) 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.

(d) The actions shall be done in accordance with Boeing Alert Service Bulletin 747-28A2185, Revision 1, dated September 21, 1995, and Boeing Service Bulletin 747-28-2146, dated August 13, 1992. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on May 23, 1996.

Issued in Renton, Washington, on April 10, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-9338 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 95-NM-121-AD; Amendment 39-9572; AD 96-08-06]

Airworthiness Directives; Saab Model SAAB SF340A and SAAB 340B Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Saab Model SAAB SF340A and SAAB 340B series airplanes, that requires visual and dye penetrant inspection(s) to detect cracks of the nose rib of the rudder, and stop drilling and blending of minor cracks. This amendment also requires replacement of the nose rib with a new nose rib and reinforcement of the nose rib, if extensive cracking is detected or if an operator elects to terminate the repetitive inspections. This amendment is prompted by the result of an inspection that revealed a cracked nose rib on the front spar of the rudder due to vibration-related stress. The actions specified by this AD are intended to prevent such stress and cracking, which could result in the deformation of the nose rib; this condition may lead to friction and jamming between the fin and the rudder and subsequent reduced controllability of the airplane.

DATES: Effective May 23, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 23, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from SAAB Aircraft AB, SAAB Aircraft Product Support, S-581.88, Linköping, Sweden. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ruth Harder, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-1721; fax (206) 227-1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Saab Model SAAB SF340A and SAAB 340B series airplanes was published in the Federal Register on January 9, 1996 (61 FR 640). That action proposed to require visual and dye penetrant inspection(s) to detect cracks of the nose rib of the rudder, and stop drilling and blending of minor cracks. That action also proposed to require replacement of the nose rib with a new nose rib and reinforcement of the nose rib, if any extensive crack is detected or if an

operator elects to terminate the repetitive inspections.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter supports the proposed rule.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 221 Saab Model SAAB SF340A and SAAB 340B series airplanes of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per airplane to accomplish the required actions, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the inspection requirement of this AD on U.S. operators is estimated to be \$53,040, or \$240 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The regulations adopted herein will 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 final rule does 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) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

96-08-06 Saab Aircraft AB: Amendment 39-9572. Docket 95-NM-121-AD.

Applicability: Model SAAB. SF340A series airplanes having serial numbers (S/N) 004 through 159 inclusive, and Model SAAB 340B having S/N's 160 through 369 inclusive; certificated in any category.

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 (b) 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 as indicated, unless accomplished previously.

To prevent vibration-related stress and cracking and consequent deformation of the nose rib, which could result in friction and jamming between the fin and the rudder and subsequent reduced controllability of the airplane, accomplish the following:

(a) Prior to the accumulation of 2,400 total flight hours, or within 800 flight hours after the effective date of this AD, whichever occurs later, perform a visual and dye penetrant inspection to detect cracks of the nose rib of the rudder, in accordance with Saab Service Bulletin 340-55-032, dated May 22, 1995.

(1) If no cracks are detected, repeat the inspection thereafter at intervals not to exceed 800 flight hours, or replace the nose rib with a new nose rib and reinforce it, in accordance with the service bulletin. Accomplishment of the replacement and reinforcement constitutes terminating action for this AD.

(2) If any minor crack [less than 25.4 mm (1.0 inch) long] is detected, prior to further flight, stop drill and blend the crack in accordance with the service bulletin. Repeat the inspection thereafter at intervals not to exceed 800 flight hours, or replace the nose

rib with a new nose rib and reinforce it, in accordance with the service bulletin. Accomplishment of the replacement and reinforcement constitutes terminating action for this AD.

(3) If any extensive crack [greater than or equal to 25.4 mm (1.0 inch) long] is detected, prior to further flight, replace the nose rib with a new nose rib and reinforce it, in accordance with the service bulletin. Accomplishment of this replacement and reinforcement constitutes terminating action for this AD.

(b) 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, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) 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.

(d) The actions shall be done in accordance with Saab Service Bulletin 340-55-032, dated May 22, 1995. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from SAAB Aircraft AB, SAAB Aircraft Product Support, S-581.88, Linköping, Sweden. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(e) This amendment becomes effective on May 23, 1996.

Issued in Renton, Washington, on April 10, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-9339 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-U

14 CFR Part 71

[Airspace Docket No. 95-ANM-19]

Establishment of Class D Airspace; Vancouver, Washington

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class D airspace at Pearson Field, Vancouver, Washington. This action is necessary to

enhance safety within the area which was previously excluded from the Portland International Airport (PDX) Class C airspace and commonly referred to as the Pearson Cutout. A minor change is also being made to the airport name, formerly called Pearson Airpark, and to the geographic coordinates of Pearson Field, Vancouver, Washington.

EFFECTIVE DATE: June 20, 1996.

FOR FURTHER INFORMATION CONTACT: James C. Frala, Operations Branch, ANM-532.4, Federal Aviation Administration, Docket No. 95-ANM-19, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone number: (206) 227-2535.

SUPPLEMENTARY INFORMATION:

History

On November 9, 1995, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class D airspace at Pearson Field, Vancouver, Washington (60 FR 56539). This proposal was the product of an airspace and procedural review of new instrument approach procedures to PDX and an analysis of the Pearson Field/Portland International utilization of airspace west of PDX. This rule was proposed to minimize potential conflicts and mitigate wake turbulence concerns. The proposed establishment of Class D airspace at Pearson Field requires pilots operating in the airspace to be in communication with the controlling Air traffic facility so that traffic information and wake turbulence advisories can be issued. Interested parties were invited to participate in the rulemaking proceeding by submitting written comments on the proposal. This action is the same as the proposal except the airport name and coordinates have been changed in this document to reflect information published in the National Flight Data Digest Number 226, dated November 24, 1995. Additionally, a change is made to reflect the dates and times the Class D airspace area is effective.

Discussion of Comments

A total of 17 individuals submitted written comments to FR Doc. 95-27830, Notice of Proposed Rulemaking (NPRM) 95-ANM-19. Additionally, verbal comments were expressed by some of the approximately 350 persons attending informal aviation gatherings. The FAA considered these comments in the adoption of this rule. Comments submitted on NPRM 95-ANM-19 reflect the views of a broad spectrum of the aviation public including individuals and organizations representing commercial and general aviation pilots.

Organizations that commented include Air Line Pilots Association (ALPA); Delta Air Lines, Inc.; Port of Portland; Experimental Aircraft Association; The City of Vancouver, Washington; Clark County Airport Owners and Managers Association; and the Washington Pilots Association.

Of the 17 who submitted written comments to the docket, 6 commenters supported and 11 commenters opposed the establishment of Class D airspace. Of the 6 supporting comments, 5 commenters agreed that this action would promote safety for users at both PDX and Pearson Field.

One commenter (ALPA) would support the establishment of Class D airspace if additional restrictions, such as requiring an operating transponder, segregating Pearson Field traffic from PDX traffic, and lowering the Pearson Field traffic pattern altitude to 700 feet mean sea level, were included in the proposed action. These suggested restrictions were evaluated and determined to be excessive and not necessary for safety. Lowering the Pearson Field pattern altitude to 700 feet would place pilots in closer proximity to terrain and to people and property on the ground. This option was rejected because it contradicts the purpose of the rule which is to enhance safety.

Of the 11 commenters opposing the rule, one commenter felt that the proposed action was an attempt to close Pearson Field. The FAA did not consider closing Pearson Field as an option. Rather, the FAA is committed to mitigating airspace management issues when airports are in close proximity to each other. The purpose of this rulemaking is to allow Pearson Field to continue to operate safely in close proximity to its larger neighbor. Three commenters felt that the proposed action would introduce jet traffic to a new route over Pearson Field and in close proximity to downtown Vancouver, Washington. Four commenters expressed concern for increased jet noise. The establishment of Class D airspace introduces a communication requirement only. No new jet routes will result from this action and this airspace action does not alter existing flight tracks. Jet noise will not be altered by this rule. Two commenters suggested that the approaches to PDX should be offset to the south to avoid conflicts in traffic flows. This option is not viable for two reasons. First, the rising terrain and obstructions southwest of the airport create serious safety obstacles to safe instrument approaches. Second, if it was feasible to offset the approaches to

the south, the approach minimums would be very high due to the terrain and the fact that the approach would not be aligned with the runway. As a result, offsetting the approaches would have an adverse effect on airport capacity. Three commenters expressed concerns for wake turbulence generated by aircraft landing and departing PDX. The FAA shares these concerns as demonstrated by this rule that is intended to facilitate the transfer of wake turbulence information to Pearson Field users. In addition to the traffic and wake turbulence advisories resulting from this rule, the FAA has agreed to assist in presentation of wake turbulence training for Pearson Field operators and to publish cautionary advisories where appropriate.

Two commenters were opposed to the action due to the additional cockpit workload of radio communications and the financial burden of acquiring a radio. The FAA recognizes that the requirement for radio communications will have some impact on users at Pearson Field, particularly those who do not have radio-equipped aircraft. However, due to the proximity of the two airports and the need to minimize potential conflicts and mitigate wake turbulence concerns, some airspace safety change is necessary. Prior to this rulemaking, FAA Air Traffic and Flight Standards personnel met with customer representatives for Pearson Field and PDX to seek solutions and minimize impacts on users at the airports. It was generally agreed that establishing Class D airspace at Pearson Field would satisfy safety concerns while imposing the least restrictions on users. Furthermore, the FAA and Pearson pilots are developing procedures for non-radio aircraft operations at Pearson Field.

The Clark County Airport Owners and Managers Association objects to this proposed action suggesting it violates their constitutional rights. They claim Grandfather Rights to the airspace in and around their airports because those airports were in existence many years prior to PDX. Title 49 United States Code, section 40103 charges the FAA with the responsibility to regulate the use of airspace for efficiency and safety. As mentioned previously, the purpose of this rule is to preserve safe operations at Pearson. This rule does not address the operation of PDX or the effects of that airport's operations on surrounding airports other than Pearson.

One commenter provided comments that were unrelated to the proposal.

During the comment period, verbal responses relating to this proposed airspace action were heard at several

aviation gatherings. Instructions and the appropriate address for submitting written comments were disseminated to the approximately 360 pilots at those gatherings who expressed an interest in this rulemaking. Verbal comments from those gatherings were noted. In general, most pilots of aircraft equipped with electrical systems expressed agreement with the rule. There was a suggestion that a control tower may be necessary at Pearson. However, others felt a control tower was neither needed nor wanted. In fact, the activity level at Pearson does not approach the level established by the FAA to support a control tower. Some expressed concern that traffic at Pearson would be delayed for PDX traffic either by denying access to the Class D airspace for aircraft arriving at Pearson, or by requiring aircraft departing Pearson Field to hold on the ground until separation from PDX traffic could be achieved. Separation services are not provided for aircraft operating under visual flight rules in Class D airspace. Air Traffic will not be controlling the flow of aircraft arriving at or departing from Pearson.

The Rule

This amendment to part 71 of Federal Aviation Regulations establishes Class D airspace at Pearson Field, Vancouver, Washington. 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. It, therefore, (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) 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).

The Proposed 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 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *
ANM WA D Vancouver, WA
Vancouver, Pearson Field, WA
(lat. 45°37'14"N, long. 122°39'23"W)
Portland International Airport, OR
(lat. 45°35'19"N, long. 122°35'51"W)

That airspace extending upward from the surface to but not including 1,100 feet MSL in an area bounded by a line beginning at the point where the 019° bearing from Pearson Field intersects the 5-mile arc from Portland International Airport extending southeast to a point 1 1/2 miles east of Pearson Field on the extended centerline of Runway 8/26, and thence south to the north shore of the Columbia River, thence west via the north shore of the Columbia River to the 5-mile arc from Portland International Airport and thence clockwise via the 5-mile arc to point of beginning. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington, on April 8, 1996.

Richard E. Prang,

Acting Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 96-9992 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 94F-0358]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified solutions of sodium chlorite in poultry processing water. This action is in response to a petition filed by Alcide Corp.

DATES: Effective April 23, 1996; written objections and requests for a hearing by May 23, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications listed in new § 173.325, effective April 23, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 1, 1994 (59 FR 54609), FDA announced that a food additive petition (FAP 4A4433) had been filed by Alcide Corp., Inc., 8561 154th Ave. NE., Redmond, WA 98052, proposing that the food additive regulations be amended to provide for the safe use of acidified solutions of sodium chlorite/chlorous acid in poultry processing water.

FDA has evaluated data in the petition and other relevant material and has consulted with scientists in the Food Safety and Inspection Service in the U.S. Department of Agriculture concerning the technological and practical aspects of the proposed use of acidified solutions of sodium chlorite. The agency concludes that the proposed use of the additive is safe and will have the intended technical effect of reducing microbial contamination on poultry. The agency also concludes that the regulation approving the additive should be entitled "acidified sodium chlorite solutions." Acidification of sodium chlorite results in partial conversion of chlorite to chlorous acid. Also, in the notice of filing, FDA announced that the petition proposed to allow the use of any of the following acids to prepare acidified sodium chlorite solutions: Phosphoric acid, citric acid, hydrochloric acid, lactic acid, malic acid, or sulfuric acid. These acids are all generally recognized as safe (GRAS) acids. The agency has concluded that the use of any GRAS acid is appropriate, and is codifying this conclusion in the regulation. Therefore, 21 CFR part 173 is amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to

approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing for this petition FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 23, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. New § 173.325 is added to subpart D to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758-19-2) with any generally recognized as safe (GRAS) acid.

(b) The additive is used as an antimicrobial agent in poultry processing water as a component of a carcass spray or dip solution prior to immersion of the carcass in a prechiller or chiller tank, or in a prechiller or chiller solution in accordance with current industry practice for use of poultry processing water.

(1) When used in a carcass spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9. The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) When used in a prechiller or chiller tank, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a

solution pH of 2.8 to 3.2. The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this method is listed in paragraph (b)(1) of this section.

Dated: April 11, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-9783 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 529

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for an approved abbreviated new animal drug application (ANADA) from Macleod Pharmaceuticals, Inc., to Anthony Products Co.

EFFECTIVE DATE: April 23, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525, has informed FDA that it has transferred the ownership of, and all rights and interests in, approved ANADA 200-115 (Gentamicin Sulfate) to Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006. Accordingly, FDA is amending the regulations in 21 CFR 529.1044a to reflect the change of sponsor.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing "000061, 000856, 054273, 057561, and 058711" and adding in its place, "000061, 000856, 000864, 054273, and 057561".

Dated: April 4, 1996.

Robert C. Livingston,
Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 96-9870 Filed 4-22-96; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of the Secretary

25 CFR Part 1001

RIN 1076-AD26

**Tribal Self-Governance Program
Interim Rule Establishing Procedures
for Awarding Negotiation/Planning
Grants**

AGENCY: Office of Self-Governance,
Office of the Secretary, Interior.

ACTION: Interim rule.

SUMMARY: In this interim rule, the Office of Self-Governance (OSG) establishes procedures for awarding negotiation grants; advance planning grants; and negotiation/planning grants to negotiate for Department of the Interior (DOI) non-Bureau of Indian Affairs (BIA) programs, pursuant to the Tribal Self-Governance Act.

DATES: The effective date of this interim rule is April 19, 1996. OSG will consider Written comments on the interim rule when revising this rule. To be considered, comments must be received on or before May 31, 1996.

ADDRESSES: Written comments on the interim rule should be sent to the Director, Office of Self-Governance, U.S. Department of the Interior, Mail Stop 2548, 1849 C Street NW., Washington DC 20240.

FOR FURTHER INFORMATION CONTACT:
Dr. Kenneth D. Reinfeld, U.S.
Department of the Interior, Office of
Self-Governance, 1849 C Street NW.,
Mail Stop 2548, Washington DC 20240,
202-219-0240.

SUPPLEMENTARY INFORMATION:

Justification for Interim Rule

This rule is not a rulemaking subject to the provisions of section 553 of the Administrative Procedure Act (5 U.S.C. 551, et seq.) (APA). Section 553(a)(2)

excepts from the scope of rulemaking rules "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts."

Even if this rule were considered rulemaking subject to the provisions of section 553 of the APA, good cause exists to publish this interim rule without prior opportunity for public comment.

Section 553 outlines the following rulemaking steps: (1) Publication of a notice of proposed rulemaking, (2) solicitation of public comment on the proposed rule, (3) review of comments received prior to developing the final rule, and (4) publication of the final rule 30 days prior to the effective date. Using this process at this time would not serve the goal of the Tribal Self-Governance Act of 1994, which is to expand tribal participation in the tribal self-governance program, because the process would diminish the ability of some selected tribes/consortia to effectively negotiate agreements for fiscal year 1997 or calendar year 1997. The process would also diminish the ability of other tribes/consortia in the near term to plan for and possibly delay their participation in tribal self-governance.

The Tribal Self-Governance Act of 1994 (Pub. L. 103-413) was enacted and became effective on October 25, 1994. While the interim rule may be changed by later rulemaking, the Act stipulates that the lack of promulgated regulations will not limit the Act's effect.

Under section 402(b) of the Act, the Director, Office of Self-Governance may select up to 20 additional participating tribes/consortia per year for the tribal self-governance program, and negotiate and enter into an annual written funding agreement with each participating tribe. In order to complete the negotiation process for 1997 funding agreements, it is necessary to make available negotiation grants to the new tribes by May 15, 1996. The Act mandates that the Secretary submit copies of the funding agreements at least 90 days before the proposed effective date to the appropriate committees of the Congress and to each tribe that is served by the BIA agency that is serving the tribe that is a party to the funding agreement. Initial negotiations with a tribe/consortium located in an area and/or agency which has not previously been involved with self-governance negotiations, will take approximately two months from start to finish.

Publication of this interim rule without prior opportunity for public comment is necessary to complete the above procedures in a timely fashion. Therefore, applying the criteria at 5

U.S.C. 553(b)(3)(B) and 553(d), good cause exists to make the rule effective less than thirty days from today's date.

Background

The tribal self-governance program is designed to promote self determination by allowing tribes to assume more control through negotiated agreements of programs operated by the Department of the Interior. The new law allows for negotiations to be conducted for programs operated by BIA and for programs operated by other bureaus and offices within the Department that are available to Indians or when there is an historical, cultural, or geographic connection to an Indian tribe.

The Tribal Self-Governance Act of 1994 requires the Secretary, upon request of a majority of self-governance tribes, to initiate procedures under the Negotiated Rulemaking Act, 5 U.S.C. 561 et seq., to negotiate and promulgate regulations necessary to carry out the tribal self-governance program. The Act calls for a negotiated rulemaking committee to be established pursuant to 5 U.S.C. 565 comprised of Federal and tribal representatives, with a majority of the tribal representatives representing self-governance tribes. The Act also authorizes the Secretary to adapt negotiated rulemaking procedures to the unique context of self-governance and the government-to-government relationship between the United States and the Indian tribes. On November 1, 1994, a majority of self-governance tribes wrote the Secretary requesting the immediate initiation of negotiated rulemaking. On February 15, 1995, the self-governance negotiated rulemaking committee was established.

On the same day, an interim rule was published in the Federal Register at 60 FR 8553 announcing the criteria for tribes to be included in an applicant pool and the establishment of the selection process for tribes to negotiate agreements pursuant to the Tribal Self-Governance Act of 1994. This interim rule allowed an additional 20 new tribes/consortia to negotiate compacts and annual funding agreements for fiscal year 1996 and calendar year 1996 as authorized by the Act. Using the same interim rule, a notice of deadline for submitting completed applications to begin participation in tribal self-governance in fiscal year 1997 or calendar year 1997 was published in the Federal Register on February 1, 1996. To date, a total of 54 compacts and annual funding agreements have been negotiated.

Since publication of the interim rule, the self-governance negotiated rulemaking committee has reached

tentative agreement on draft provisions relating to the procedures for awarding negotiation grants; advance planning grants; and negotiation/planning grants to negotiate for DOI non-BIA programs. These provisions along with other sections of the negotiated rules are subject to notice and public comment procedures as part of the rulemaking process. Given the fact that more time is needed to reach agreement on other sections of the negotiated rules, it is not possible to provide notice and obtain public comment on the rule so as to award the grants in a timely fashion using fiscal year 1996 funds.

Purpose of Rule

This interim rule establishes procedures which are consistent with the self-governance negotiated rulemaking committee's negotiations for awarding negotiation and planning grants. The interim rule is intended to allow the grants to be awarded using fiscal year 1996 funds.

This interim rule will take immediate effect to allow the grant selection process for the upcoming year to begin under an interim rule that has been tentatively agreed upon by the self-governance negotiated rulemaking committee.

The Department is adopting this rule before the self-governance negotiated rulemaking process is completed. This interim rule will be subject to negotiation and amendment by the negotiated rulemaking process. The self-governance negotiated rulemaking committee will use any comments received following the publication of this interim rule in negotiating the final rule. Furthermore, the portion of the interim rule governing the awarding of the grants will be subject to additional comment once the proposed regulations recommended by the self-governance rulemaking committee are published in the Federal Register. The final published rule will supersede this interim rule.

A. E.O. 12612

The Department has determined that this interim rule does not have significant federalism effects.

B. E.O. 12630

In accordance with Executive Order 12630, the Department has determined that this interim rule does not have significant takings implications.

C. E.O. 2778

The Department has certified to the Office of Management and Budget that this interim rule meets the applicable

standards provided in sections 2(a) and 2(b)(2) of Executive Order 12778.

D. E.O. 12886

This interim rule is not a significant regulatory action under Executive Order 12866, and therefore will not be reviewed by the Office of Management and Budget.

E. Regulatory Flexibility Act Statement

This interim 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.*).

F. NEPA Statement

The Department has determined that this interim rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

G. Information Collection Statement

The information collection requirements contained in this interim rule are included in current collections 1076-0090, 0091, 0096, 1030 and OMB Circulars A-102, A-110, and SF-424.

H. Authorship Statement

The primary author of this document is Dr. Kenneth Reinfield, Office of Self-Governance.

List of Subjects in 25 CFR Part 1001

Indians, Native Americans.

For the reasons given in the preamble, title 25, part 1001 is amended as follows:

PART 1001—SELF-GOVERNANCE PROGRAM

1. The authority citation for part 1001 continues to read as follows:

Authority: 26 U.S.C. 450 note, 458aa-458gg.

2. Sections 1001.7 through 1001.10 are added to read as follows:

§ 1001.7 Availability, amount, and number of planning and negotiation grants.

(a) What is the purpose of this section? This section describes how to apply for planning and negotiation grants authorized by section 402(d) of the Act to help meet tribal costs incurred:

(1) In meeting the planning phase requirement of Pub. L. 103-413, including planning to negotiate non-BIA programs, services, functions and activities; and

(2) In conducting negotiations.

(b) What types of grants are available? Three categories of grants may be available:

(1) Negotiation grants for tribes/consortia selected from the applicant pool as described in § 1001.5 of these regulations;

(2) Planning grants for tribes/consortia requiring advance funding to meet the planning phase requirement of Pub. L. 103-413; and

(3) Financial assistance for tribes/consortia to plan for negotiating for non-BIA programs, services, functions and activities, as described in § 1001.10.

(c) Will grants always be made available to meet the planning phase requirement as described in section 402(d) of Pub. L. 103-413? No. Grants to cover some or all of the planning costs that a tribe/consortium may incur may be made available depending upon the availability of funds appropriated by Congress. We will publish notice of availability of grants in the Federal Register as described in this section.

(d) May a tribe use its own resources to meet its planning and negotiation expenses in preparation for entering into self-governance? Yes. A tribe/consortium may use its own resources to meet these costs. Receiving a grant is not necessary to meet the planning phase requirement of the Act or to negotiate a compact and annual funding agreement.

(e) What happens if there are insufficient funds to meet the anticipated tribal requests for planning and negotiation grants in any given year? If appropriated funds are available but insufficient to meet the total requests from tribes/consortia, we will give first priority to those that have been selected from the applicant pool to negotiate an annual funding agreement. We will give second priority to tribes/consortia that require advance funds to meet the planning requirement for entry into the self-governance program. We will give third priority to tribes/consortia that require negotiation/planning funds to negotiate for DOI non-BIA programs.

(f) How many grants will the Department make each year and what funding will be available? The number and size of grants awarded each year will depend on Congressional appropriations and tribal interest. Each year, we will publish a notice in the Federal Register which provides relevant details about the application process, including: The funds available, timeframes, and requirements for negotiation and advance planning specified in this part.

§ 1001.8 Selection criteria for tribes/consortia to receive a negotiation grant.

(a) Who may be selected to receive a negotiation grant? Any tribe/consortium that has been accepted into the applicant pool in accordance with § 1001.5 and has been selected to negotiate a self-governance annual funding agreement is eligible to apply for a negotiation grant. Each year, we will publish a notice in the Federal Register with all relevant details as to how tribes/consortia which have been selected can apply for negotiation grants.

(b) What must a tribe/consortium do to receive a negotiation grant?

(1) To receive a negotiation grant, a tribe/consortium must:

(i) Be selected from the applicant pool to negotiate an annual funding agreement;

(ii) Be identified as eligible to receive a negotiation grant; and

(iii) Not have received a negotiation grant within the 3 years preceding the date of the latest Federal Register announcement described in § 1001.7.

(2) The tribe/consortium must submit a letter affirming its readiness to negotiate and formally request a negotiation grant to prepare for and negotiate a self-governance agreement. These grants are not competitive.

(c) May a selected tribe negotiate without applying for a negotiation grant? Yes. In this case, the tribe should notify us in writing so that funds can be reallocated for other grants.

§ 1001.9 Selection criteria for tribes/consortia seeking advance planning grant funding.

(a) Who is eligible to apply for a planning grant that will be awarded before a tribe/consortium is admitted into the applicant pool? Any tribe/consortium that is not a self-governance tribe and needs advance funding in order to complete the planning phase requirement may apply. Tribes/consortia that have received a planning grant within 3 years preceding the date of the latest Federal Register announcement described in § 1001.7 are not eligible.

(b) What must a tribe/consortium seeking a planning grant submit in order to meet the planning phase requirements? A tribe/consortium must submit the following material:

(1) a tribal resolution or other final action of the tribal governing body indicating a desire to plan for tribal self-governance;

(2) audits from the last 3 years which document that the tribe meets the requirement of being free from any material audit exception;

(3) a proposal that describes the tribe's/consortium's plans to conduct:

(i) legal and budgetary research, and

(ii) internal tribal government and organization planning;

(4) a timeline indicating when planning will start and end; and

(5) evidence that the tribe/consortium can perform the tasks associated with its proposal (i.e., submit resumes and position descriptions of key staff or consultants to be used).

(c) How will tribes/consortia know when and how to apply for planning grants? Each year, we will publish in the Federal Register a notice of the availability of planning grants for additional tribes as described in § 1001.7. This notice will identify the specific details for applying.

(d) What criteria will be used to award planning grants to those tribes/consortia requiring advance funding to meet the planning phase requirement of Public Law 103-413? Advance planning grants are discretionary and based on need. The following criteria will be used to determine whether to award a planning grant to a tribe/consortium before the tribe is being selected into the applicant pool:

(1) A complete application as described in §§ 1001.9(b) and 1001.9(c);

(2) A demonstration of financial need. We will rank applications according to the percentage of tribal resources to total resources as indicated in the latest A-128 audit. We will give priority to applications that demonstrate financial need by having a lower level of tribal resources as a percent of total resources; and

(3) Other factors that demonstrate the readiness of the tribe/consortium to enter into a self-governance agreement, including previous efforts of the tribe/consortium to participate in self-governance.

(e) Can tribes/consortia that receive advance planning grants also apply for a negotiation grant? Yes. Tribes/consortia that receive advance planning grants may submit a completed application to be included in the applicant pool. Once approved for inclusion in the applicant pool, the tribe/consortium may apply for a negotiation grant according to the process identified in § 1001.7 above.

(f) When and how will a tribe/consortium know whether it has been selected to receive an advance planning grant? Within 30 days of the deadline for submitting applications we will notify the tribe/consortium by letter whether it has been selected to receive an advance planning grant.

§ 1001.10 Selection criteria for other planning and negotiating financial assistance.

(a) What is the purpose of this section? This section describes how to apply for other financial assistance for planning and negotiating of a DOI non-BIA program, service, function or activity that may be available, as well as the selection process.

(b) Are there other funds that may be available to self-governance tribes/consortia for planning and negotiating with DOI non-BIA bureaus? Yes. Tribes/consortia may contact the Director, Office of Self-Governance to determine if funds are available for the purpose of planning and negotiating with DOI non-BIA bureaus under this section. A tribe/consortium may also request information from a DOI non-BIA bureau on any funds which may be available from that bureau.

(c) Who is eligible to apply for financial assistance to plan and negotiate for a DOI non-BIA program? Any existing self-governance tribe/consortium is eligible.

(d) Under what circumstances may planning and negotiation financial assistance be made available to tribes/consortia? At the discretion of the Director, grants may be awarded when requested by the tribe and coordinated with the DOI non-BIA agency involved.

(e) How does the tribe/consortium apply for a grant to plan and negotiate for a DOI non-BIA program? When such funds are available, we will publish a notice of their availability and a deadline for submitting applications for such grants in the Federal Register as indicated in § 1001.7.

(f) What must be included in the application? The application must include the following:

(1) the tribal resolution or other final action of the tribal governing body indicating that the tribe/consortium intends to negotiate for a DOI non-BIA program;

(2) a copy of the proposal or summary that was submitted to the DOI non-BIA bureau;

(3) a time line indicating when planning will begin and end;

(4) the planning resources from all other sources that are approved and/or anticipated for the planning activity; and

(5) the amount requested and a justification of why it is needed by the tribe/consortium.

(g) What criteria will we use to award grants to those tribes/consortia requesting financial assistance to plan and negotiate for a DOI non-BIA program? The award of such grants is discretionary. After consulting with the

requesting tribe/consortium and the appropriate DOI non-BIA bureau, the Director will determine whether to award a grant to plan and negotiate for a DOI non-BIA program. The determination will be based upon the complexity of the project, the availability of resources from all other sources, and the relative need of the tribe/consortium to receive such funds for the successful completion of the planning and negotiating activity, as determined by the percentage of tribal resources to total resources as indicated in the latest A-128 audit. All decisions to award or not to award grants as described in paragraphs (e) and (f) of this section are final for the Department.

Dated: April 4, 1996.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96-9740 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-02-M

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 756

[HO-003-FOR]

Hopi Tribe Abandoned Mine Land Reclamation Plan

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

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving, with certain exceptions and additional requirements, a proposed amendment to the Hopi Tribe Abandoned Mine Land Reclamation (AMLR) plan (hereinafter, the "Hopi Tribe plan") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The Hopi Tribe proposed revisions of and additions to plan provisions pertaining to the purpose of the plan; eligible lands and water subsequent to certification; coordination with other programs; land acquisition, management, and disposal; reclamation on private land and rights of entry; public participation; organization of the Hopi Tribe; personnel staffing policies; purchasing policies, procurement procedures, and accounting systems; economic conditions on the Hopi Reservation; a description of flora and fauna at abandoned mine sites; the Hopi Tribe's authority to administer its plan, as amended, in the absence of a specific statute; changing the name of the designated agency; and affirmation that the manual for purchasing policies and

procedures is in accordance with the Office of Management and Budget's (OMB) Common Rule. Additionally, the Hopi Tribe is proposing numerous editorial and recodification changes. The amendment revised the Hopi Tribe plan to meet the requirements of and incorporate the additional flexibility afforded by the revised Federal regulations and SMCRA, as amended, and improve operational efficiency.

EFFECTIVE DATE: April 23, 1996.

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Telephone: (505) 248-5070.

SUPPLEMENTARY INFORMATION:

I. Background on the Hopi Tribe Plan

On June 28, 1988, the Secretary of the Interior approved the Hopi Tribe plan. General background information on the Hopi Tribe plan, including the Secretary's findings and the disposition of comments, can be found in the June 28, 1988, Federal Register (53 FR 24262). Subsequent actions concerning the Hopi Tribe plan and plan amendments can be found at 30 CFR 756.16, 756.17, and 756.18.

II. Proposed Amendment

By letter dated November 2, 1995, the Hopi Tribe submitted a proposed amendment to its plan (administrative record No. HO-148) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). The Hopi Tribe submitted the proposed amendment in response to a September 26, 1994, letter (administrative record No. HO-145.1) that OSM sent to the Hopi Tribe in accordance with 30 CFR 884.15(b), and at its own initiative.

The provisions of the Hopi Tribe plan that the Hopi Tribe proposed to revise or add were: the table of contents, including a list of appendices; a preface to the amended reclamation plan; a list of addenda and errata, including a list of figures; the Chairman's letter of designation and Hopi Tribe resolution; the General Counsel's opinion on the authority of the Hopi Tribe to conduct an AMLR program; Part I, purpose of the Hopi Tribe plan; Part II, eligible lands and water subsequent to certification; Part III, coordination of the Hopi AMLR Program with other programs; Part IV, land acquisition, management, and disposal; Part V, reclamation on private land; Part VI, rights of entry; Part VII, Hopi Department of Natural Resources (DNR) policy on public participation; Part VIII, organization of the Hopi Tribe; Part IX, personnel staffing policies; Part X, purchasing policies and procurement procedures; Part XI, accounting systems and management accounting; Part XII, economic conditions on the Hopi

Reservation; and Part XIII, a description of flora and fauna at abandoned mine sites. The Hopi Tribe also proposed numerous minor editorial and grammatical revisions and recodification changes. Finally, the Hopi Tribe proposed changes to the appendices included in its plan as follows: (a) provided as "Appendix 1," the "Constitution and By-Laws of the Hopi Tribe," which was approved December 19, 1936, and amended on August 1, 1969, February 14, 1980, and December 7, 1993, (b) provided cover pages for Appendices 2 through 12, and (c) changed the title of Appendix 7 from "Hopi Tribe Resolution H-93-80" to "Hopi Tribe Resolution H-93-80 and Subsequent Correspondence to the Bureau of Census."

In addition, the Hopi Tribe proposed the deletion of the following sections in their entirety: (a) Section 884.13(e)(1), which is replaced by specific criteria for eligible lands and waters subsequent to certification at Part II of the Hopi Tribe plan; (b) Sections 884.13(e)(2) and 884.13(e)(3), which are replaced by a description of current problems and needs and current proposals at Part II, section H of the Hopi Tribe plan; and (c) Section 884.13(f)(2), Description of Aesthetic, Cultural and Recreational Conditions of the Hopi Reservation.

The Hopi Tribe also proposed adding the following items to its plan: (1) A memorandum dated May 18, 1995, from the Hopi Tribe's Assistant General Counsel affirming the authority of the Tribe's AMLR Program to administer the Hopi Tribe plan as amended in the absence of any AMLR statute; (2) Hopi Tribal Resolution H-134-89 that provides documentation of the Tribe's action changing the name of the Office of Natural Resources to the Department of Natural Resources; and (3) a memorandum dated August 31, 1995, from the Tribe's Office of Financial Management that affirms that the Hopi Tribe "Purchasing Policies and Procedures Manual" is in accordance with OMB's Common Rule.

OSM announced receipt of the proposed amendment in the December 7, 1995, Federal Register (60 FR 62786), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. HO-150). Because no one requested a public hearing or meeting, none was held. The public comment period ended on January 8, 1996.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 884.14 and 884.15, finds, with certain

exceptions and additional requirements, that the proposed plan amendment submitted by the Hopi Tribe on November 2, 1995, meets the requirements of the corresponding Federal regulations and is consistent with SMCRA. Thus, the Director approves the proposed amendment.

1. Nonsubstantive Revisions to the Hopi Tribe Plan Provisions

The Hopi Tribe proposed revisions to the following previously-approved plan provisions that are nonsubstantive in nature and consist of minor editorial, punctuation, grammatical, and recodification changes (corresponding Federal regulation or SMCRA provisions are listed in parentheses):

Table of Contents (there are no counterpart Federal regulations or SMCRA provisions), title of Part II, "Eligible Lands and Waters Subsequent to Certification;"

Table of Contents, (there are no counterpart Federal regulations or SMCRA provisions), List of Appendices;

List of Addenda and Errata, (there are no counterpart Federal regulations or SMCRA provisions), title for this part;

List of Figures, (there are no counterpart Federal regulations or SMCRA provisions), title of Figure 4 and deletion of Figure 5;

Chairman's Letter of Designation and Hopi Tribe Resolution, (30 CFR 884.13(a)), designation of agency authorized to administer approved plan;

Opinion of Legal Counsel, (30 CFR 884.13(b)), authority of designated agency to conduct the AMLR program in accordance with the requirements of Title IV of SMCRA;

Part III, (30 CFR 884.13(c)), coordination of Tribal AML programs with other programs;

Sections IV, A(2) (c), (d), (e), B(2), and C (30 CFR Part 879), land acquisition, management, and disposal;

Part V and Figures 1 and 2, (30 CFR Part 882), reclamation on private land;

Sections VI, A, B, and C, (30 CFR Part 877), rights of entry;

Part VII, (30 CFR 884.13(c)(7)), Hopi DNR policy on public participation;

Part VIII and Figure 4, (30 CFR 884.13(d)(1)), organization of the Hopi Tribe;

Part IX, (30 CFR 884.13(d)(2)), personnel staffing policies;

Part X, (30 CFR 884.13(d)(3)), purchasing and procurement;

Part XI, (30 CFR 884.13(d)(4)), management accounting;

Deletion of section 884.13(e)(1) [replaced by Part II] and deletion of sections 884.13(e) (2) and (3) [replaced by section II, H], (30 CFR 884.13 (c) (1) and (2)), purpose of Hopi Tribe

reclamation plan and criteria for ranking and identifying projects;

Part XIII, (30 CFR 884.13(f)(2)), flora and fauna;

Appendices 1 through 12, (there are no counterpart Federal regulations or SMCRA provisions), addition of cover pages; and

Appendix 7, (there is no counterpart Federal regulation or SMCRA provision), change of title of appendix.

Because the proposed revisions to these previously-approved Hopi Tribe plan provisions are nonsubstantive in nature, the Director finds that they meet the requirements of the Federal regulations and are consistent with the corresponding provisions of SMCRA. Therefore, the Director approves the proposed revisions to these plan provisions.

In addition, the Director is accepting the following supporting documents for inclusion to the Hopi Tribe AMLR plan:

Memorandum from Assistant General Counsel/Legislative Counsel to DNR dated May 18, 1995, concerning elimination of Title IV from the draft Hopi Code Mining Ordinance;

Hopi Tribal Council Resolution H-134-89, adopted August 29, 1989; and

Memorandum from the Hopi Tribe Office of Financial Management to DNR dated September 7, 1995, concerning purchasing procedures.

2. Substantive Revisions to the Hopi Tribe Plan Provisions That Are Substantially Identical to the Corresponding Provisions of the Federal Regulations and SMCRA

The Hopi Tribe proposed revisions to the following plan provisions that are substantive in nature and contain language that is substantively identical to the requirements of the corresponding Federal regulations and SMCRA provisions (listed in parentheses):

Preface to Amended Reclamation Plan, (section 411 of SMCRA and 30 CFR Part 875), program goals and objectives and eligible projects;

Section I, B, (30 CFR 884.13(a)), designation of administrative authority;

Section I, C, (section 403(a) of SMCRA), introductory paragraph for reclamation priorities;

Section I, C (4) and (5), (section 403(a) (4) and (5) of SMCRA), deletion of existing C (4) and recodification of C(5) and (6) and C(4) and (5);

Section I, C, (deleted section 402(g)(2) of SMCRA), deletion of provisions concerning allocation of funds;

Sections II, A(1) (a) through (f), (30 CFR 874.12 (a) through (h)), eligible coal lands and water;

Section II, A(1)(g), (30 CFR 874.16), contractor responsibility;

Sections II, B(1) (a) and (b), (30 CFR 875.14(a) (1) and (2)), eligible lands and water subsequent to certification;

Sections II, B(1)(c), (d)(i) and (iii), (e), and (g), (30 CFR 875.15(a), (b)(1) and (3), (c), and (e)), reclamation priorities for noncoal program;

Sections II, C through F, (30 CFR 875.16, 875.17, 875.19, and 875.20), exclusion of certain noncoal

reclamation sites, noncoal land acquisition authority, limited liability, and contractor responsibility;

Section II, H and [deletion of] ranking and selection of noncoal reclamation projects and Table I, Comprehensive/ Problem Evaluation Matrix, (30 CFR 884.13 (c) and (e)), description of needs, proposed construction and activities;

Section IV, A(2)(b), (30 CFR 879.11), lands eligible for acquisition;

Part XII, (30 CFR 884.13(f)(1)), economic conditions of the Hopi Reservation; and

Appendix 1, (there is no counterpart Federal regulation or SMCRA provision), Constitution and By-Laws of the Hopi Tribe, as amended.

Because these proposed revisions to the Hopi Tribe plan provisions are substantively identical to the corresponding provisions of the Federal regulations and SMCRA or concern proposed deletions of provisions deleted from Title IV of SMCRA, the Director finds that they meet the requirements of the Federal regulations and are consistent with SMCRA. The Director approves these proposed revisions to the Hopi Tribe plan provisions.

3. Preface to Amended Reclamation Plan

The Hopi Tribe proposed the addition of a preface to the Hopi Tribe plan, which provides, in part, a discussion in the introductory paragraph of the reasons for the amended reclamation plan. The preface discusses the Abandoned Mine Reclamation Act of 1990 (Pub. L. 101-508), but there is no mention of the Energy Policy Act of 1992. (Pub. L. 102-486, EPACT), which was enacted October 24, 1992. EPACT amended Title IV of SMCRA in several ways. The Hopi Tribe incorporated in the proposed revisions to the Hopi Tribe plan provisions addressing some of the amended Federal requirements. The Director finds that the preface is consistent with title IV of SMCRA and is in compliance with the implementing Federal regulations, but suggests that the introductory paragraph be revised to also reference the Energy Policy Act of 1992 and provide that the plan amendment has been prepared to be in conformance with it.

The introductory paragraph also provides that the amendment has been prepared to meet the requirements of 30 CFR Parts 870 (Abandoned Mine Reclamation Fund-Fee Collection and Coal Production Reporting), 872 (Abandoned Mine Reclamation Funds), 873 (Future Reclamation Set-Aside Program), 874 (General Reclamation Requirements), 875 (Noncoal Reclamation), 876 (Acid Mine Drainage Treatment and Abatement Program), and 886 (State and Tribal Reclamation Grants). However, the amendment contains no provisions concerning a future reclamation set-aside program or an acid mine drainage treatment and abatement program. The Director recommends that the references to the provisions concerning a future reclamation set-aside program and an acid mine drainage treatment and abatement program should be deleted.

4. Section I, A, Purpose of the Hopi Tribe AMLR Plan

a. *Section I, A.*—The Hopi Tribe proposed to revise Part I to provide a general description of funding priorities similar to those at sections 403 (a) and (b)(1) of SMCRA, which pertain only to coal, and to include reclamation activities pertaining to the adverse effects and impacts of mineral mining and processing practices [noncoal] similar to those provided at sections 411 (c) and (e) of SMCRA.

However, the Hopi Tribe did not retain the distinctions between coal and noncoal by setting out separate provisions for each. Title IV of SMCRA and the Federal regulations distinctly and separately provide requirements concerning coal reclamation at section 403 and 30 CFR Part 874 and noncoal reclamation at section 411 and 30 CFR Part 875. The Director finds that the Hopi Tribe's proposed replacement of the word "coal" with the phrase "mining and processing practices" at section I, A inappropriately combines coal and noncoal reclamation activities, and is, therefore, inconsistent with SMCRA and not in compliance with the Federal regulations. The Director is requiring, in order to properly reflect the objectives and priorities for expenditures of moneys from the abandoned mine land fund, the Hopi Tribe to revise Part I by creating separate provisions for coal and noncoal reclamation activities in order to be consistent with sections 403 and 411 of SMCRA and in compliance with the Federal regulations at 30 CFR Parts 874 and 875.

b. *Section I, A(1).*—Section I, A(1) provides, in part, that one purpose of the Hopi AMLR plan is to "protect the

health, safety, and general welfare of members of the Hopi Tribe * * *." The language contained in this section is similar to sections 403(a) (1) and (2) and 411(c) (1) and (2) of SMCRA, except that sections 403 and 411 distinguish between the "protection of public health, safety, general welfare, and property from extreme danger of adverse effects" of mining (emphasis added) and the "protection of public health, safety, and general welfare from adverse effects" of mining. Section I, A of the Hopi Tribe plan is a general description of the purpose the plan itself. As such, the Director finds that, even though section I, A(1) does not distinguish between the "extreme danger of adverse effects" and the "adverse effects" of mining and processing practices, the plan at sections I, C (1) and (2) and proposed II, B(1)(d) (i) and (ii) provide for coal and noncoal reclamation priorities, which specifically address the "extreme danger of the adverse effects" and the "adverse effects" consistent with sections 403(a) and 411(c) of SMCRA. Therefore, the Director approves the proposed language of section I, A(1).

c. *Section I, A(2).*—The proposed revisions at section I, A(2) provide that another purpose of the Hopi AMLR plan is to "restore land and water resources degraded by the adverse effects of mining and processing practices for both aesthetic and conservation reasons." This language is similar to sections 403(a)(3) and 411(c)(3) of SMCRA, except that sections 403 and 411 also provide for the restoration of the environment previously degraded by mining practices; and section 403(a)(3), which concerns coal reclamation only, includes restoration measures for conservation and development of soil, water (excluding channelization), woodland, fish and wildlife, recreation resources, and agricultural productivity. The specific priorities for coal and noncoal reclamation concerning restoration of land and water resources and the environment previously degraded by mining practices are provided for in the Hopi Tribe plan at section I, C(3) and proposed section II, B(1)(d)(iii). These provisions are substantively identical to sections 403(a)(3) and 411(c)(3) of SMCRA. Therefore, the Director finds that the general description concerning restoration of land and water resources provided in the purpose of the Hopi Tribe plan at section I, A(2) is consistent with sections 403 and 411 of SMCRA. The Director approves the revisions to this plan provision.

d. *Section I, A(3).*—The Hopi Tribe proposed to revise section I, A of the

Hopi Tribe plan by adding new language at paragraph (3) "to provide for protecting, repairing, replacing, constructing, or enhancing facilities related to water supply, including water distribution facilities and treatment plants, to replace water supplies adversely affected by mining and processing practices." The Director finds that proposed section I, A(3), which is similar to section 403(b)(1) of SMCRA, is inconsistent with SMCRA for two reasons. First of all, the Hopi Tribe is proposing to extend the provisions of section I, A(3) to noncoal reclamation activities by proposing to change the word "coal" to "mining and processing practices." The provisions of section 403 of SMCRA apply only to coal, and as proposed at I, A(3) in the Hopi Tribe plan, the water replacement provision includes all mining and processing practices, and is not limited to only coal mining practices. Secondly, section 403(b)(1) of SMCRA also only applies in those States or Indian tribes that have not certified to the completion of coal reclamation. The Hopi Tribe provided certification of completion of coal reclamation in a letter from the Chairman and Chief Executive Officer of the Hopi Tribe dated February 2, 1994 (59 FR 29719, June 9, 1994). The Director requires the Hopi Tribe to revise its AMLR plan by deleting section I, A(3) and recodifying the subsequent paragraphs accordingly.

e. *Section I, A(4).*—The Hopi Tribe proposed to add new language at section I, A(4) "to provide for the protection, repair, replacement, construction, or enhancement of public facilities such as utilities, roads, recreation, and conservation facilities adversely affected by mining and processing practices." This provision is similar to section 403(a)(4) of SMCRA, except that I, A(4) applies to "mining and processing practices" while section 403(a)(4) pertains only to public facilities adversely affected by coal mining practices (emphasis added). Also, subsequent to certification, reclamation projects involving the protection, repair, replacement, construction, or enhancement of utilities, such as those relating to water supply, roads, and other facilities that have been adversely affected by mining and processing practices, and the construction of public facilities in communities impacted by coal or other mineral mining and processing practices, are provided for at section 411(e) of SMCRA. Therefore, the Director finds that section I, A(4) is inconsistent with sections 403(a)(4) and 411(e) of SMCRA. The Director is requiring the Hopi Tribe to revise

section I, A(4) to reflect the objectives and priorities concerning public facilities set forth at section 411(e) of SMCRA.

5. Sections II, A(1), (f) and (h), Coal Reclamation After Certification

a. *Section II, A.*—Section II, A does not contain provisions concerning limited liability for coal reclamation activities similar to the Federal regulations at 30 CFR 874.15. This plan amendment does provide at proposed section II, E limited liability provisions, which are viewed by OSM, consistent with the Federal regulations at 30 CFR Parts 874 and 875, which provide separate and distinct provisions for coal and noncoal reclamation, including limited liability provisions, as only applying to noncoal reclamation activities. As provided in OSM's September 26, 1994, 30 CFR Part 884 issue letter (administrative record No. HO-145.1), the Hopi Tribe was given the option to adopt limited liability provisions for coal reclamation activities similar to the counterpart Federal regulations at 30 CFR 874.15. Because the Hopi Tribe was given the discretion to determine whether to include in its plan limited liability provisions for coal reclamation activities, the Director finds that section II, A is in compliance with 30 CFR Part 875 and approves section II, A without a specific limited liability provision for coal. The Director cautions the Hopi Tribe, however, that should any coal projects occur subsequent to the Hopi Tribe's certification of completion of coal reclamation, the Hopi Tribe AMLR program may be held liable under Federal law for any costs or damages as a result of any action or omitted action while carrying out its approved abandoned mine reclamation plan. The Hopi Tribe may wish to revise section II, A to extend its limited liability coverage to coal reclamation projects.

b. *Section II, A(1).*—Proposed section II, A(1) of the Hopi Tribe AMLR plan provides that February 2, 1994, is the effective date of the Hopi Tribe's certification that all known abandoned coal mine problems had been addressed. This date is actually the date that the Hopi Tribe submitted to OSM its certification of completion of coal reclamation with a request for concurrence by the Secretary of the Interior. OSM approved the Hopi Tribe's certification effective June 9, 1994 (see 59 FR 29721). The Director is not requiring the Hopi Tribe to revise section II, A(1) to reflect the correct effective date because between February 2, 1994, which is the date of the Hopi Tribe's submittal, and June 9, 1994,

which is the effective date of the certification, no new coal problems were identified as evidenced by the lack of public response to the proposed rule Federal Register notice seeking public participation in the certification process (see 59 FR 29720). Therefore, the Director is taking this opportunity to clarify that the effective date of the Hopi Tribe's certification of completion of coal reclamation is June 9, 1994.

Also, proposed section II, A(1) requires the Hopi Tribe to abate coal problems found after the effective date of certification of completion of coal reclamation in the first grant cycle following discovery of any coal problem subject to the availability of funds distributed to the Hopi Tribe in that cycle. The Director finds that this requirement is consistent with the requirements at 30 CFR 875.14(b) of the Federal regulations, except that § 875.14(b) also provides that "[t]he coal project would be subject to the coal provisions specified in sections 401 through 410 of SMCRA." This language ensures that should a coal problem occur, a State or Indian tribe that has certified to the completion of coal reclamation, would carry out subsequent coal reclamation activities under the State of Indian tribe authorities relating to coal and not pursuant to noncoal authority contained in section 411 of SMCRA. Therefore, the Director approves section II, A(1) to the extent that it requires the Hopi Tribe to abate any new coal problems that arise after the effective date of the certification of completion of coal reclamation and requires the Hopi Tribe to modify section II, A(1) to require that any coal project would be subject to the provisions of sections 401 through 410 of SMCRA or otherwise amend its AMLR plan to provide that new coal projects identified after the effective date of certification would be subject to the coal provisions of SMCRA.

c. *Section II, A(1)(h).*—The Hopi Tribe proposed at section II, A(1)(h) to require that Form OSM-76 be submitted to OSM upon coal project completion to report accomplishments achieved through the project. This provision is in compliance with the Federal regulations at 30 CFR 886.23 to the extent that the Hopi Tribe is required to submit Form OSM-76 to OSM upon project completion. However, 30 CFR 886.23 also requires the submission of other forms as specified by OSM, including reporting forms for each grant and any other closeout reports. The grant document awarding AML funds to a State or Indian tribe includes a condition requiring the grantee to submit financial status reports,

performance reports, and other such reports according to the timing, content, and format as required by OSM. Such documents are signed, not only by the OSM Field Office Director, but also by an officer of the grantee authorized to accept the award with all its conditions. Because the grant reporting requirements are attached to the grant document, the Hopi Tribe AMLR plan appropriately does not need to provide for reports concerning the grant itself. Therefore, the Director finds section II, A(1)(h) is in compliance with the Federal regulations at 30 CFR 886.23 and is not requiring the Hopi Tribe to add requirements at section II, A(1)(h) concerning reporting information on other forms specified by OSM. The Director approves section II, A(1)(h).

6. Sections II, B(1)(d)(ii), (f), and G, Noncoal Reclamation After Certification

a. *Section II, B(1)(d)(ii).*—The Hopi Tribe proposed to add language at section II, B(1)(d)(i) through (iii) to provide criteria for determining the priority of noncoal reclamation projects and construction of facilities. The proposed criteria are similar to the criteria provided in the Federal regulations at 30 CFR 875.15(b)(1) through (3), except that section II, B(1)(d)(ii) of the Hopi Tribe AMLR plan includes, as priority 2, the protection of property from the adverse effects of mineral mining and processing practices. 30 CFR 875.15(b)(2) provides, as priority 2, for the protection of public health, safety, and general welfare from the adverse effect of mineral mining and processing practices. The Director finds that section II, B(1)(d)(ii) of the Hopi Tribe AMLR plan, by including the protection of property from the adverse effects of noncoal mining as a second level priority, is not in compliance with the Federal regulations, which provide for the protection of property from the extreme danger of the adverse effects of noncoal mining as a level one priority. Therefore, the Director requires the Hopi Tribe to revise section II, B(1)(d)(ii) by deleting the word "property" or otherwise modify its plan to provide the same criteria as that at 30 CFR 875.15(b)(2) for priority 2 noncoal reclamation.

b. *Section II, B(1)(f).*—The Hopi Tribe proposed at section II, B(1)(f) to provide that where the Chairman of the Hopi Tribe determines there is a need for activities or construction of specific public facilities related to the coal or mineral industry on Tribal lands impacted by coal or mineral development, the Tribe may submit a grant application to OSM requesting funds to carry out such activities or

construction. This provision is in compliance with the Federal regulations at 30 CFR 875.15(d), which allow a State or Indian Tribe to request funding for a public facility if the Governor of a State or head of a governing body of an Indian tribe determines there is a need for the construction of a public facility related to the coal or minerals industry. 30 CFR 875.15(d) also requires that where a State or Tribe determines there is a need for activities or construction, the Director of OSM must concur in that need. As discussed in the preamble of the final rule Federal Register notice (see 59 FR 28136, 28162-3, May 31, 1994), OSM, concerned that the AML program not be sidetracked from its primary mission to reclaim lands and waters damaged by coal and noncoal mining processes, must determine whether a need exists for projects involving the construction of facilities pursuant to section 411(f) SMCRA. This determination is an action carried out solely by OSM, and the State or Tribe is not involved in the determination made by OSM. Therefore, the Hopi Tribe plan does not need to provide for this action. The Director approves section II, B(1)(f), and is taking this opportunity to reiterate that, prior to granting AML funds for public facility projects proposed under section 411(f) of SMCRA and the Federal regulations at 30 CFR 875.15(d), OSM's Director will concur with the Hopi Tribe Chairman's statement of need for such projects.

c. *Section II, G.*—The Hopi Tribe proposed at section II, G that Form OSM-76 be submitted to OSM upon noncoal project completion to report accomplishments achieved through the project. The Director finds that this provision is in compliance with the Federal regulations at 30 CFR 886.23(b). The Director also notes that the documents awarding grants require, as a condition of acceptance, certain information to be reported by the grantee, which complies with the reporting requirements of 30 CFR 886.23(a). Therefore, the Director approves proposed section II, G (see finding No. 5(c)).

7. *Sections IV, A(1), 2(a)(i), and B(1), Land Acquisition, Management, and Disposal*

a. *Section IV, A(1).*—The Hopi Tribe proposed to revise section IV, A(1) to provide, in part, that land adversely affected by coal and noncoal mining practices, including refuse piles and all coal refuse piles thereon, may be acquired by the Hopi Tribe for the purposes of the reclamation program when the acquisition of the lands meets

the requirements of section 407 of SMCRA (emphasis added). This provision is in compliance with the Federal regulations at 30 CFR 879.11(a) and (c), concerning lands eligible for acquisition. However, the Federal regulations at 30 CFR 875.17 extend the land acquisition authority to noncoal. At section IV, A(1), the Hopi Tribe proposed changing the phrase "coal mining practices" to the phrase "coal and noncoal mining practices" in one instance, but did not change "coal refuse" to a term that ensures that refuse on lands adversely affected by noncoal mining practices may also be acquired under this provision. The Director approves section IV, A(1), but requires the Hopi Tribe to revise it by deleting the word "coal" from the phrase "coal refuse thereon" to ensure that this provision extends to refuse on land adversely affected by past noncoal practices.

b. *Section IV, A(2)(a)(i).*—The Hopi Tribe proposed revisions at section IV, A(2)(a)(i) concerning appraisals to provide for a "valuation of the fair market value * * *" and "principle of best and highest use * * *." The provisions of section IV, A(2)(a)(i) are in compliance with the Federal regulations at 30 CFR 879.12 (a) and (d), except that the language proposed by the Hopi Tribe concerning fair market value and use is not the same language as that used in the recognized standards for acquisitions. 30 CFR 879.12(d) requires OSM or an Indian tribe which acquires land to comply with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (URA), 42 U.S.C. 4601, *et seq.*, and 41 CFR Part 114-50. URA applies to all Federal or federally-assisted activities that involve the acquisition of real property. The regulations implementing URA are at 49 CFR Part 24. 49 CFR 24.103 requires that a detailed appraisal shall reflect nationally recognized standards, including the Uniform Appraisal Standards for Federal Land Acquisition (see 54 FR 8912, 8934, March 2, 1989). The "Uniform Appraisal Standards for Federal Acquisitions" handbook, which by reference is the standard required by the Federal regulations at 30 CFR 879.12, provides for a "determination of the fair market value" and "the principle of highest and best use."

Even though the language proposed by the Hopi Tribe at section IV, A(2)(a)(i) does not use the standardized language for appraisals, the Director interprets the terms "valuation of fair market value" and "the principle of best and highest use" as having the same meaning as the recognized standards for a "determination of fair market value"

and the "principle of highest and best use." Therefore, the Director finds section IV, A(2)(a)(i) to be in compliance with the Federal regulations at 30 CFR 879.12 and approves the proposed revisions.

c. *Section IV, B(1).*—As proposed, section IV, B(1) provides that "[l]and acquired under rules of section A of this part Hopi AML Program and Tribal Council concurrence, for any lawful purpose that is not inconsistent with the reclamation activities and post-reclamation uses for which it was acquired." The proposed deletion of the phrase "may be used, pending" between the phrases "section A of this part" and "Hopi AML Program and Tribal Council concurrence" causes the sentence to become unclear. The counterpart Federal regulations at 30 CFR 879.14 provide the missing language as follows: "[l]and acquired under this part may be used for any lawful purpose." The Director finds that section IV, B(1) is in compliance with 30 CFR 879.14, and approves the proposed revisions concerning the references to "section A" and "this part." The Director, however, requires the Hopi Tribe to remove the deletion of the phrase "may be used, pending."

8. *Section VI, C, Rights of Entry for Emergency Reclamation*

The Hopi Tribe proposed to delete existing section VI, C concerning entry for emergency reclamation. The Federal regulation at 30 CFR 877.14(a) provides for entry by OSM, its agents, employees, or contractors upon land where an emergency exists and on any other land to have access to the land where the emergency exists to restore, reclaim, abate, control, or prevent the adverse effects of coal [and noncoal as provided by 30 CFR 875.17] mining practices and to do all things necessary to protect the public health, safety, or general welfare. The preamble of the final rule for 30 CFR Part 877 (see 47 FR 28574, 28583, June 30, 1982) states that final rule 30 CFR 877.14 concerning emergency reclamation activities applies exclusively to OSM, its agents, employees, and contractors. In the case of emergency reclamation on Hopi Indian lands, OSM is the authority because the Hopi Tribe did not request authority to conduct emergency response reclamation under the original plan approval (see 53 FR 24262, June 28, 1988) and has not subsequently sought emergency power through the amendment process. Because the emergency program on Hopi Indian lands rests exclusively with OSM, the Director finds the deletion of existing section VI, C of the Hopi Tribe plan to

be in compliance with the Federal regulations at 30 CFR Part 877. Therefore, the Director approves the deletion.

9. Section 884.13(f)(2), Description of Aesthetic, Cultural and Recreational Conditions of the Hopi Reservation

The Hopi Tribe proposed deletion of § 884.13(f)(2), which provided a description of aesthetic, cultural and recreational conditions of the Hopi Reservation. The counterpart Federal regulation at 30 CFR 884.13(f)(2) requires that the reclamation plan include a general description of the conditions prevailing in different geographic areas of the Indian lands where reclamation is planned, including significant esthetic, historic or cultural, and recreational values. The Hopi Tribe did not provide, in this amendment, a justification for the proposed deletion. Because 30 CFR 884.13(f) is a specific requirement for information that shall be included in a State or Tribe reclamation plan, the Director finds that the proposed deletion of § 884.13(f)(2) of the Hopi Tribe plan is not in compliance with the Federal regulation at 30 CFR 884.13(f)(2). The Director, therefore, requires the Hopi Tribe to remove its proposed deletion of § 884.13(f)(2) or otherwise provide the information required by 30 CFR 884.13(f)(2) in its reclamation plan.

IV. Summary and Disposition of Comments

Following are summaries of all substantive written comments on the proposed amendment that were received by OSM, and OSM's responses to them.

1. Public comments

OSM invited public comments on the proposed amendment, but none were received.

2. Federal agency comments

Pursuant to 30 CFR 884.15(a) and 884.14(a)(2), OSM solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Hopi Tribe plan (administrative record Nos. HO-149 and 152).

The State Historic Preservation Office for the State of Arizona responded on January 9, 1996, that the amendment had been reviewed and stated that the proposed changes did not pertain to cultural resource preservation (administrative record No. HO-151).

V. Director's Decision

Based on the above findings, the Director approves, with certain

exceptions and additional requirements, the Hopi Tribe's proposed plan amendment as submitted on November 2, 1995.

With the requirement that the Hopi Tribe further revise its plan provisions, the Director does not approve, as discussed in:

(1) finding No. 4(a), Part I, concerning the purpose of the Hopi Tribe plan; finding No. 4(d), section I, A(3), concerning facilities related to water supplies; and finding No. 4(e), section I, A(4), concerning public facilities projects;

(2) finding No. 6(a), section II, B(1)(d)(ii), concerning the priority 2 noncoal reclamation activities; and

(3) finding No. 9, § 884.13(f)(2), concerning proposed deletion of provisions related to a description of aesthetic, cultural and recreational conditions of the Hopi Reservation.

The Director approves, as discussed in:

(1) finding No. 1, the Table of Contents, concerning the title of Part II and List of Appendices; List of Addenda and Errata, concerning the title; List of Figures, concerning the title of Figure 4 and deletion of Figure 5; Chairman's Letter of Designation and Hopi Tribe Resolution, concerning the designation of the Tribal agency authorized to administer the approved plan; Opinion of Legal Counsel, concerning the authority of the designated agency to conduct the AMLR program in accordance with the requirements of Title IV of SMCRA; Part III, concerning coordination of Tribal AML programs with other programs; sections IV, A(2) (c), (d), (e), B(2), and C, concerning land acquisition, management, and disposal; Part V and Figures 1 and 2, concerning reclamation on private land; sections VI, A, B, and C, concerning rights of entry; Part VII, concerning the Hopi DNR policy on public participation; Part VIII and Figure 4, concerning organization of the Hopi Tribe; Part IX, concerning personnel staffing policies; Part X, concerning purchasing and procurement; Part XI, concerning management accounting; deletion of sections 884.13(e) (1), (2), and (3), concerning the purpose of Hopi Tribe reclamation plan and criteria for ranking and identifying projects; Part XIII, concerning flora and fauna; Appendices 1 through 12, concerning the addition of cover pages; Appendix 7, concerning the title of the appendix; a memorandum from the Assistant General Counsel/Legislative Counsel to DNR dated May 18, 1995, concerning the elimination of Title IV from the draft Hopi Code Mining Ordinance; Hopi Tribal Council Resolution H-134-89,

adopted August 29, 1989; and a memorandum from the Hopi Tribe Office of Financial Management to DNR dated September 7, 1995, concerning purchasing procedures;

(2) finding No. 2, preface to the amended reclamation plan, concerning program goals and objectives and eligible projects; section I, B, concerning the designation of administrative authority; section I, C, concerning reclamation priorities; sections I, C (4) and (5), concerning deletion of existing C(4) and recodification of C (5) and (6) as C (4) and (5); section I, C, concerning deletion of allocation of funds provisions; sections II, A(1) (a) through (f), concerning eligible coal lands and water; section II, A(1)(g), concerning contractor responsibility; sections II, B(1) (a) and (b), concerning eligible lands and water subsequent to certification; sections II, B(1)(c), (d) (i) and (iii), (e), and (g), concerning reclamation priorities for noncoal program; sections II, C through F, concerning exclusion of certain noncoal reclamation sites, noncoal land acquisition authority, limited liability, and contractor responsibility; section II, H, concerning description of needs, proposed construction and activities, and deletion of ranking and selection of noncoal reclamation projects and Table I, Comprehensive/Problem Evaluation Matrix; section IV, 2(b), concerning lands eligible for acquisition; Part XII, concerning economic conditions of the Hopi Reservation; and Appendix 1, concerning the amended constitution and by-laws of the Hopi Tribe;

(3) finding No. 3, preface to the amended reclamation plan, concerning the introductory paragraph;

(4) finding No. 4(b), section I, A(1), concerning the protection of the health, safety, and general welfare of members of the Hopi Tribe and finding No. 4(c), concerning the restoration of land and water resources;

(5) finding No. 5(a), section II, A, concerning limited liability provisions for coal reclamation activities and finding No. 5(c), section II, A(1)(h), concerning reports;

(6) finding No. 6(b), section II, B(1)(f), concerning the need for activities or construction of specific public facilities related to the coal or mineral industry on Tribal lands impacted by coal or mineral development and finding No. 6(c), section II, G, concerning reports;

(7) finding No. 7(b), section IV, A(2)(a)(i) concerning appraisals; and

(8) finding No. 8, section VI, C, concerning entry for emergency reclamation.

With the requirement that the Hopi Tribe further revise its plan provisions, the Director approves, as discussed in:

(1) finding No. 5(b), section II, A(1), concerning the abatement of any new coal problems that arise after the effective date of the certification of completion of coal reclamation;

(2) finding No. 7(a), section IV, A(1), concerning the acquisition of lands by the Hopi Tribe; and

(3) finding No. 7(c), section IV, B(1), concerning management of acquired lands.

The Director approves the plan provisions as proposed by the Hopi Tribe with the provision that they be fully promulgated in identical form to the plan provisions submitted to and reviewed by OSM and the public.

The Federal regulations at 30 CFR Part 756.17, codifying decisions concerning the Hopi Tribe plan, are being amended to implement this decision. This final rule is being made effective immediately to expedite the Tribe plan amendment process and to encourage Tribes to bring their plans into conformity with the Federal standards without undue delay. Consistency of Tribe and Federal standards is required by SMCRA

VI. Procedural Determinations

1. 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).

2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that 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 Tribe or State AMLR plans and revisions thereof since each such plan is drafted and promulgated by a specific Tribe or State, not by OSM. Decisions on proposed Tribe or State AMLR plans and revisions thereof submitted by a Tribe or State are based on a determination of whether the submittal meets the requirements of title IV of SMCRA (30 U.S.C. 1231-1243) and the applicable Federal regulations at 30 CFR Parts 884 and 888.

3. National Environmental Policy Act

No environmental impact statement is required for this rule since agency decisions on proposed Tribe or State AMLR plans and revisions thereof are categorically excluded from compliance

with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

4. 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.*).

5. 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 Tribe or State submittal which is the subject of this rule is based upon 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 established by SMCRA or previously promulgated by OSM will be implemented by the Tribe or State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 756

Abandoned mine reclamation programs, Indian lands, Surface mining, Underground mining.

Dated: April 16, 1996.

Russell F. Price,

Acting Regional Director, Western Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter E of the Code of Federal Regulations is amended as set forth below:

PART 756—“INDIAN TRIBE ABANDONED MINE LAND RECLAMATION PROGRAMS”

1. The authority citation for Part 756 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.* and Pub. L. 100-71.

2. Section 756.17 is revised to read as follows:

§ 756.17 Approval of the Hopi Tribe's Abandoned Mine Land Reclamation Plan Amendments.

The following amendments to the Hopi Tribe's abandoned mine land reclamation plan are approved.

(a) The Hopi Tribe certification of completion of coal reclamation, as submitted on February 2, 1994, is approved effective June 9, 1994.

(b) With the exceptions of Part I, concerning the purpose of the Hopi tribe plan; section I, A(3) concerning facilities related to water supplies; section I, A(4), concerning public facilities projects; section II, B(1)(d)(ii), concerning the protection of property; and section 884.13(f)(2), concerning a description of aesthetic, cultural and recreational conditions of the Hopi Reservation, revisions to and additions of the following plan provisions, as submitted to OSM on November 2, 1995, are approved effective April 23, 1996.

Table of Contents—Title of Part II and List of Appendices;

List of Addenda and Errata—Title for this part;

List of Figures—Title of Figure 4 and deletion of Figure 5;

Preface to Amended Reclamation Plan—Introductory paragraph, program goals and objectives, and eligible projects;

Chairman's Letter of Designation and Hopi Tribe Resolution—Designation of Tribal agency authorized to administer approved plan;

Opinion of Legal Counsel—Authority of designated agency to conduct the AMLR program in accordance with the requirements of Title IV of SMCRA;

Section I, A(1)—Protection of the health, safety, and general welfare of members of the Hopi Tribe;

Section I, A(2)—Restoration of land and water resources;

Section I, B—Designation of administrative authority;

Section I, C—Reclamation priorities;

Sections I, C (4) and (5)—Deletion of existing C(4) and recodification of C(5) and (6) as C(4) and (5);

Section I, C—Deletion of allocation of funds provisions;

Section II, A—[Lack of] Limited liability provision for coal;

Section II, A(1)—Abatement of any new coal problems that arise after the effective date of the certification of completion of coal reclamation;

Sections II, A(1) (a) through (f)—Eligible coal lands and water;

Section II, (A)(1)(g)—Contractor responsibility;

Section II, A(1)(h)—Reports;

Sections II, B(1) (a) and (b)—Eligible lands and water subsequent to certification;

Sections II, B(1)(c), (d) (i) and (iii), (e), and (g)—Reclamation priorities for noncoal program;

Section II, B(1)(f)—Need for activities or construction of specific public facilities related to the coal or mineral industry on Tribal lands impacted by coal or mineral development;

Section II, G—Reports;

Sections II, C through F—Exclusion of certain noncoal reclamation sites, noncoal land acquisition authority, limited liability, and contractor responsibility;

Section II, H and [deletion of] ranking and selection of noncoal reclamation projects and Table I, Comprehensive/Problem Evaluation Matrix—Description of needs, proposed construction and activities;

Part III—Coordination of Tribal AML programs with other programs;

Section IV, A(1)—Acquisition of lands by the Hopi Tribe;

Section IV, A(2)(a)(i)—Appraisals;

Section IV, A(2)(b)—Lands eligible for acquisition;

Sections IV, A(2)(c), (d), (e), B(2), and C—Land acquisition, management, and disposal;

Section IV, B(1)—Management of acquired lands;

Part V and Figures 1 and 2—Reclamation on private land;

Section VI, A, B, and C—Rights of entry;

Deletion of section VI, C—Entry for emergency reclamation;

Part VII—Hopi Department of Natural Resources (DNR) policy on public participation;

Part VIII and Figure 4—Organization of the Hopi Tribe;

Part IX—Personnel staffing policies;

Part X—Purchasing and procurement;

Part XI—Management accounting;

[Deletion of] sections 884.13(e) (1), (2), and (3)—Purpose of Hopi Tribe plan and criteria for ranking and identifying projects;

Part XII—Economic conditions of the Hopi Reservation;

Part XIII—Flora and fauna;

Appendices 1 through 12—Addition of cover pages;

Appendix 1—Constitution and By-Laws of the Hopi Tribe, as amended;

Appendix 7—Title of the appendix;

Memorandum from the Assistant General Counsel/Legislation Counsel to DNR dated May 18, 1995—Elimination of Title IV from the draft Hopi Code Mining Ordinance;

Hopi Tribal Council Resolution H-134-89, adopted August 29, 1989; and

Memorandum from the Hopi Tribe Office of Financial Management to DNR dated September 7, 1995—Purchasing procedures.

3. Section 756.18 is amended by adding paragraphs (a) through (h) to read as follows:

§ 756.18 Required amendments to the Hopi Tribe's Abandoned Mine Land Reclamation Plan.

* * * * *

(a) By June 24, 1996, the Hopi Tribe shall revise the introductory paragraph at Part I, or otherwise revise the purpose of the Hopi Tribe plan, to provide separate and distinct provisions for coal and noncoal reclamation activities to be consistent with sections 403 and 411 of SMCRA and in compliance with the Federal regulations at 30 CFR Parts 874 and 875 in order to properly reflect the objectives and priorities for expenditures of monies from the abandoned mine land fund.

(b) By June 24, 1996, the Hopi Tribe shall delete section I, A(3) and recodify any subsequent paragraphs accordingly, or otherwise revise the Hopi Tribe plan,

to provide appropriate provisions subsequent to the certification of completion of coal reclamation.

(c) By June 24, 1996, the Hopi Tribe shall revise Section I, A(4), or otherwise revise the Hopi Tribe plan, to require the same objectives and priorities concerning public facilities as set forth at section 411(e) of SMCRA.

(d) By June 24, 1996, the Hopi Tribe shall revise Section II, A(1), or otherwise revise the Hopi Tribe plan, to require that any coal reclamation activities subsequent to certification of completion of coal reclamation are subject to the provisions of sections 401 through 410 of SMCRA.

(e) By June 24, 1996, the Hopi Tribe shall revise Section II, B(1)(d)(ii) by deleting the word "property" for priority 2 noncoal reclamation, or otherwise revise the Hopi Tribe plan to provide for the protection of public health, safety, and general welfare from the adverse effects of mineral mining and processing practices.

(f) By June 24, 1996, the Hopi Tribe shall revise Section IV, A(1) by deleting the word "coal" from the phrase "coal refuse thereon," or otherwise revise the Hopi Tribe plan to ensure that lands eligible for acquisition include those on which refuse from both coal and noncoal mining practices are located.

(g) By June 24, 1996, the Hopi Tribe shall revise Section IV, B(1) by reinstating the phrase "may be used, pending."

(h) By June 24, 1996, the Hopi Tribe shall revise the Hopi Tribe plan by reinstating Section 884.13(f)(2), or otherwise modify its plan to include information concerning significant esthetic, historic or cultural, and recreational values.

[FR Doc. 96-9938 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 861

Department of Defense Commercial Air Carrier Quality and Safety Review Program

AGENCY: Department of the Air Force, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Air Force revises its regulation on DoD quality and safety criteria for air carriers providing or seeking to provide airlift services to the DoD. The revision clarifies air carrier prerequisites before

an air carrier can solicit DoD business and be used by DoD agencies. Specifically, the change clarifies that cargo carriers must have previously performed cargo business in the 12 continuous months immediately prior to applying for DoD business. The revision also changes the Commercial Airlift Review Board (CARB) membership from six voting members to four.

This revision serves to notify the aviation industry of the above changes. The changes are necessary for the DoD Commercial Airlift Review Board to effectively and legally carry out its aviation safety responsibilities as specified in the National Defense Authorizations Act for fiscal year 1987.

EFFECTIVE DATE: April 23, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Dennis D. Emmons, Chief, DoD Air Carrier Survey and Analysis Division, Directorate of Operations, Headquarters Air Mobility Command (HQ AMC/DOB), Scott AFB IL 62225-5302, telephone (618) 256-4801/4806.

SUPPLEMENTARY INFORMATION: This part is published as a final rule because it implements Public Law 99-661 (FY87 National Defense Authorization Act, § 1204, Requirements Concerning Transportation of Members of the Armed Forces by Chartered Aircraft) and DoD Directive 4500.53 (Commercial Passenger Airlift Management and Quality Control). Additionally, and as part of the final rule determination, this part is related to public contracts and to provisions for agency management.

The Department of the Air Force has determined that this regulation is not a major rule as defined by Executive Order 12866, is not subject to the relevant provisions of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601-661), does not contain reporting or recordkeeping requirements under the criteria of the Paperwork Reduction Act of 1980 (44 U.S.C. 35), and poses no negative environmental impact as defined in the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq).

List of Subjects in 32 CFR Part 861

Air carriers, Aviation safety.

Therefore, 32 CFR Part 861 is amended as follows:

PART 861—DEPARTMENT OF DEFENSE COMMERCIAL AIR CARRIER QUALITY AND SAFETY REVIEW PROGRAM

1. The authority citation for Part 861 continues to read as follows:

Authority: 10 U.S.C. 8013; 10 U.S.C. 2640.

2. Section 861.3 is amended by revising paragraph (d)(1) to read as follows:

§ 861.3 DOD commercial air carrier quality and safety requirements.

* * * * *

(d) * * *

(1) Quality and Safety Requirements—prior experience. Commercial air carriers or operators applying to conduct passenger or cargo business for the United States Department of Defense are required to possess 12 months of continuous service equivalent to the service sought by DoD. The service must have been performed for the 12 continuous months immediately prior to applying for DoD business. Prior experience must be equivalent in difficulty and complexity in regard to distance, weather systems, international or national procedures, similar aircraft, schedule demands, aircrew experience, and management required.

* * * * *

3. Section 861.4 is amended by revising paragraph (g)(1) and (2) to read as follows:

§ 861.4 DOD Commercial Airlift Review Board procedures.

* * * * *

(g) * * *

(1) Four voting members will constitute the CARB; two senior, knowledgeable individuals appointed by Commander, AMC; one similarly knowledgeable individual appointed by USCINTRANS; and one appointed by Commander, MTMC. At least one of the voting HQ AMC members and the MTMC member will be of general/flag officer or civilian equivalent rank. Other non-voting CARB members will be appointed as necessary to facilitate the CARB deliberative process. A non-voting recorder will also be appointed.

(2) The HQ AMC senior member will act as the CARB chairperson. A voting member who will not be present at any meeting of the CARB, may be represented by a knowledgeable alternate empowered with the voting responsibilities of the voting member. Three voting members (or their alternate) shall constitute a quorum. Decisions shall be by majority vote. In the case of a tie vote, the chairperson will have the deciding vote.

* * * * *

Patsy J. Conner,
Air Force Federal Register Liaison Officer.
[FR Doc. 96-9928 Filed 4-22-96; 8:45 am]
BILLING CODE 3910-01-W

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-96-028]

RIN 2115-AE46

Special Local Regulations: River Race Augusta; Augusta, GA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary Special Local Regulations for the River Race Augusta. This event will be held from 7 a.m. to 5 p.m. est (eastern standard time) on May 17, 18, and 19, 1996. There will be approximately seventy-five participants racing 16 to 18 foot outboard power boats on that portion of the Savannah River at Augusta, Georgia, between U.S. Highway 1 (Fifth St) Bridge at mile marker 199.45 and Eliot's Fish Camp at mile marker 197. The boats will be competing at high speeds and at close range on a prescribed course. The nature of the event and the closure of the Savannah River creates an extra or unusual hazard in the navigable waters. These temporary regulations are necessary to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATES: This rule is effective from 7 a.m. to 5 p.m. eastern standard time on May 17, 18, and 19, 1996.

FOR FURTHER INFORMATION CONTACT: ENS M.J. DaPonte, Coast Guard Group Charleston at (803) 724-7621.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for these regulations and good cause exists for making them effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impractical. The information to hold the event was not received until April 4, 1996, and there was not sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Discussion of Regulations

The temporary regulations are needed to provide for the safety of life during River Race Augusta. These regulations are intended to promote safe navigation on the waters off Augusta on the Savannah River during the races by controlling the traffic entering, exiting, and traveling within these waters. The anticipated concentration of spectator and participant vessels associated with

the River Race poses a safety concern, which is addressed in these special local regulations. The temporary regulations will not permit the entry or movement of spectator vessels and other nonparticipating vessel traffic between the U.S. Highway Route 1 (Fifth Street) Bridge at mile marker 199.45 and Eliot's Fish Camp at mile marker 197 from 7 a.m. to 5 p.m. est, on May 17, 18 and 19, 1996. The temporary regulations will permit the movement of spectator vessels and other non-participants after the termination of race each day, and during intervals between scheduled events at the discretion of the Coast Guard Patrol Commander.

Regulatory Evaluation

This rulemaking is not a significant regulatory action under Section 3(f) of the Executive Order 12866 and does not require an assessment of the potential costs and benefits under Section 6(a)(3) of that Order. It has been exempted from review by the Office of Management and Budget 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 proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. These temporary regulations will last for only 10 hours each day of the event.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this action will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under Section 3 of the Small Business Act (15 U.S.C. 632).

For reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this action will not have a significant economic impact on a substantial number of small entities.

Collection of Information

These temporary regulations contain no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that

the rulemaking does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action consistent with section 2.B.2. of Commandant Instruction M16475.1B. In accordance with that section, this action has been environmentally assessed (EA completed), and the Coast Guard has concluded that it will not significantly affect the quality of the human environment. An environmental assessment and a finding of no significant impact have been prepared and are available in the docket for inspection or copying.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Final Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary § 100.35–T96–028 is added to read as follows:

§ 100.35–T96–028 River Race Augusta; Savannah River, Augusta GA.

(a) Definitions:

(1) *Regulated Area.* The regulated area is formed by a line drawn directly across the Savannah River at the U.S. Highway 1 (Fifth Street) Bridge at mile marker 199.45 and directly across the Savannah River at Eliot's Fish Camp at mile marker 197. The regulated area encompasses the width of the Savannah River between these two lines.

(2) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Group Charleston, South Carolina.

(b) Special Local Regulations.

(1) Entry into the regulated area is prohibited to all non participants.

(2) After termination of the River Race Augusta each day, and during intervals between scheduled events, at the discretion of the Coast Guard Patrol Commander, all vessels may resume normal operations.

(c) *Effective Dates:* This section is effective at 7 a.m. and terminates at 5 p.m. EST on May 17, 18 and 19, 1996, unless otherwise specified in the

Seventh Coast Guard District Local Notice to Mariners.

Dated: April 10, 1996.

P.J. Cardaci,

Captain U.S. Coast Guard, Commander, Seventh Coast Guard District, Acting.

[FR Doc. 96–9880 Filed 4–22–96; 8:45 am]

BILLING CODE 4910–14–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1275

RIN 3095–AA59

Preservation and Protection of and Access to the Presidential Historical Materials of the Nixon Administration; Amendment of Public Access Regulations

AGENCY: National Archives and Records Administration.

ACTION: Final rule and interim final rule.

SUMMARY: This rule revises the procedures to be followed by the National Archives and Records Administration (“NARA”) for preserving and protecting the Presidential historical materials of the Nixon Administration, for providing public access to these materials, and for providing for the reproduction of the Nixon White House tape recordings, based on a Settlement Agreement reached through mediation among Public Citizen and Stanley I. Kutler, the National Archives and Records Administration, and William E. Griffin and John H. Taylor, co-executors of the Estate of Richard M. Nixon, parties to *Stanley I. Kutler and Public Citizen v. John W. Carlin, Archivist of the United States, and William E. Griffin and John H. Taylor, Co-executors of Richard M. Nixon's Estate*, Civ. A. No. 92–0662–NHJ (D.D.C.) (Johnson, J.). Furthermore, the final rule clarifies various terms that appear in 36 CFR Part 1275. This final rule and interim final rule will affect the heirs of former President Nixon and other individuals whose names appear in the materials, as well as members of the general public interested in conducting research regarding those materials.

DATES: The effective date for this final rule and interim final rule is May 23, 1996.

Comments on the amendments to §§ 1275.42, 1275.48, and 1275.64 must be received by close of business June 24, 1996. NARA will issue a final rule confirming or further amending these amendments after this comment period closes.

ADDRESSES: All comments must be submitted in writing to the Regulation Comment Desk, Policy and Planning Division (PIRM-POL), Room 3200, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Nancy Allard at (301) 713–6730.

SUPPLEMENTARY INFORMATION: Professor Stanley Kutler and Public Citizen commenced an action against the Archivist of the United States on March 19, 1992, by filing a complaint under the Administrative Procedure Act, 5 U.S.C. 701, *et seq.* The complaint alleged that the Archivist had failed to carry out his obligations under the Presidential Recordings and Materials Preservation Act of 1974 (“PRMPA”), 44 U.S.C. 2111 note, concerning the release of approximately 3,700 hours of tape recordings made during the Presidency of Richard M. Nixon. Thereafter, former President Nixon intervened and filed cross-claims; after his death in 1994, his co-executors were substituted in his place.

During the course of the litigation, which entailed substantial discovery and motions, the principal disputes revolved around the issue of how to reconcile the disclosure requirements of the PRMPA and the privacy interests of Mr. Nixon and his family, as well as the other interests legally protected by the PRMPA. A major portion of the controversy centered on the issue of the timing of releases of the tapes (all at once or in segments), and whether the releases could be made before some or all of the tape segments found to be private or personal were returned to Mr. Nixon or his estate as required by law.

Following the release of approximately 60 hours of tape recordings subpoenaed by the Watergate Special Prosecution Force (“WSPF”) during its investigation, NARA had decided that the best way to proceed with the release of the body of the approximately 3,700 hours of Nixon White House tape recordings was to release Watergate-related segments of the tape recordings in small monthly groupings on an ongoing basis. The first of these releases was noticed in the Federal Register on April 2, 1993, 58 FR 17433, and took place on May 17, 1993, without any objections from affected parties.

The second and third releases were noticed in the Federal Register on June 3, 1993, and July 2, 1993, to take place on July 15, 1993 (later extended to August 13, 1993), and August 26, 1993, respectively. 58 FR 31548 (June 3, 1993); 58 FR 35983 (July 2, 1993).

Former President Nixon raised certain objections to these proposed releases. When NARA rejected former President Nixon's contention that those releases should not go forward, he sought relief in the district court. On August 9, 1993, Judge Royce Lamberth of the United States District Court for the District of Columbia issued an order in the *Kutler* case preliminarily enjoining NARA from carrying out the releases of Watergate-related tape segments scheduled for release on August 13 and 26, 1993, pending (1) segregation and return to former President Nixon of all private or personal conversations on the tape recordings; and (2) processing of the tape recordings as a single "integral file segment" before release to the public.

On March 25, 1994, the proposed amendments to the current PRMPA regulations were published for public comment at 59 FR 14128. At that time, NARA believed that the proposed amendments were required to clarify various terms that appear in 36 CFR Part 1275; clarify the nature of the archival processing being conducted on the Nixon Presidential historical materials; and provide for the reproduction of the available Nixon White House tape recordings.

During the comment period, originally 60 days but extended by an additional 30 days, 59 FR 27257 (May 26, 1994), NARA received comments from eight individuals and organizations in response to these proposed regulations. The comments consisted of both objections to and support for the proposed amendments, although many of the comments were generally supportive of the proposed regulatory changes. The Nixon estate submitted extensive comments objecting to the proposed amendments.

The *Kutler* case was referred to a court-appointed mediator, and most of the issues were resolved by the parties in a Settlement Agreement, which is attached hereto as Appendix A to 36 CFR Part 1275. As a result of the mediation, NARA is amending certain of its regulations as set forth below. Other comments have been incorporated into this final and interim final rule. Although NARA does not take a position as to whether it is necessary to resubmit the proposed changes to the regulations as a result of the Settlement Agreement, NARA nevertheless is publishing as an interim final rule for a 60-day comment period those sections of Part 1275 which have been revised in accordance with the provisions of the Settlement Agreement reached among the parties. Those sections of the proposed rule published on March 25, 1994, that have not been further revised

due to the Settlement Agreement are issued as a final rule. No additional comments will be considered on these sections, which include 36 CFR 1275.16(e) and (g), 1275.20, 1275.46, 1275.56, 1275.66 and 1275.70. NARA had previously proposed to amend § 1275.16(b), but now has decided that an amendment to this section is not necessary. NARA is amending the current regulations in accordance with the terms of the Settlement Agreement.

Interim Final Rule Provisions (Sections Affected by the Settlement Agreement)

The following amended sections of 36 CFR Part 1275 are being issued as an interim final rule to allow public comment.

NARA had previously proposed to amend § 1275.42(a) to clarify the manner in which NARA intends to proceed with the archival processing and release of the tape recordings and all other textual Nixon Presidential historical materials. To address these concerns, the proposed amendments to § 1275.42(a) would have allowed the release of the tape recordings in groupings that would not necessarily have constituted "integral file segments," but which would have permitted the opening of portions of the tape recordings without the need for the approximately 3,700 hours to be released at once. The current regulations provide that Nixon White House materials will be disclosed to the public in "integral file segments."

As a result of the Settlement Agreement in the *Kutler* case, NARA is now amending § 1275.42(a) to describe specifically the schedule for the opening of the approximately 3,700 hours of tape recordings, as well as the procedures for allowing interested and affected parties—including the Nixon estate—the opportunity to review (and object as appropriate to) a particular segment of tape recordings being proposed for opening. The Settlement Agreement also takes into account the fact that due to the extensive nature of the tape recordings collection, it would be impossible for the Nixon estate to review all portions of the tape recordings proposed for opening within the allotted 30-day period. As a result, the current revised amendments to § 1275.42(a) incorporate a procedure whereby the Nixon estate will be given sufficient lead time to review each segment of tape recordings NARA proposes for opening.

In addition, the previously proposed amendments to § 1275.42(a) provided that the Archivist was free to release segments of the tape recordings prior to transferring private or personal material

in accordance with current § 1275.48, thereby allowing NARA to continue processing and opening Watergate-related segments of the tape recordings at the earliest reasonable date, in accordance with its statutory and regulatory responsibility. Based on the Settlement Agreement in the *Kutler* case, however, NARA is now amending § 1275.42(a)(2) to allow for identification of additional private or personal materials located during the review of the tape recordings and return to the Nixon estate at approximately the time that NARA proposes each segment for public release.

In accordance with the Settlement Agreement in the *Kutler* case, NARA is amending § 1275.44 by adding a new subsection (e) which sets forth the precise procedures for the Nixon estate to raise any objections to those tape recordings that NARA has designated as relating to abuses of governmental power, as well as the standard to be applied by the specially appointed review panel in reviewing those objections. For those segments designated abuses of governmental power, the Nixon estate has agreed to accept the review panel's decisions as binding, thereby foregoing its right to appeal decisions regarding its objections in the normal course pursuant to § 1275.46. In addition, although the Nixon estate has not waived its appeal rights available for any objections with respect to the remaining tape segments, subsection (e) provides that the Nixon estate may, at any time, elect to use the procedures used for raising objections to the abuses of governmental power tape segments. Subsection (e) also specifies the standard that will be applied by the specially appointed review panel in reviewing the objections to the remaining tape recordings should the Nixon estate elect to use the alternative procedure.

NARA is amending § 1275.48(a) to make clear that no portion of the original tape recordings or master preservation copy is to be returned to the heirs of former President Nixon. NARA's position is that it is complying with the PRMPA by retaining the entire original tape recordings and a master preservation copy containing these materials. This is one of the issues in the *Kutler* case and the parties to the Settlement Agreement have agreed to resolve this issue, including the validity of this particular section and of § 1275.64(e), in the courts. NARA is also amending this section to make clear that it restricts access to all private or personal material on the original tape

recordings and master preservation copy that NARA maintains.

NARA had previously proposed to amend § 1275.64 to include a provision allowing for the reproduction of tape recordings opened to the public. The issue of whether to provide copies of tape recordings has been considered by NARA on several occasions. At the time the current regulations were written, NARA decided to maintain its prior position of not allowing copies of tape recordings, although it specifically stated that this position would be reviewed periodically. 51 FR 7228 (Feb. 28, 1986). In accordance with the Settlement Agreement in the *Kutler* case, § 1275.64 is being amended to state that copies of the tapes will be made available following the public release of the last of the tape segments contemplated in § 1275.42(a). However, if the last tape segment is not released by December 31, 1999, NARA will allow members of the public to obtain copies only of the abuses of governmental power tapes, together with any other tapes publicly released as of the effective date of the Settlement Agreement, beginning January 1, 2000. If the releases contemplated in § 1275.42(a) are not completed by December 31, 2002, NARA will, beginning January 1, 2003, allow members of the public to obtain copies of all tapes that have been made available to the public by that date and tapes that subsequently become available, as they are released. NARA is also adding § 1275.64(e) to make clear that the Archivist will produce and maintain a master preservation copy of the original tape recordings for preservation purposes.

Final Rule Provisions

The following amendments to 36 CFR Part 1275 are being adopted as a final rule. No comments will be accepted on these provisions.

Section 1275.16(e) clarifies the nomenclature used throughout the regulations and distinguishes between "Archivist," defined as the Archivist of the United States or his or her designated agent, and "archivist," as defined in the current subsection, *i.e.*, as an employee of NARA, who, by education or experience, is specially trained in archival science.

Section 1275.16(g) clarifies the definition of "archival processing" to ensure that nothing in the subsection creates any obligation on the part of the Archivist to perform any one particular archival processing task listed in the subsection. In so doing, NARA intends to make clear that transcripts of the tape recordings need not be made. Although

the current regulations indicate that the processing of the Nixon White House materials may undergo one or more of several archival processing phases, including the preparation of transcripts, NARA does not believe that the regulations intended to obligate the processing archivists to transcribe all of the approximately 3,700 hours of tape recordings before releasing them to the public. NARA does not believe this is an obligation because the tapes are the original record. NARA has created tape logs to serve as a subject guide to the tape recordings. NARA chose to create tape logs instead of transcriptions because NARA has estimated that it would take at least 400,000 hours of staff time to accomplish such transcriptions. In addition, because of the sound quality of the tape recordings, NARA could not guarantee the accuracy of the transcriptions. Furthermore, the definition of "archival processing" in § 1275.16(g) has been expanded to reflect the archival processing of the Nixon Presidential historical materials that actually has been taking place.

Section 1275.20 is amended to be consistent with the amended definition of "Archivist" set forth in amended § 1275.16(e).

Sections 1275.46(d) and 1275.46(f) are amended to be consistent with the amended definition of "Archivist" set forth in amended § 1275.16(e).

Section 1275.64(b) is also amended to be consistent with the nomenclature distinction between "Archivist" and "archivist" as set forth in § 1275.16(e).

Section 1275.66(a) is amended to accommodate two different possibilities with respect to the reproduction of released Nixon materials other than tape recordings: copying by researchers on self-service government copiers; and copying by contract vendors at the request of NARA. This change reflects not only current practice at the Nixon Presidential Materials Staff, but common practice at other Presidential libraries within the NARA system as well as NARA regulations regarding copying of archival documents.

Sections 1275.70(a) and 1275.70(b) are amended to be consistent with the nomenclature distinction between "Archivist" and "archivist" as set forth in § 1275.16(e).

Typographical corrections are made to § 1275.46(i) and § 1275.56.

Other

NARA has issued these regulations as an interim final rule under the good cause exception to the Administrative Procedures Act. NARA believes that the proper execution of the agency's function—in this case, the release of the

Nixon Presidential historical materials at the earliest reasonable date—requires prompt implementation of the amendments to Part 1275, including the provisions that have been modified by the Settlement Agreement. Therefore, NARA finds it in the public interest to issue these regulations as an interim final rule.

The amendments to 36 CFR Part 1275 are not a significant regulatory action for purposes of Executive Order 12866 of September 30, 1993. As required by the Regulatory Flexibility Act, it is hereby certified that these regulatory amendments will not have a significant impact on small business entities. For purposes of Title II, Subtitle E of Public Law 104–121, this rule is not a major rule as defined in section 804 of the act.

List of Subjects in 36 CFR Part 1275

Archives and Records

For the reasons set forth in the preamble above, Part 1275 of Title 36 of the Code of Federal Regulations is amended as follows:

PART 1275—PRESERVATION AND PROTECTION OF AND ACCESS TO THE PRESIDENTIAL HISTORICAL MATERIALS OF THE NIXON ADMINISTRATION

1. The authority citation for part 1275 continues to read as follows:

Authority: Sec. 102(a) of the National Archives and Records Administration Act of 1984, Pub. L. 98–497; 44 U.S.C. 2104; and sections 103 and 104 of the Presidential Recordings and Materials Preservation Act, 88 Stat. 1695; 44 U.S.C. 2111 note.

2. Section 1275.16 is amended by revising paragraphs (e) and (g) to read as follows:

§ 1275.16 Definitions.

* * * * *

(e) *Archivist*. The term "Archivist" shall mean the Archivist of the United States or his designated agent. The term "archivist" shall mean an employee of the National Archives and Records Administration who, by education or experience, is specially trained in archival science.

* * * * *

(g) *Archival processing*. The term "archival processing" may include the following general acts performed by archivists with respect to the Presidential historical materials: Shelving boxes of documents in chronological, alphabetical, numerical or other sequence; surveying and developing a location register and cross-index of the boxes; arranging materials; refoldering and reboxing the documents and affixing labels; producing finding

aids such as folder title lists, scope and content notes, biographical data, and series descriptions; rewinding, duplicating and preserving the original tape recordings; enhancing the tape recordings on which the conversations are wholly or partially unintelligible so that extraneous noises may be filtered out; producing general subject matter logs of the tape recordings; reproducing and transcribing tape recordings; reviewing the materials to identify items that appear subject to restriction; identifying items in poor physical condition and assuring their preservation; identifying materials requiring further processing; and preparation for public access of all materials which are not subject to restriction.

* * * * *

3. Section 1275.20 is revised to read as follows:

§ 1275.20 Responsibility.

The Archivist is responsible for the preservation and protection of the Nixon Presidential historical materials.

4. Section 1275.42 is amended by revising paragraph (a) to read as follows:

§ 1275.42 Processing period; notice of proposed opening.

(a) (1) The archivists will conduct archival processing of those materials other than tape recordings to prepare them for public access. In processing the materials, the archivists will give priority to segregating private or personal materials and transferring them to their proprietary or commemorative owner in accordance with § 1275.48. In conducting such archival processing, the archivists will restrict portions of the materials pursuant to §§ 1275.50 and 1275.52. All materials other than tape recordings to which reference is made in § 1275.64 will be prepared for public access and released subject to restrictions or outstanding claims or petitions seeking such restrictions. The Archivist will open for public access each integral file segment of materials upon completion of archival processing of that segment.

(2) The archivists will conduct archival processing of the tape recordings to prepare them for public access in accordance with the provisions set forth in the Settlement Agreement (see Appendix A to this part). In conducting the archival processing of the tape recordings, the archivists will restrict segments of the tape recordings pursuant to §§ 1275.50 and 1275.52. The tape segments which consist of abuses of governmental power information, as defined in § 1275.16(c), will be given priority processing by the

archivists and will be prepared for public access and released following review and resolution of objections from the Nixon estate and other interested parties as set forth in the Settlement Agreement (see Appendix A to this Part). After the tape segments which consist of abuses of governmental power information have been released, the archivists will conduct archival processing of those tape recordings which were taped in the Cabinet Room, as set forth in the Settlement Agreement, Appendix A to this Part. Following release of the Cabinet Room tape recordings, the remaining tape recordings will be prepared for public access and released in five segments in accordance with the schedule set forth in the Settlement Agreement. In addition, NARA will identify and return any additional private or personal segments to the Nixon estate, at approximately the time that NARA proposes each segment for public release.

* * * * *

5. Section 1275.44 is amended by adding new paragraph (e) to read as follows:

§ 1275.44 Rights and privileges; right to a fair trial.

* * * * *

(e)(1) In place of the right to make all other objections with respect to the tape segments that NARA has designated as abuses of governmental power materials, the Nixon estate may object to their release only on the ground that such designation by NARA is clearly inconsistent with the term "abuses of governmental power" as used in § 104(a)(1) of the Presidential Recordings and Materials Preservation Act (PRMPA) and defined in § 1275.16(c), as qualified by § 1275.50(b). Any such objection may not be based on isolated instances of alleged failure by NARA to apply the appropriate review standard, but only on a pattern of misapplication of the requirements of the PRMPA and its implementing regulations. Further, any such objection must be accompanied by specific examples of alleged review errors and contain sufficient information to enable the review panel of three Presidential Library archivists appointed by the Archivist, as described in the Settlement Agreement, Appendix A to this Part, to locate those examples readily.

(2) If an objection is made by the Nixon estate to the abuses of governmental power tape segments, the matter shall be immediately referred to a panel of three Presidential Library archivists appointed by the Archivist as

set forth in the Settlement Agreement, Appendix A to this Part. The decision of the panel shall be either that the Nixon estate's objection is sustained or that it is rejected. The decision shall include a brief statement of the panel's reasons, but it need not include an item-by-item determination. In deciding whether the designation by NARA of the material proposed to be released is clearly inconsistent with the definition of "abuses of governmental power", the panel shall consider whether the release would seriously injure legitimate interests of identifiable individuals, whether the errors suggest a pattern of misinterpretation, and any other factor that bears on the issue of whether NARA's designation of material as relating to "abuses of governmental power" was reasonable, considered as a whole. The panel's decision shall be final and binding on all parties to the *Kutler* litigation, and no party may exercise any right to appeal to any person, board, or court that might otherwise be available.

(3) The Nixon estate may, at any time, elect to use the procedures outlined in paragraphs (e)(1) and (e)(2) of this section for the tape recordings other than the abuses of governmental power segments, except that the standard under which objections shall be made by the Nixon estate, and under which the review panel shall decide their merits, is whether the release taken as a whole is plainly inconsistent with the requirements of the Presidential Recordings and Materials Preservation Act of 1974 and these regulations. If the Nixon estate elects to use the procedures in paragraph 1 of the Settlement Agreement (Appendix A to this Part) in place of the provisions in paragraphs 4 (b) and (d) and 5(c) of the Settlement Agreement for a tape segment, the estate cannot subsequently revert back to the formal objection process set forth in this section for that tape segment.

§ 1275.46 [Amended]

6. Section 1275.46 is amended by removing in paragraph (d) and paragraph (f), wherever it appears, the term "Archivist of the United States" and adding in its place the term "Archivist," and by removing in paragraph (i)(2) the term "reasonably" and adding in its place the term "reasonably."

7. Section 1275.48 is amended by revising paragraph (a) to read as follows:

§ 1275.48 Transfer of materials.

(a) The Archivist will transfer sole custody and use of those materials determined to be private or personal, or

to be neither related to abuses of governmental power nor otherwise of general historical significance, to former President Nixon's estate, or, when appropriate and after notifying the Nixon estate, to the former staff member having primary proprietary or commemorative interest in the materials; however, no physical part of any original tape recording or a master preservation copy to which reference is made in § 1275.64 shall be transferred to the heirs of former President. NARA will maintain the original tape recordings and a master preservation copy, including the private and personal segments, in a manner consistent with the PRMPA and these regulations and will restrict access to all private or personal material on the originals and the master preservation copy.

* * * * *

§ 1275.56 [Amended]

8. Section 1275.56 is amended by removing the term "administrative" and replacing it with the term "administrative."

9. Section 1275.64 is amended by removing in paragraph (b) the term "Archivists" and replacing it with the term "archivists" and adding new paragraphs (d) and (e) to read as follows:

§ 1275.64 Reproductions of tape recordings of Presidential conversations.

* * * * *

(d) The reproduction for members of the public of the reference copies of the available tape recordings described in paragraph (a) of this section will be permitted as follows: Copies of tape recordings will be made available following the public release of the last of the tape segments contemplated in § 1275.42(a). If the releases contemplated in § 1275.42(a) are not completed by December 31, 1999, NARA will, beginning January 1, 2000, allow members of the public to obtain copies only of the abuses of governmental power tapes, together with any other tapes publicly released as of the effective date of the Settlement Agreement. If the releases contemplated in § 1275.42(a) are not completed by December 31, 2002, NARA will, beginning January 1, 2003, allow members of the public to obtain copies of all tapes that have been made available to the public by that date and tapes that subsequently become available as they are released. Such copying will be controlled by NARA or its designated contractor. The fees for the reproduction of the tape recordings under this section shall be those prescribed in the schedule set forth in part 1258 of this chapter or pertinent

successor regulation, as that schedule is amended from time to time.

(e) The Archivist shall produce and maintain a master preservation copy of the original tape recordings for preservation purposes.

10. Section 1275.66 is amended by revising paragraph (a) to read as follows:

§ 1275.66 Reproduction and authentication of other materials.

(a) Copying of materials other than tape recordings described in § 1275.64 may be done by NARA, by a contractor designated by NARA, or by researchers using self-service copiers. Such self-service copying shall be done in accordance with the NARA policy on self-service copying set forth at 36 CFR 1254.71, to ensure that such copying will not harm the materials or disrupt reference activities.

* * * * *

§ 1275.70 [Amended]

11. Section 1275.70 is amended by removing in paragraph (a) the term "an Archivist" and adding in its place the term "an archivist" and by removing in paragraph (b) the term "NARA Archivists" and adding in its place the term "NARA archivists."

* * * * *

12. Appendix A to Part 1275 is added to read as follows:

Appendix A—Settlement Agreement

Settlement Agreement filed April 12, 1996, in *Stanley I. Kutler and Public Citizen v. John W. Carlin, Archivist of the United States, and William E. Griffin and John H. Taylor, Co-executors of Richard M. Nixon's Estate*, Civil Action No. 92-0662-NHJ (D.D.C.) (Johnson, J.)

Settlement Agreement

This Settlement Agreement ("Agreement") is made by and entered into among plaintiffs Stanley I. Kutler and Public Citizen; defendant/cross-claim defendant John W. Carlin, in his official capacity as Archivist of the United States; and defendant-intervenor/cross-claimants John H. Taylor and William E. Griffin, co-executors of the estate of Richard M. Nixon ("the Nixon estate"), in the above-entitled action by and through the parties' undersigned attorneys.

It is hereby agreed, by and among the parties, appearing through their undersigned attorneys, that this action is partially settled on the following terms:

Terms of Agreement

1(a). As soon as practicable, the National Archives and Records Administration ("the Archives") will publicly release the segments of tape recordings made during the Presidency of Richard M. Nixon ("tape recordings" or "tapes") identified by the Archives as relating to "abuses of governmental power," as defined by 36 C.F.R. Part 1275, along with the corresponding portions of the tape log and

any other finding aid. The date of that release, which is expected to be on or about November 15, 1996, shall be determined in the following manner.

(b). No later than April 15, 1996, the Archives shall deliver to an agent of the Nixon estate a copy of the approximately 201 hours of abuses of governmental power tape segments that it proposes to release, together with the corresponding portions of the tape log and any other finding aid, for review by the Nixon estate to determine whether it intends to object to the release. The Archives agrees to provide a period of orientation to the designated Nixon estate agent with respect to the review of the abuses of governmental power tape segments and to be available to respond to questions thereafter.

(c). In place of the right to make all other objections with respect to the tape recordings that the Archives has designated as abuses of governmental power materials, the Nixon estate agrees that it may object to their release only on the ground that such designation by the Archives is clearly inconsistent with the term "abuses of governmental power" as used in section 104(a)(1) of the Presidential Recordings and Materials Preservation Act of 1974 ("the Act"), 44 U.S.C. § 2111 note, and defined in 36 C.F.R. 1275.16(c), as qualified by 36 C.F.R. 1275.50(b). Any such objection shall be in writing and may not be based on isolated instances of alleged failure by the Archives to apply the appropriate review standard, but only on a pattern of misapplication of the requirements of the Act and its implementing regulations. Further, any such objection must be accompanied by specific examples of alleged review errors and contain sufficient information to enable the review panel described in subparagraph 1(e) below to locate those examples readily. Nothing in this paragraph shall preclude the Nixon estate and the Archives from having informal discussions regarding the appropriate treatment of any of the abuses of governmental power tape segments.

(d). The Nixon estate shall have until October 1, 1996, to submit any objection in accordance with subparagraph 1(c) above. If no such objection is filed, the Archives shall proceed to issue a notice of proposed release pursuant to 36 C.F.R. 1275.42 as soon as possible, but no later than October 15, 1996.

(e). If an objection is made, the matter shall be immediately referred to a panel of the following three Presidential Library archivists: David Alsbrook, Frances Seeber, and Claudia Anderson. If any of these three persons is unable to serve, the Archivist shall appoint a substitute who is acceptable to the other parties.

(f). The panel shall have such access to the tapes as it deems necessary to make its decision. The decision of the panel shall be either that the Nixon estate's objection is sustained or that it is rejected. The decision shall include a brief statement of the panel's reasons, but it need not include an item-by-item determination. In deciding whether the designation by the Archives of the material proposed to be released is clearly inconsistent with the definition of "abuses of governmental power," the panel shall consider whether the release would seriously injure legitimate interests of identifiable

individuals, whether the errors suggest a pattern of misinterpretation, and any other factor that bears on the issue of whether the Archives' designation of material as relating to abuses of governmental power was reasonable, considered as a whole. The decision of the panel shall be made within sixty (60) days of the date of the objection. However, if the panel determines that exceptional circumstances interfere with its ability to meet this deadline, the panel shall have up to an additional sixty (60) days to make its decision. The Archives shall notify the other parties of the need for an extension and briefly describe the reasons therefor. The panel's decision shall be final and binding on all parties, and no party may exercise any right to appeal to any person, board, or court that might otherwise be available. Nothing contained in this Agreement shall preclude the panel from advising the Archives of any particular processing errors that it believes may have been made, but the Archivist shall make the final determination as to whether to accept such advice.

(g). If the objection of the Nixon estate is sustained, the Archives shall re-review the tapes sufficiently to address the concerns raised by whatever aspect of the objection is sustained. At the conclusion of such re-review, the same process of review, first by the Nixon estate and then by the panel in the event of further objection, shall be repeated for those tape segments concerning the subject matter of the sustained objection prior to any release of tape recordings designated as relating to abuses of governmental power.

(h). The Nixon estate agrees to inform the Archives and plaintiffs whether it intends to file objections as soon as it has made its decision. If there is an objection by the Nixon estate and it is overruled, the Federal Register notice shall be published within ten (10) days of the date of the panel's decision.

(i). If, following the Federal Register notice, no objection by other individuals to a release is received within the time provided by law, the Archives shall release the tape recordings within ten (10) days after such time has expired. If objections are received, they shall be promptly considered by the Archives and shall be decided as soon thereafter as practical. Any materials as to which an objection to release has been timely filed shall not be released until such objection has been resolved pursuant to 36 C.F.R. 1275.44. All materials not objected to shall be released no later than thirty (30) days after the time for objections has expired, provided that the Archives may withhold any additional conversation to which no objection has been made, pending final resolution of an objection to another conversation, if (i) such additional conversation is in close proximity on the tapes to the objected-to conversation and it would be burdensome for the Archives to separate out the releasable and objected-to portions, or (ii) the subjects of the releasable and the objected-to conversations are closely related to one another and the Archives determines that it might be misleading or might unfairly prejudice a living individual to release only one conversation. Any release under this Agreement shall include the

corresponding portions of the tape log and any other finding aid.

(j). The Archives shall send to plaintiff Kutler, to arrive no later than the day that the release of the tapes occurs, a copy of the portions of the tape log and any other finding aid that correspond to the tapes being released. The Archives shall also make suitable arrangements for plaintiff Kutler to listen to such tapes on the date of their release, and/or on such other subsequent business days as plaintiff Kutler shall designate.

2(a). Although the Agreement provides that the Archives will identify and return to the Nixon estate a copy of any private or personal materials identified on the tapes, the parties have been unable to reach agreement regarding the Archivist's retention and maintenance of the original tape recordings in their entirety, including those segments deemed to be private or personal, along with a master preservation copy. The government's position is that it is complying with the Act by retaining the original tapes and a master preservation copy, including those portions containing private or personal conversations. The Nixon estate's position, with which plaintiffs agree, is that the family has statutory, constitutional, and other rights that prevent the Archives from retaining private or personal materials, on both the original tapes and all copies.

(b). The parties have agreed to litigate the issue described in subparagraph 2(a) above, including the validity of 36 C.F.R. 1275.48(a) and 1275.64(e) as proposed for amendment. The parties further agree that the Court shall retain jurisdiction of that issue, as provided in paragraph 14 below, and that the right to litigate this issue includes the right to seek review in the United States Court of Appeals for the District of Columbia Circuit and the United States Supreme Court. If there is litigation between the Nixon estate and the Archivist over the issue described in subparagraph 2(a) above, the plaintiffs shall support the Nixon estate in any such litigation by filing a brief supporting the estate's position in District Court. The parties agree to make all reasonable efforts to expedite resolution of this issue.

(c). This Agreement and all discussions, negotiations and exchanges of information leading to it shall be entirely without prejudice to any positions the parties may take in the event of such litigation. Nothing in this Agreement, in any discussions leading to it, or in any information or materials exchanged by the parties as part of the mediation may be relied on or disclosed by any party to support or rebut the position of any party with respect to the treatment of private or personal materials on the original tapes. Nothing in this subparagraph prevents any party from expressing its understanding as to the meaning and effect of the legal position of another party.

3. The Archives will provide to the Nixon estate any additional private or personal materials at approximately the time that the Archives proposes each segment identified in paragraphs 4 and 5 below for public release. Any additional copies of that material (other than on a master preservation copy, the status of which will be determined in

accordance with the resolution of the issue as described in subparagraph 2(a) above), will be destroyed by appropriate method, with appropriate means of verification.

4(a). The second group of tapes to be processed for release is the approximately 278 hours recorded in the Cabinet Room. The projected date for publishing a notice of proposed opening of tapes in that group is August 1, 1997. The Archives will make the Cabinet Room tapes proposed for release available to the Nixon estate in no fewer than four (4) segments. The process by which those tapes will be reviewed by the Nixon estate, and the objections handled by the Archives, is set forth in the following subparagraphs of this paragraph 4.

(b). The Nixon estate agrees to review each segment as it is received and promptly to call to the attention of the Archives any concerns that it may have. The Archives and the Nixon estate agree to attempt to work out their differences informally in order to minimize any objections to a proposed release. To facilitate informal consultation between the Nixon estate and the Archives concerning the tape review, the Archivist shall designate a panel member identified in subparagraph 1(e) above who will serve as a contact with the Nixon estate and assure access to information relating to Presidential libraries practices and procedures that may arise in the course of the tape review. The designated individual will be responsible for assuring that the Nixon estate has access to the appropriate person to answer its concerns. The Nixon estate may communicate with the designated individual orally or in writing. If the Archives agrees with the Nixon estate that any portion of a segment that has been sent to the Nixon estate as a proposed release should not be released, the Archives shall assure that there is appropriate documentation to reflect that change.

(c). The Nixon estate will have a period of at least six (6) months in which to review all of the Cabinet Room tapes, beginning on the date the Archives makes the first installment of such tapes available to the estate for review (but in no event will the six (6) months begin earlier than November 15, 1996). During the review of the Cabinet Room tapes, the Nixon estate will employ an agent or agents who will spend an average of at least thirty two (32) hours a week (total) in actual review of the tapes. The Nixon estate may request from the Archives an extension of the six-month review period, which the Archives shall grant if good cause is shown.

(d). If, during its review, the Nixon estate becomes aware that there are materials proposed for release that it believes should not be heard even by individuals on the registry list, it will promptly advise the Archives of any such materials so that they can be reviewed and/or segregated by the Archives before any other individual is permitted to listen to them. The Nixon estate will cooperate with the Archives so that the required Federal Register notice is published as soon as possible, but in no event shall such notice be provided later than ten (10) days after the time the Nixon estate completes its review. Final objections from the Nixon estate to the release of portions of the tapes shall be filed in accordance with 36

C.F.R. Part 1275 no later than the date for filing objections by other persons. Thereafter, subject to paragraph 7 below, the provisions of subparagraphs 1(i) and 1(j) above will apply.

5(a). The remaining tapes, consisting of approximately 2338 hours, shall be processed for release in five (5) segments. Because the precise number of hours of tapes for each month cannot readily be determined, the parties have agreed to divide the releases into the segments set forth below. The Archives will begin processing (which includes, but is not limited to, tape review, preparing tapes for declassification review, tape editing and production of finding aids) each segment before processing of the preceding segment is concluded. Processing of the tapes in each segment is projected to take from about fifteen (15) to about twenty three (23) months. The approximate number of hours of tapes to be reviewed in each segment is set forth in parentheses in the following listing of the segments. The projected number of months between the completion of the Archives' processing of the immediately preceding segment and the completion of the Archives' processing of each listed segment is set forth in brackets.

1. February 1971–July 1971 (437 hours) [8 months]
2. August 1971–December 1971 (405 hours) [7 months]
3. January 1972–June 1972 (440 hours) [7 months]
4. July 1972–October 1972 (410 hours) [6 months]
5. November 1972–July 1973 (646 hours) [10 months]

(b). The time estimates in this Agreement are not enforceable as such, but the parties agree to have the Court retain jurisdiction to consider requests that it enter a binding order setting a schedule for the Archives to complete the processing of the tapes. No party may seek such an order unless that party first provides twenty (20) days' written notice to the other parties of that party's intention to seek such an order. Further, no party may seek such an order except on the ground that the Archives has unreasonably failed to meet the estimates contained herein by a substantial amount. The type of proof that will demonstrate reasonableness on the part of the Archives in this regard may include, but will not necessarily be limited to, a showing that the Archives is reasonably allocating its resources among its various programs and activities in the event that it experiences a shortage of resources, including any occasioned by court order.

(c). Portions of each segment processed by the Archives shall be provided to the Nixon estate when the processing of each month of tape recorded material is completed, unless there are a very few hours for two (2) or more months, which may then be combined into a single unit. During its review of the chronological tape segments, the Nixon estate will employ an agent or agents who will spend an average of at least thirty two (32) hours a week (total) in actual review of the tapes, forty eight (48) weeks of the year. As its review of the tapes proceeds, the Nixon estate shall provide a written report of its progress to the Archives and the plaintiffs on

a bimonthly basis. The report shall include the number of hours worked in each week, the number of hours of tapes reviewed in each week, and the Nixon estate's projected completion date for review of the segment currently under review. The provisions of subparagraphs 4(b) and 4(d) above shall apply to the review, objections, and releases with respect to the chronological tape segments, subject to paragraph 7 below.

(d). If one of the other parties to this Agreement determines that the Nixon estate's review is not being conducted diligently or in good faith, or that the estate's estimated completion date(s) of one or more segments is unreasonable, that party may petition the Archivist to establish an earlier date(s) for the completion of the review of that segment and/or of future segments. Any such date(s) established by the Archivist shall provide the Nixon estate with a reasonable opportunity to protect and assert its interests without unduly delaying the release of the tapes, and shall be based upon consideration of the progress of the Archives' review and its scheduled completion date(s); the progress to date of the estate's review; and the time reasonably necessary to complete the estate's review and to formulate and present any objections. The Archives may also propose earlier dates for the completion of the review by the Nixon estate on the basis provided for in this subparagraph. If a proposal for an earlier date is made, the Nixon estate will have a reasonable opportunity to respond.

6. Once the Archives has completed processing the approximately 2338 hours of tapes discussed in paragraph 5 above, and has made corresponding releases, the Archives shall identify any additional copies of partial tape segments in its possession. If the Archives determines that some or all of such additional partial tape segments are duplicative of any tape recordings that it has already processed, the Archives may dispose of the duplicative tape segments, following notification to the parties, subject to paragraph 3 above. To the extent that such partial tape segments are not duplicative of the tape recordings already processed, the Archives shall promptly process such non-duplicative portions and shall treat any portions determined to be private or personal consistently with the resolution of the issue to be litigated as described in paragraph 2 above.

7(a). After completion of the procedures described in paragraph 4 above, the Cabinet Room tapes that are found to be releasable under paragraph 4 above may be released if either there has been a final decision by the district court on the issue to be litigated as described in subparagraph 2(a) above, or the release is scheduled after April 1, 1998, whichever of these two events happens sooner.

(b). After completion of the procedures described in paragraph 5 above, the tapes described in paragraph 5(a) above that are found to be releasable may be released if either there has been a final judgment by the district court, which is not subject to further review by appeal or certiorari, with regard to the issue to be litigated as described in subparagraph 2(a) above, or there has been a final decision by the United States Court of

Appeals for the District of Columbia Circuit on this issue, or the release is scheduled to take place after November 1, 1999, whichever of these three events happens sooner.

(c). As used in subparagraphs 7(a) and (b) above, the term "final decision" means a decision not subject to reconsideration under Rule 59 of the Federal Rules of Civil Procedure, or Rules 35 or 40 of the Federal Rules of Appellate Procedure, respectively.

8. The Nixon estate may, at any time, elect to use the procedures in paragraph 1 above with respect to any tape segment in place of the provisions of paragraphs 4(b) and (d) and 5(c) above, with the following substitution: The standard under which objections shall be made, and under which the panel shall decide their merits, is whether the release taken as a whole is plainly inconsistent with the requirements of the Act and its implementing regulations. Provided, however, that once the Nixon estate elects to use the procedures in paragraph 1 above in place of the provisions in paragraphs 4(b) and (d) and 5(c) above, it cannot subsequently revert back to the formal objection process set forth in 36 C.F.R. Part 1275 for that tape segment.

9. Within thirty (30) days of the Court's entry of an order as described in paragraph 14 below, the Archivist shall designate a particular person who shall be responsible for responding to reasonable inquiries from the plaintiffs on the status of the releases and objections. Such designation may be changed at any time at the Archivist's discretion by a notice to plaintiffs through their counsel.

10. If the Archives appoints a Senior Archival Panel as defined in 36 C.F.R. 1275.46(d) and (e), no party to the Agreement may object to the appointment of such a panel on the ground that the suggestion to appoint such a panel was originated by an individual other than the processing archivists assigned to the Archives' Nixon Presidential Materials Staff.

11. The Archives will allow members of the public to obtain copies of publicly accessible portions of the tapes after the releases described in paragraph 5 above, are completed; provided, however, that if the releases described in paragraph 5 above are not completed by December 31, 1999, the Archives will allow members of the public to obtain copies only of the abuses of governmental power tapes, together with any other tapes publicly released as of the date of the filing of this Agreement with the Court, beginning January 1, 2000. Further provided, that if the releases described in paragraph 5 above are not completed by December 31, 2002, the Archives will, beginning January 1, 2003, allow members of the public to obtain copies of all tapes that have been made available to the public by that date and tapes that subsequently become available, as they are released.

12(a). Promptly after the Court enters the Order provided for in paragraph 14 below, plaintiff Kutler will withdraw his request under the Freedom of Information Act, 5 U.S.C. 552, for any and all tape logs and other finding aids, which is pending in *Kutler v. Carlin, et al.*, Civ. A. No. 92-0661-NHJ (D.D.C.). In all other respects, plaintiff Kutler's request in that action shall be unaffected by this Agreement.

(b). Nothing in this Agreement shall affect the processing by the Archives of any dictabelts, which are a collection of recordings of former President Nixon and other White House staff members dictating memoranda, correspondence and speech drafts, that are included in the materials that are subject to the Act.

13. Pursuant to Rule 315 of this Court, the plaintiffs and the defendant shall attempt to resolve the plaintiffs' claim for attorneys' fees and expenses and shall advise the Court no later than forty-five (45) days after this Court has entered the Order provided for in paragraph 14 below on whether they have been able to resolve the issue of attorneys' fees and expenses. If no resolution has been reached, they will, at that time, recommend a schedule to the Court to resolve such claim.

14. The parties agree to the dissolution of the preliminary injunction entered on August 9, 1993, and dismissal with prejudice of this action, including all claims and cross-claims, except for the issue to be litigated as described in subparagraph 2(a) above, and any fees and expenses claimed pursuant to paragraph 13 above, by filing the attached Joint Motion to Vacate Preliminary Injunction and to Dismiss Claims, and the attached Consent Order. The parties agree that the Court shall retain jurisdiction to: (a) Consider the entry of an order in accordance with the terms of paragraph 5 above; (b) resolve the issue to be litigated as described in subparagraph 2(a) above; (c) determine any fees and expenses claimed pursuant to paragraph 13 above; and (d) for the purpose of enforcing the terms of this Agreement. The parties further agree that such jurisdiction, except with respect to the issue described in paragraph 2 above, will be retained only until the later of the implementation of paragraph 11 above or the completion of the releases called for in paragraph 5 above. Plaintiffs and the Nixon estate further agree that they will not challenge any regulations issued by the Archives which implement and are consistent with this Agreement.

15. The terms of this Agreement may not be altered except with the written consent of the parties. Nothing in this Agreement constitutes an admission of liability or wrongdoing on the part of any party.

Executed this 12th day of April, 1996.

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Dated: April 18, 1996.

John W. Carlin,

Archivist of the United States.

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FEDERAL MARITIME COMMISSION

46 CFR Part 572

[Docket No. 94-31]

Information Form and Post-Effective Reporting Requirements for Agreements Among Ocean Common Carriers Subject to the Shipping Act of 1984

AGENCY: Federal Maritime Commission.

ACTION: Final Rule; Extension of time for filing Petition for Reconsideration.

SUMMARY: On March 21, 1996, (61 FR 11564), the Federal Maritime Commission published a final rule amending its regulations governing the information submission requirements for agreements among ocean carriers subject to the Shipping Act of 1984. Extension of time for filing a petition for reconsideration has been requested by the Asia North America Eastbound Rate Agreement, Japan-United States Eastbound Freight Conference, Transpacific Westbound Rate Agreement and their members. The request is granted; this extension does not affect the effective date of the final rule.

DATES: Petition for Reconsideration due May 19, 1996.

FOR FURTHER INFORMATION CONTACT:

Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North

Capitol St., NW., Washington, D.C. 20573, (202) 523-5725.

Joseph C. Polking,

Secretary.

[FR Doc. 96-9872 Filed 4-22-96; 8:45 am]

BILLING CODE 6730-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 675

[Docket No. 960129019-6019-01; I.D. 041796A]

Groundfish of the Bering Sea and Aleutian Islands Area; Pacific Ocean Perch in the Western Aleutian District

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is closing the directed fishery for Pacific ocean perch in the Western Aleutian District of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the total allowable catch of Pacific ocean perch in this area. EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), April 18, 1996, until 12 midnight, A.l.t., December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907-586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the BSAI exclusive economic zone is managed by NMFS according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 675.

In accordance with § 675.20(a)(7)(ii), the initial total allowable catch of Pacific ocean perch for the Western Aleutian District was established by the Final 1996 Harvest Specifications of Groundfish (61 FR 4311, February 5, 1996) for the BSAI as 5,143 metric tons (mt). As of March 30, 1996, 1,465 mt remains. The directed fishery for Pacific ocean perch in the Western Aleutian District was closed under § 675.20(a)(8) on March 20, 1996 (58 FR 12041, March 25, 1996) and reopened on April 15, 1996 (Action filed by the Office of the Federal Register on April 15, 1996, and scheduled for publication in the Federal Register on April 19, 1996.).

The Director, Alaska Region, NMFS (Regional Director), has determined, in accordance with § 675.20(a)(8), that the Pacific ocean perch initial total allowable catch in the Western Aleutian District subarea soon will be reached. Therefore, the Regional Director has established a directed fishing allowance of 5,093 mt after determining that 50 mt will be taken as incidental catch in directed fishing for other species in the Western Aleutian District. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the Western Aleutian District.

Maximum retainable bycatch amounts for applicable gear types may be found in the regulations at § 675.20(h).

Classification

This action is taken under § 675.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 17, 1996.

Richard W. Surdi,

*Acting Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.*

[FR Doc. 96-9971 Filed 4-18-96; 3:09 pm]

BILLING CODE 3510-22-F

Proposed Rules

Federal Register

Vol. 61, No. 79

Tuesday, April 23, 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 AGRICULTURE

Office of the Secretary

7 CFR Parts 15 and 15d

Nondiscrimination in USDA Conducted Programs and Activities

AGENCY: Department of Agriculture.

ACTION: Proposed rule.

SUMMARY: The United States Department of Agriculture (USDA or the Department) is proposing to revise its regulations governing nondiscrimination in programs and activities conducted by the Department. The proposal would remove the current regulation on this subject found at 7 CFR part 15, subpart B (Subpart B), and place it in a new part 15d; clarify that the regulation applies to all Department-conducted programs and activities, not just to direct assistance programs; add familial status and marital status to the protected classes contained in the regulation; add a provision on Department agencies' compliance efforts; reflect that the Assistant Secretary for Administration has been delegated the authority to make final determinations as to whether prohibited discrimination occurred and the correction action required to resolve complaints; remove the Appendix to the regulation that lists the Department programs subject to these provisions; and make other clarifications to the regulation.

DATES: Comments must be received by May 23, 1996.

ADDRESSES: Send comments to Director of Civil Rights, Department of Agriculture, Washington, DC 20250. Comments will be available for public inspection at Room 1322, South Building, Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Andrew Johnson, Director, Policy and Planning, Civil Rights, 202-720-1130; or Ron Walkow, Attorney-Advisor, Office of General Counsel, 202-720-6056.

SUPPLEMENTARY INFORMATION: The Department in 1964 first adopted regulations to cover nondiscrimination in all programs and activities directly administered by USDA (29 FR 16966). At that time, the regulations were intended to complement the newly enacted Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) by covering those programs and activities not subject to Title VI; that is, programs and activities in which USDA or an agency thereof made available a benefit directly to persons rather than through a recipient. However, these regulations were made a part of the Department's Title VI regulations; specially, they were issued at Subpart B where they have remained to this day. Since then, subpart B has been amended on several occasions to include a variety of protected classes in addition to race, color, and national origin. (38 FR 22465; 42 FR 65202; 47 FR 25458). Subpart B also was amended to provide that individuals who believe they were subject to discrimination under the regulations may file a complaint with the Department (50 FR 25687; 54 FR 31164).

Since Title VI is not the authority for the regulations, having these regulations codified as part of the Department's Title VI regulations has resulted in some confusion over the years. Accordingly, the Department is proposing to remove the regulations from subpart B of part 15 and reissue them in a new regulation, part 15d of Title 7. Along these same lines, the authority provision of the regulation would be revised to clarify that the authority for the regulation is 5 U.S.C. 301, not Title VI.

In addition to removing and reissuing the regulation, the Department is proposing to make some minor substantive changes to the regulation. First, the regulation will be reworded to clarify that it applies to discrimination in all Department-conducted programs and activities; that is, to any allegation that a USDA employee discriminated against a member of the public—whether in a direct assistance program or in any other manner.

Second, the Department is also proposing to add familial status and marital status to the protected classes covered by the regulation. Over the years, the Department has added protected classes to the regulation in order to reflect those classes protected

by the various Federal civil rights laws. Two of those classes not currently included are familial status (which is included in the Fair Housing Act (42 U.S.C. 3601 *et seq.*) and marital status (which is included in the Equal Credit Opportunity Act (15 U.S.C. 1691 *et seq.*). Accordingly, the proposed rule would include these classes.

The proposed regulation would delete the provision now contained in subpart B at § 15.51(b). The Department believes that the broad language used in proposed § 15d.2 is sufficient to make clear that the Department will not discriminate in any of its conducted programs, without having to provide specific examples, of prohibited discriminatory acts. By this action, the Department does not intend to substantively affect the scope of the protections currently covered by § 15.51(b).

The Department is also proposing to add a new section on the efforts of the Department to ensure compliance with this part since it is as crucial to have an ongoing evaluation of Department agencies' compliance with this section as it is to have a complaint process. Therefore, the enforcement sections, *i.e.* proposed §§ 15d.3 and 15d.4, provide for the Department engaging in compliance activities and in complaint resolution. Specific provisions noting how these efforts will be implemented within the Department will be set forth in internal regulations and guidelines.

The proposed regulation would reflect that the authority to make final determinations for the Department as to (1) whether discrimination occurred and the corrective action required by the Department to resolve complaints and (2) whether Department agencies' efforts to comply with nondiscrimination requirements are sufficient will no longer be delegated to the Director, Office of Civil Rights Enforcement,¹ but instead has been delegated to Assistant Secretary for Administration (ASA). This delegation already has been effectuated in 7 CFR part 2, and that change would be reflected in the proposed regulation. The Department believes that determinations of this magnitude should be elevated to the sub-cabinet level. In addition, this

¹ The Office of Civil Rights Enforcement has been reorganized into two entities within Departmental Administration, *i.e.*, Civil Rights and Civil Rights Adjudication and Enforcement.

change would make the determining official in program discrimination complaints the same official, i.e. the ASA, who makes final determinations on employment discrimination complaints within the Department. Civil Rights Adjudication and Enforcement (AE) will be responsible for conducting the investigations on complaints and evaluating agencies' efforts to comply with the discrimination prohibition provisions of this new Part.

The Department is also proposing to remove the provisions in § 15.52(a) that require covered agencies of the Department to provide notice of the public's right to file a complaint under that Subpart. Under the proposed new Part 15d, this requirement will be transferred to the Department's internal regulations. The Department now believes that internal instructions such as the notice requirement now in § 15.52(a) are more appropriate in such a regulatory setting. However, until such internal regulations are issued, agencies of the Department will continue to follow the procedures currently required in § 15.52(a).

The Department is next proposing to remove the appendix to the regulation (currently "Appendix to Subpart B"), which purports to list the programs and activities conducted by the Department. The Department has found that it is difficult to maintain the accuracy of this list on a regular basis when it is contained in the Code of Federal Regulations. Additionally, having the Appendix in the Code of Federal Regulations does not contribute to the effectiveness of the regulation. Accordingly, the Department would remove the Appendix and maintain such a list of programs and activities in internal guidelines to be maintained by Civil Rights (CR).

The proposed regulation would contain a new provision that would state that nothing in the regulation shall be construed as making unlawful any program or activity conducted by the Department that is otherwise lawful. The purpose of this provision is to make clear the intent of the regulation. That is, this regulation is not intended to prohibit the Department from doing anything that it is not already prohibited from doing by the Constitution and various Federal statutes. The regulation merely states the nondiscrimination policy of the Department; it does not create any additional rights for individuals and entities that deal with the Department. The proposed language would make clear this intention as well as the legal effect of the regulation.

Finally, the Department proposes to add a provision stating that complaints

filed under the regulation that are subject to a Department complaint process that is implemented under specific statutory authority will be processed under the statutory complaint process. Thus, for example, a complaint alleging that the Department discriminated on the basis of disability in a conducted program will be processed under 7 CFR part 15e, which implements the Rehabilitation Act.

In conclusion, the proposed regulation would set forth the nondiscrimination policy of the Department, provide for compliance efforts by the Department, notify the public that it may file complaints with the Department alleging discrimination, and provide that complainants will be notified of the final determinations on their complaints. The Department believes that the detailed internal procedures on the processing of these complaints should be contained in internal regulations rather than in the Code of Federal Regulations. These internal regulations will address such matters as the duties of Department agencies under the regulation, guidelines on what constitutes a proper investigation, and the standards for "good-cause" extension of the 180-day filing period. The Department will issue these internal regulations as soon as is practicable after this proposed rule has been made final. Once completed, the internal regulations will be available for public inspection.

This proposed rule has been determined to be "not-significant" for purposes of Executive Order 12866, and therefore has not been reviewed by the Office of Management and Budget. USDA certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.). USDA also certifies that this proposed rule would not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

USDA is providing a 30-day comment period for this rule. Comment is invited on all aspects of the proposal, including the appropriateness and effect of the proposed changes, and any additional or alternative measures that would serve the goals of USDA as outlined in the proposal.

List of Subjects in 7 CFR Parts 15 and 15d

Nondiscrimination.

In consideration of the foregoing, the Department proposes to amend Title 7 of the Code of Federal Regulations, Subtitle A, as follows:

PART 15—[AMENDED]

1. The authority citation for part 15 continues to read as follows:

Authority: 5 U.S.C. 301; 29 U.S.C. 794.

2. Part 15, subpart B (§§ 15.50–15.52) and the appendix thereto would be removed; and

3. A new Part 15d would be added as follows:

PART 15d—NONDISCRIMINATION IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE UNITED STATES DEPARTMENT OF AGRICULTURE

Sec.

15d.1 Purpose.

15d.2 Discrimination prohibited.

15d.3 Compliance.

15d.4 Complaints.

15d.5 Effect of regulation.

Authority: 5 U.S.C. 301.

§ 15d.1 Purpose.

The purpose of this part is to set forth the nondiscrimination policy of the United States Department of Agriculture in programs or activities conducted by the Department, including such programs and activities in which the Department or any agency thereof makes available any benefit directly to persons under such programs and activities.

§ 15d.2 Discrimination prohibited.

No agency, officer, or employee of the United States Department of Agriculture shall exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States on the ground of race, color, religion, sex, age, national origin, marital status, familial status, or disability under any program or activity conducted by such agency, officer, or employee.

§ 15d.3 Compliance.

The Office of the Director of Civil Rights shall evaluate each agency's efforts to comply with this part and report to the Assist Secretary for Administration the results of such evaluations, including recommendations for improving such efforts. The Assistant Secretary shall make a final determination as to the merits of such recommendations and the actions to be taken to improve such efforts.

§ 15d.4 Complaints.

(a) Any person who believes that he or she (or any specific class of individuals) has been, or is being, subjected to practices prohibited by this part may file on his or her own, or through an authorized representative, a written complaint alleging such

discrimination. No particular form of complaint is required. The complaint must be filed within 180 calendar days from the date the person knew or reasonably should have known of the alleged discrimination, unless the time is extended for good cause by the Assistant Secretary for Administration or his designee. Any person who complains of discrimination under this part in any fashion shall be advised of his or her right to file a complaint as herein provided.

(b) All complaints under this part should be filed with the Director of Civil Rights Adjudication and Enforcement, United States Department of Agriculture, Washington, DC 20250, who will investigate the complaints. The Assistant Secretary for Administration will make final determinations as to the merits of complaints under this part and as to the corrective actions required to resolve the complaints. The complainant will be notified of the final determination on his or her complaint.

(c) Any complaint filed under this part that is subject to a Department complaint process that is implemented under specific statutory authority will be processed under the statutory complaint process.

§ 15d.5 Effect of regulation.

Nothing in this part shall be construed as making unlawful any program or activity conducted by the Department that is otherwise lawful.

Dated: April 16, 1996.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 96-9900 Filed 4-22-96; 8:45 am]

BILLING CODE 3410-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95-NM-192-AD]

Airworthiness Directives; Empresa Brasileira de Aeronautica, S.A. (EMBRAER) Model EMB-120 Series Airplanes

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 certain EMBRAER Model EMB-120 series airplanes. This proposal would

require repetitive inspections to detect cracks in the wing rib-to-skin support brackets (shear clips), and replacement of cracked brackets with new or serviceable brackets. This proposal also would require the eventual replacement of certain brackets with new brackets, which would terminate the requirement for the inspections. This proposal is prompted by reports of cracks in the wing rib-to-skin support brackets in both the lower and upper skin of the wings. The actions specified by the proposed AD are intended to prevent cracking of those support brackets, which can subsequently lead to the loosening of the rivets in the wing skin, leakage of fuel through the rivet holes, and, ultimately, the reduction of the structural integrity of the wing.

DATES: Comments must be received by June 3, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-192-AD, 1601 Lind Avenue SW., Renton, Washington 98055-4056. 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 EMBRAER, Empresa Brasileira De Aeronautica S/A, Sao Jose dos Campos - SP, Brazil. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Curtis Jackson, Aerospace Engineer, Airframe and Propulsion Branch, ACE-117A, FAA, Atlanta Aircraft Certification Office, Small Airplane Directorate, Campus Building, 1701 Columbia Avenue, Suite 2-160, College Park, Georgia 30337-2748; telephone (404) 305-7358; fax (404) 305-7348.

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 shall 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 Number 95-NM-192-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, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-192-AD, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

Discussion

The Departamento de AviaCão Civil (DAC), which is the airworthiness authority for Brazil, recently notified the FAA that an unsafe condition may exist on certain EMBRAER Model EMB-120 series airplanes. The DAC advises that it has received reports of cracks in the rib-to-skin fitting brackets (shear clips) both in the lower and upper skin of the wings on Model EMB-120 series airplanes. The development of cracking of the shear clips can occur in the wing skin riveting line and can cause the complete failure of the ledge of the shear clips, resulting in separation of the skin from the shear clip on the affected area. Although there are several shear clips per rib, the simultaneous occurrence of cracking in several shear clips will affect the wing's structural integrity. The cause of the cracking is attributed to fatigue. Cracking of those support brackets can cause rivets in the wing skin to loosen and, consequently, permit fuel to leak into the wing through the rivet holes. Propagation of such cracking, if not corrected, could reduce the structural integrity of the wing and permit fuel leakage into the wing.

EMBRAER has issued Service Bulletin (SB) 120-57-0031, dated July 6, 1995, which describes procedures for repetitive internal visual inspections to detect cracks in the wing rib-to-skin support brackets (shear clips), and replacement of cracked brackets with new or serviceable parts. The service

bulletin also describes procedures for a terminating action for the repetitive inspections. That action involves replacement of all wing rib-to-skin support brackets of ribs 15 and 16 with brackets having a new part number; inspection to detect cracking of the wing skin support brackets of ribs 18, 19, 20, 21, and 22; and replacement of cracked brackets with new or serviceable brackets having the same part number. The DAC classified this service bulletin as mandatory and issued Brazilian airworthiness directive (DA) 95-05-01 R1, dated August 25, 1995, in order to assure the continued airworthiness of these airplanes in Brazil.

This airplane model is manufactured in Brazil and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, the proposed AD would require repetitive internal visual inspections to detect cracks in the wing rib-to-skin support brackets (shear clips). If cracks are found that are within certain limits (in length), this proposed AD would permit flights to continue, but the inspections would be required to be conducted more often. If cracks are found that are outside certain limits, the bracket would be required to be replaced prior to further flight, and additional inspection of other adjacent support brackets would be required to be accomplished. This proposed AD also would require that all wing rib to skin support brackets of ribs 15 and 16 be replaced with new brackets. This replacement would constitute terminating action for the required inspections. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Operators should note that, in addition to the inspection for cracking of the wing skin brackets recommended in the referenced Embraer service bulletin, this proposed AD would require that a repetitive visual inspection of the wing skin for fuel leakage be accomplished within every 50 flight hours until the terminating

action has been accomplished. The FAA finds that inspections for such fuel leakage [fuel leakage as defined and classified in the Airplane Maintenance Manual (AMM)] are necessary to provide an indication of the urgency of need to inspect for cracking of the wing skin brackets.

The FAA estimates that 169 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 6 work hours per airplane to accomplish the proposed visual inspection for cracking, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of this proposed inspection action on U.S. operators is estimated to be \$60,840, or \$360 per airplane, per inspection cycle.

It would take approximately 56 work hours to accomplish the proposed replacement of support brackets, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$1,000 per airplane. Based on these figures, the cost impact of the proposed replacement on U.S. operators is estimated to be \$736,840, or \$4,360 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this proposed AD, and that no operator would accomplish those actions in the future if this proposal were not adopted. However, the FAA has been advised that the terminating modification already has been installed on a number of airlines that are subject to this AD. Therefore, the future economic cost impact of this rule on U.S. operators is expected to be less than the cost impact figures indicated above.

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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

EMBRAER: Docket 95-NM-192-AD.

Applicability: Model EMB-120 airplanes, serial numbers 120001, 120003, 120004, and 120006 through 120304 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (e) 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 as indicated, unless accomplished previously.

To prevent reduced wing structural integrity and fuel leakage of the wing due to cracking of wing rib-to-skin support brackets, accomplish the following:

Note 2: The term "fuel leakage" and "stain," as used throughout this AD, are used as they are defined and classified in Chapter 28, Fuel, of the Airplane Maintenance Manual (AMM).

(a) Within 10 days after the effective date of this AD: Perform a visual inspection of the wing skin along rib lines 15 and 16 to detect any fuel leakage other than a stain. Thereafter, repeat this inspection every 50 flight hours until the requirements of paragraph (d) of this AD have been accomplished.

(b) For airplanes on which fuel leakage is detected during any inspection required by

paragraph (a) of this AD: Within 50 flights after detection of fuel leakage; perform an internal visual inspection to detect cracking of the wing rib-to-skin support brackets (shear clips) that connect the lower and upper wing skins to ribs 15 and 16, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 120-57-0031, dated July 6, 1995, at the time specified in paragraph (b)(1), (b)(2), or (b)(3) of this AD, as applicable.

(1) If no cracking is detected: Repeat the internal visual inspection required by paragraph (b) of this AD thereafter at intervals not to exceed 1,200 flight cycles until the requirements of paragraph (d) of this AD have been accomplished.

(2) If any cracking is detected in only one wing skin support bracket and that cracking is more than half the length of the bracket; and if any cracking also is detected in up to two additional wing skin support brackets and that cracking is less than half the length of the bracket: Repeat the internal visual inspection required by paragraph (b) of this AD thereafter at intervals not to exceed 400 flight cycles, until the requirements of paragraph (d) of this AD have been accomplished.

(3) If any cracking is detected other than that specified in paragraph (b)(2) of this AD: Prior to further flight, replace any support bracket that is cracked beyond the limits specified in paragraph (b)(2) of this AD with a new bracket, in accordance with the Accomplishment Instructions of the service bulletin. Following any replacement, prior to further flight, perform an additional internal visual inspection to detect cracking of the support brackets that connect the wing skins to ribs 18, 19, 20, 21, and 22 in accordance with the service bulletin.

(i) If no cracking is found, repeat the internal visual inspection required by paragraph (b) of this AD thereafter at intervals not to exceed 1,200 flight cycles until the requirements of paragraph (d) of this AD are accomplished.

(ii) If any cracking is found, prior to further flight, replace any cracked bracket with a serviceable part, in accordance with the service bulletin.

(c) For airplanes on which no wing fuel leakage is detected during any inspection required by paragraph (a) of this AD: Perform an internal visual inspection to detect cracking of the wing rib-to-skin support brackets (shear clips) that connect the lower and upper wing skins to ribs 15 and 16, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 120-57-0031, dated July 6, 1995, at the time specified in paragraph (c)(1), (c)(2), (c)(3), or (c)(4) of this AD, as applicable. Thereafter, repeat this inspection as intervals not to exceed 1,200 flight cycles until the requirements of paragraph (d) of this AD are accomplished.

(1) For airplanes that have accumulated less than 4,000 total flight cycles as of the effective date of this AD: Inspect prior to the accumulation of 5,200 total flight cycles, or within 1,200 flight cycles after the effective date of this AD, whichever occurs later.

(2) For airplanes that have accumulated 4,000 or more total flight cycles, but less than

8,000 total flight cycles as of the effective date of this AD: Inspect within 1,200 flight cycles after the effective date of this AD.

(3) For airplanes that have accumulated 8,000 or more total flight cycles, but less than 12,000 total flight cycles as of the effective date of this AD: Inspect within 800 flight cycles after the effective date of this AD.

(4) For airplanes that have accumulated 12,000 or more total flight cycles as of the effective date of this AD: Inspect within 400 flight cycles after the effective date of this AD.

(d) Within 2 years after the effective date of this AD: Replace all wing rib-to-skin support brackets of ribs 15, 16, and 18 with new brackets in accordance with EMBRAER Service Bulletin 120-57-0031, dated July 6, 1995. Prior to further flight following the replacement, perform a visual inspection to detect cracking of the wing skin support brackets of ribs 19, 20, 21, and 22. If any cracking is found, prior to further flight, replace cracked brackets with serviceable brackets in accordance with the service bulletin. Accomplishment of these requirements constitutes terminating action for the requirements of this AD.

(e) 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, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(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.

Issued in Renton, Washington, on April 17, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-9934 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 95-NM-268-AD]

Airworthiness Directives; de Havilland Model DHC-8-301, -311, and -315 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the superseding of an existing airworthiness directive (AD), applicable to certain de Havilland Model DHC-8-301, -311, and

-315 series airplanes, that currently requires modification of the airspeed limitations placard and revision of the Airplane Flight Manual to specify operating at lower airspeeds when the airplane is operating at full flaps. That action also provides for the optional termination of the requirements of the AD for certain airplanes. That action was prompted by a report that incorrect rivets were installed on the outboard flaps assemblies of these airplanes. The actions specified in that AD are intended to prevent structural failure of the outboard flaps of the wings due to the installation of incorrect rivets in the flap assemblies, which could result in reduced controllability of the airplane. This action would require installation of the terminating modification on certain airplanes.

DATES: Comments must be received by June 3, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-268-AD, 1601 Lind Avenue SW., Renton, Washington 98055-4056. 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 Bombardier, Inc., Bombardier Regional Aircraft Division, Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: Franco Pieri, Aerospace Engineer, Airframe Branch (ANE-171), FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256-7526; 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 shall 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 Number 95-NM-268-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, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 95-NM-268-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

On December 22, 1995, the FAA issued AD 95-26-17, amendment 39-9475 (61 FR 5277, February 12, 1996), applicable to certain de Havilland Model DHC-8-301, -311, and -315 series airplanes, to require modification of the airspeed limitations placard to indicate that the airplane must be flown at reduced airspeed when flying at 35 degrees flaps. Additionally, that AD requires a revision to the FAA-approved Airplane Flight Manual (AFM) for all airplanes to include information relative to reducing airspeed at 35 degrees flaps. For Model DHC-8-311 and -315 series airplanes, that AD also provides for an optional termination action for the requirements of the AD by modifying the outboard flaps (installation of Modification 8/2066).

That action was prompted by a report that incorrect rivets were installed on the outboard flaps assemblies of these airplanes. The actions specified in that AD are intended to prevent structural failure of the outboard flaps of the wings due to the installation of incorrect rivets in the flap assemblies, which could result in reduced controllability of the airplane.

In the preamble to AD 95-26-17, the FAA indicated that it regarded the requirements of that AD to be interim action, and that it was considering

additional rulemaking to mandate the optional terminating action that was provided in that AD. This notice follows from the FAA's decision to mandate that terminating action.

Description of Pertinent Service Information

De Havilland has issued Service Bulletin S.B. 8-57-24, Revision 'A,' dated September 26, 1995, which describes installation of Modification 8/2066 at the outboard flaps. That modification entails drilling out the suspect rivets and installing new DD rivets. The modification positively addresses the previously identified unsafe condition associated with the suspect rivets, and accomplishment of it eliminates the need for the airspeed limitations placard (which was the subject of AD 95-26-17). This modification, however, is applicable only to Model DHC-8-311 and -315 series airplanes; a corrective modification has not yet been developed for Model DHC-8-301 series airplanes.

Transport Canada classified the de Havilland service bulletin as mandatory and issued Canadian airworthiness directive CF-95-05R1, dated October 19, 1995, in order to assure the continued airworthiness of these airplanes in Canada.

Description of the Proposed Requirements

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, Transport Canada Aviation has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada Aviation, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would supersede AD 95-26-17.

For Model DHC-8-301 series airplanes, it would continue to require modification of the airspeed limitations placard and revision of the AFM to specify operating at lower airspeeds when the airplane is operating at full flaps.

For Model DHC-8-311 and -315 series airplanes, it would require that

the terminating modification (Modification 8/2066) be installed on within two years. The modification would be required to be accomplished in accordance with the service bulletin described previously. Once the modification is installed, the currently-required placard and AFM revision may be removed. Additionally, this proposal would require that Modification 8/2066 be installed on certain outboard flap assemblies prior to their installation on these airplanes.

The FAA has determined that long term continued operational safety will be better assured by design changes to remove the source of the problem, rather than by special operating procedures. Long term special operating procedures may not be providing the degree of safety assurance necessary for the transport airplane fleet. This, coupled with a better understanding of the human factors associated with numerous continual special procedures, has led the FAA to consider placing less emphasis on special procedures and more emphasis on design improvements. The proposed modification requirement of this AD action is in consonance with these considerations.

Cost Impact

There are approximately 18 de Havilland Model DHC-8-301, -311, and -315 series airplanes of U.S. registry would be affected by this proposed AD.

The actions that are currently required by AD 95-26-17 (modification of the airspeed limitations placard and revision of the Airplane Flight Manual) affect all 18 U.S.-registered airplanes. Those actions take approximately .5 work hour per airplane to accomplish, at an average labor rate of \$60 per work hour. The cost of required parts is negligible. Based on these figures, the cost impact on U.S. operators of the actions currently required is estimated to be \$540, or \$30 per airplane.

The new actions that are proposed in this AD action (installation of the terminating modification) would affect 14 U.S.-registered Model DHC-8-311 and -315 series airplanes. The proposed actions would take approximately 60 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Required parts would be provided by the manufacturer at no cost to operators. Based on these figures, the cost impact on U.S. operators of the proposed requirements of this AD is estimated to be \$50,400, or \$3,600 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of

the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

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 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 removing amendment 39-9475 (61 FR 5277, February 12, 1996), and by adding a new airworthiness directive (AD), to read as follows:

De Havilland, Inc.: Docket 95-NM-268-AD. Supersedes AD 95-26-17, amendment 39-9475.

Applicability: Model DHC-8-301, -311, and -315 series airplanes; as listed in de Havilland Service Bulletin S.B. 8-57-24, Revision 'A', dated September 26, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (f) 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 as indicated, unless accomplished previously.

(a) Within 30 days after February 27, 1996 (the effective date of AD 95-26-17, amendment 39-9475, accomplish the modification of the airspeed limitation placards (Modification 8/2498) in accordance with de Havilland Service Bulletin S.B. 8-57-24, Revision 'A', dated September 26, 1995.

(b) Prior to further flight following accomplishment of the modification required by paragraph (a) of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) by accomplishing either paragraph (b)(1) or (b)(2) of this AD, as applicable; and operate the airplane in accordance with those limitations.

(1) For Model DHC-8-301 series airplanes: Include the information specified in DHC-8 Model 301 Flight Manual, PSM 1-83-1A, Flight Manual Revision 57, dated September 26, 1995, which specifies a lower airspeed limitation at full flaps. This may be accomplished by inserting a copy of Flight Manual Revision 57 into the AFM.

(2) For Model DHC-8-311 and -315 series airplanes: Include the following statement in section 2, paragraph 2.4.1.2., of the AFM. This may be accomplished by inserting a copy of this AD in the AFM.

"Flap extended speed (V_{FE}): Flaps 35 degrees 130 knots IAS"

(c) For Model DHC-8-311 and -315 series airplanes: Within 2 years after the effective date of this AD, install Modification 8/2066 in accordance with de Havilland Service Bulletin S.B. 8-57-24, Revision 'A', dated September 26, 1995. Such installation constitutes terminating action for the requirements of paragraphs (a) and (b) of this AD.

Following accomplishment of Modification 8/2066, the airspeed limitations placard (Modification 8/2498) required by paragraph (a) of this AD and the AFM limitation required by paragraph (b) of this AD may be removed.

(d) Except as required by paragraph (e) of this AD: As of February 27, 1996 (the effective date of AD 95-26-17, amendment 39-9475), Modification 8/2498 must be accomplished in accordance with de Havilland Service Bulletin S.B. 8-57-24, Revision 'A', dated September 26, 1995, prior to installation of any outboard flap assembly having a part number and serial number that is listed in de Havilland Service Bulletin S.B.

8-57-24, Revision 'A', dated September 26, 1995.

(e) For Model DHC-8-311 and -315 series airplanes: As of two years after the effective date of this AD, prior to the installation of any outboard flap assembly having a part number and serial number that is listed in de Havilland Service Bulletin S.B. 8-57-24, Revision 'A', dated September 26, 1995, install Modification 8/2066 on the affected flap assembly in accordance with that service bulletin. Installation of this modification terminates the requirements specified in paragraphs (a), (b), and (d) of this AD.

(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 (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(g) Special flight permits may be issued in accordance with §§ 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.

Issued in Renton, Washington, on April 17, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 96-9933 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Ch. I

Federal Regulatory Review; Notice of Intent

AGENCY: Bureau of Indian Affairs, Interior

ACTION: Notice of intent.

SUMMARY: The President's Regulatory Reform Initiative requires Federal agencies to streamline the regulatory process, to remove obsolete regulations, and to reduce the regulatory burden on the general public. The Bureau of Indian Affairs (BIA) is committed to a goal of eliminating or improving over 500 pages of regulations by June 1, 1996. We will remove obsolete or unnecessary rules and rewrite existing regulations in the clearer, more precise and understandable format of "Plain English." This approach to regulation writing is intended to make rules easier to understand without changing their meaning.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Deputy Commissioner of Indian Affairs, Bureau of Indian Affairs, Mail Stop 4145-MIB, 1849 C Street NW., Washington, DC 20240, or telephone (202) 208-5116. Calls will be referred to the Deputy Commissioner's regulation reform team members for further coordination.

SUPPLEMENTARY INFORMATION: By June 1, 1996, the BIA will publish rules for public and tribal review. The rules

included in this notice were identified in the Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization report and by tribes and BIA program staff. Additional rules the Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization recommended for revision will be considered separately (25 CFR Part 61, Preparation of Rolls of Indians, 25 CFR Part 89, Attorney Contracts with Indian Tribes, 25 CFR Part 144, American Indian Trust Funds

Management Reform Act, and 25 CFR Part 287, Buy Indian Act).

This effort does not preclude any consultation currently planned or underway. Tribal consultation on regulations with substantive rulemaking will continue as planned. For the rules involving only "Plain English" revision, consultation will be scheduled if the comments received following publication of the proposed rules indicate a need for further consultation.

LIST OF RULES THE BIA WILL REWRITE PLAIN ENGLISH AND PUBLISH AS PROPOSED RULES

25 CFR part	Title of rule
1	Applicability of Rules of the Bureau of Indian Affairs.
2	Appeals from Administrative Actions.
26	Employment Assistance for Adult Indians.
27	Vocational Training for Adult Indians.
31	Federal Schools for Indians.
33	Transfer of Indian Education Functions.
43	Maintenance and Control of Student Records in Bureau Schools.
152	Issuance of Patents in Fee, Certificates of Competency, Removal of Restrictions, and Sale of Certain Indian Lands.
154	Osage Roll, Certificate of Competency.
169	Rights-of-Way over Indian Lands.
175	Indian Electric Power Utilities.
273	Education Contracts under Johnson O'Malley Act.

LIST OF RULES CURRENTLY IN THE RULEMAKING PROCESS—BIA WILL MAKE SUBSTANTIVE REVISIONS, REMOVE OBSOLETE OR UNNECESSARY REQUIREMENTS, REWRITE IN "PLAIN ENGLISH," AND PUBLISH AS PROPOSED OR FINAL RULES

25 CFR part	Title of rule
5	Preference in Employment.
10	Adult and Juvenile Detention Standards for Facilities and Programs.
12	The Indian Police.
36	Minimum Academic Standards for the Basic Education of Indian Children and National Criteria for Dormitory Situations.
39	The Indian School Equalization Program.
40	Administration of Educational Loans, Grants and Other Assistance for Higher Education.
41	Grants to Tribally Controlled Community Colleges and Navajo Community College.
46	Administration of the Adult Education Program—NEW RULE.
81	Tribal Reorganization Under a Federal Statute.
82	Petitioning Procedures for Tribes Reorganized Under Federal Statute and Other Organized Tribes.
101	Loans to Indians from the Revolving Loan Fund.
103	Loan Guaranty, Insurance and Interest Subsidy.
150	Land Records and Title Documents.
162	Leasing and Permitting.
166	General Grazing Regulations.
170	Roads of the Bureau of Indian Affairs.
171	Operation and Maintenance.
211	Leasing of Tribal Lands for Mining.
212	Leasing of Allotted Lands for Mining.
213	Leasing of Restricted Lands of Members of Five Civilized Tribes, Oklahoma for Mining, Except Oil and Gas.
214	Leasing of Osage Reservation Lands, Oklahoma, for Mining, Except Oil and Gas.
215	Lead and Zinc Mining Operations and Leases, Quapaw Agency.
216	Surface Exploration, Mining, and Reclamation of Lands.
217	Management of Tribal Assets of Ute Indian Tribe, Uintah and Ouray Reservation, Utah, by the Tribe and the Ute Distribution Corp.
227	Leasing of Certain Lands in Wind River Indian Reservation, Wyoming, for Oil and Gas Mining.
256	Housing Improvement Program.
286	Indian Business Development Program.

LIST OF RULES THAT ARE OBSOLETE OR REPLACED BY NEW RULES—BIA WILL REMOVE THESE RULES

25 CFR part	Title of rule
45	Special Education.
65	Preparation of a Membership Roll of Delaware Indians of Western Oklahoma.
66	Preparation of Rolls of Delaware Indians.
76	Enrollment of Indian of the San Pasqual Band of Mission Indians in California.
142	Operation of U.S.M.S. "North Star" between Seattle, Washington and Stations of the Bureau of Indian Affairs and other Government Agencies, Alaska.
250	Indian Fishing—Hoopa Valley Indian Reservation.
271	Contracts under Indian Self-determination Act—Replaced with new Part 900.
272	Grants under Indian Self-determination Act—Replaced with new Part 900.
274	School Construction Contracts or Services for Tribally Operated Previously Private Schools.
276	Uniform Administrative Requirements for Grants—Replaced with new Part 900.
278	Special Grants for Economic Development and Core Management Grants to Small Tribes—Replaced with new Part 900.

Dated: April 12, 1996.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96-9745 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-02-P

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV-075-FOR]

West Virginia Permanent Regulatory Program

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

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of proposed amendments to the West Virginia permanent regulatory program (hereinafter referred to as the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendments concern revisions to the West Virginia Surface Mining Reclamation Regulations. The amendments are intended to improve the clarity and effectiveness of the West Virginia program, and to revise the State program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received on or before 4:00 p.m. on May 23, 1996. If requested, a public hearing on the proposed amendments will be held at 1:00 p.m. on May 20, 1996. Requests to present oral testimony at the hearing must be received on or before 4:00 p.m. on May 8, 1996.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Mr. James C. Blankenship, Jr., Director, Charleston Field Office at the address listed below.

Copies of the proposed amendment, the West Virginia program, and the administrative record on the West Virginia program are available for public review and copying at the addresses below, during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting the OSM Charleston Field Office.

Mr. James C. Blankenship, Jr., Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301, Telephone: (304) 347-7158
West Virginia Division of Environmental Protection, 10 McJunkin Road, Nitro, West Virginia 25143, Telephone: (304) 759-0515.

In addition, copies of the proposed amendments are available for inspection during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Morgantown Area Office, 75 High Street, Room 229, P.O. Box 886, Morgantown, West Virginia 26507, Telephone (304) 291-4004

Office of Surface Mining Reclamation and Enforcement, Beckley Area Office, 323 Harper Park Drive, Suite 3, Beckley, West Virginia 25801, Telephone (304) 255-5265.

FOR FURTHER INFORMATION CONTACT: Mr. James C. Blankenship, Jr., Director, Charleston Field Office; Telephone: (304) 347-7158.

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program

On January 21, 1981, the Secretary of the Interior conditionally approved the West Virginia program. Background information on the West Virginia program, including the Secretary's findings, the disposition of comments,

and the conditions of the approval can be found in the January 21, 1981, Federal Register (46 FR 5915-5956). Subsequent actions concerning the West Virginia program and previous amendments are codified at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Discussion of the Proposed Amendment

By letter dated April 2, 1996 (Administrative Record Number WV-1024), the West Virginia Division of Environmental Protection (WVDEP) submitted an amendment to its approved permanent regulatory program pursuant to 30b CFR 732.17. The amendment contains revisions to the West Virginia Surface Mining Reclamation Regulations (CSR section 38-2-1 *et seq.*).

The last time the State regulations were significantly revised was on February 21, 1996. The Director partially approved the revisions in the February 21, 1996, Federal Register (61 FR 6511-6537). See 30 CFR 948.15 for the provisions partially approved. See 30 CFR 948.16 for required amendments.

Proposed Amendments

1. Section 38-2-2-106 Definition of "Safety factor." This definition is revised to mean the ratio of the sum of the resisting forces to the sum of the loading or driving forces as determined by acceptable engineering practices. Prior to this change, the term was defined as the ratio of the sum of the resisting forces to the sum of the loading forces.

2. Section 38-2-3.2(e) Readvertisement of permit applications. This provision is amended by adding the phrase, "that do not significantly affect the health, safety or welfare of the public and," to the first sentence. With this change, a limited number of minor

changes may be grouped and advertised in one additional notice if the changes do not significantly affect the health, safety or welfare of the public.

3. Section 38-2-2.6(h)(5) Certification of drainage/sediment control structure designs. This provision is amended by changing a cited reference concerning dams. "Article 5D of Chapter 20" is deleted and replaced by "Article 14 of Chapter 22."

4. Section 38-2-3.8(c) Revision or reconstruction of existing structures and support facilities. This provision is amended by adding the following language: "Provided, that those structures and facilities, where it can be demonstrated that reconstruction or revision would result in greater environmental harm and the performance standards set forth in the Act and these regulations can otherwise be met, may be exempt from revision or reconstruction." This amendment, in effect, provides an alternative to requiring revision or reconstruction of structures or support facilities in cases where greater environmental harm would result from the revisions or reconstruction.

5. Section 38-2-3.27 Permit renewals and extensions. The introductory paragraph of this provision is amended by deleting the word "may" and adding in its place the word "shall." In addition, language has been deleted that required all backfilling and grading be completed within 60 days prior to the expiration date of the permit, and that an application for Phase I bond release be filed prior to the expiration date of the permit. As amended, the provision provides that the Director of the Division of Environmental Protection (DEP) shall waive the requirements for renewal if the permittee certifies in writing that all coal extraction is completed, that all backfilling and regrading will be completed and reclamation activities are ongoing.

6. Section 38-2-4.4 Infrequently used access road. This provision is revised by deleting and adding rule citations, as amended, infrequently used access roads may not be exempt from the requirements of §§ 38-2-4.2, 4.7(a), 4.8, 4.9, and 5.3.

7. Section 38-2-4.12 Certification of primary roads. This provision is amended by deleting the requirement that changes documented in the as-built plans be submitted to the Director of DEP as a permit revision. In its place, the following language is added: "If as-built plans are submitted, the certification shall describe how and to what extent the construction deviates from the proposed design, and shall explain how and certify that the road

will meet performance standards. In effect, this amendments replaces a requirement that all changes documented as-built plans be submitted as a permit revision, with a requirement that when changes are certified, the certification shall include an explanation and certification that the changes will meet performance standards.

8. Section 38-2-5.4(c) Safety standards for embankment type structures. The first paragraph of this provision is amended by deleting the phrase "which may include slurry impoundments." With this amendment, the provision's safety standards apply to all embankment type sediment control or other water retention structures.

9. Section 38-2-11.6(a) Review of permits for adequacy of bond. This provision is amended to add a requirement that permits will not be renewed until the appropriate amount of bond has been posted.

Also, subparagraphs (a) (2), (3), and (4) are deleted. These subparagraphs provided that existing permits (for underground mines, preparation plants, and coal refuse sites) shall be subject to the site-specific bond criteria of § 38-2-11.6 at the time of application for renewal or mid-term review, shall not be renewed by the Director of DEP until the appropriate amount of bond is posted. See the first paragraph in 11.6(a) for language similar to that which is being deleted.

10. Section 38-2-11.6(c)(6), (d)(6), (e)(5), (f)(5) Bond reduction credits. These provisions are being amended to delete, in various places, the phrase "within five (5) years of the date of SMA approval." In effect, the amount of bond reduction credits assigned is no longer contingent upon the "five years from the date of SMA approval" criterion.

11. Section 38-2-12.2(e) Bond release—chemical treatment. The existing language of this provision is deleted and replaced by the following:

Notwithstanding any other provisions of this rule, no bond release or reduction will be granted if, at the time, water discharged from or affected by the operation requires chemical treatment in order to comply with applicable effluent limitations or water quality standards; Provided, That the Director may approve a request for Phase I but not Phase II or III, release if the applicant demonstrates to the satisfaction of the Director that either:

- (A) The remaining bond is adequate to assure long term treatment of the drainage; or
- (B) The operator has irrevocably committed other financial resources which are adequate to assure long term treatment of the drainage; Provided, That the alternate financial resources must be in acceptable form, and meet the standards set forth in Section 11 of

the Act and Section 11 of these regulations; Provided, however, That alternate financial arrangements shall provide a mechanism whereby the Director can assume management of the resources and treatment work in the event that the operator defaults for any reason; And provided further, That default on a treatment obligation under this paragraph shall be considered equivalent to a bond forfeiture, and the operator will be subject to penalties and sanctions, including permit blocking, as if a bond forfeiture had occurred.

In order to make such demonstration as referenced above, the applicant shall address, at a minimum, the current and projected quantity and quality of drainage to be treated, the anticipated duration of treatment, the estimated capital and operating cost of the treatment facility, and the calculations which demonstrate the adequacy of the remaining bond or of the alternate financial resources.

In effect, the added language would allow, under the specified circumstances, Phase I bond release on operations which require chemical treatment in order to comply with applicable effluent limitations or water quality standards.

The Director notes that the State's definition of "chemical treatment" at § 38-2-2.20 has only been partially approved by OSM. Specifically, the language of the definition that excludes passive treatment systems from being considered "chemical treatment" was not approved to the extent that such passive treatment systems would be applied in the context of § 38-2-12.2(e) to authorize bond release for sites with discharges that require passive treatment to meet discharge standards. For a complete explanation of the partial disapproval of the State's definition of "chemical treatment," see Finding B-2, in the February 21, 1996, Federal Register (61 FR 6511) page 6517.

12. Section 38-2-14.14(e)(4) Valley fills—rock core chimney drains. This provision is being amended by deleting the third sentence, which concerns the control of surface water runoff, and replacing that language with the following:

Surface water runoff from areas above and adjacent to the fill shall be diverted into properly designed and constructed stabilized diversion channels which have been designed using best current technology to safely pass the peak runoff from a 1.0 year, 24-hour precipitation event. The channel shall be designed and constructed to ensure stability of the fill, control erosion, and minimize water infiltration into the fill.

13. Section 38-2-14.15(m) Coal processing waste disposal. This provision is being amended by deleting the prohibition at 14.15(m)(1) that coal processing waste "will not contain acid producing or toxic forming material." A

new provision at 14.15(m)(2) is added to provide as follows:

(2) The coal processing waste will not be placed in the backfill unless it has been demonstrated to the satisfaction of the Director that: (A) the coal processing waste to be placed based upon laboratory testing to be non-toxic and/or non-acid producing; or (B) an adequate handling plan including alkaline additives has been developed and the material after alkaline addition is non-toxic and/or non-acid producing.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comments on the proposed amendments submitted by the State of West Virginia to its permanent regulatory program. Specifically, OSM is seeking comments on the revisions to the State's regulations that were submitted on April 2, 1996 (Administrative Record No. WV-1024). Comments should address whether the proposed amendments satisfy the applicable program approval criteria of 30 CFR 732.15. If the amendments are deemed adequate, they will become part of the West Virginia 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 OSM Charleston Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by the close of business on May 8, 1996. If no one requests an opportunity to testify at the public hearing by that date, 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 remarks and appropriate questions.

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

Public Meeting

If only one person or group requests to testify at a hearing, a public meeting, rather than a public hearing, may be held, and the results of the meeting included in the Administrative Record.

Persons wishing to meet with OSM representatives to discuss the proposed amendments may request a meeting at the OSM Charleston Field Office listed under **ADDRESSES** 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 in advance at the locations listed under **ADDRESSES**. A written summary of each public meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 (Reduction of Regulatory Burden) for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary, and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (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 the Surface Mining Control and Reclamation Act (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 the Office of Management and Budget 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.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: April 12, 1996.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 96-9937 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 110

[CGD07-96-017]

RIN 2115-AA98

Special Anchorage Areas; Ashley River, Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish two new anchorage areas in the Ashley River, Charleston, South

Carolina to replace an existing anchorage. Due to pending construction of two 1000 ft piers at the George M. Lockwood Municipal Marina, in Charleston, the current anchorage will not be available for anchoring recreational vessels. The Municipal Marina has received a construction permit to build the piers from the U.S. Army Corps of Engineers. The new anchorages will be necessary to replace the one described in 33 CFR 110.72d. The proposed anchorages are across the Ashley River from the current anchorage and though not designated as Federal anchorages, they are already widely used by recreational vessels as overflow from the current anchorage.

DATES: Comments must be received on or before June 24, 1996.

ADDRESSES: Comments should be mailed to the Captain of the Port Charleston, Marine Safety Office Charleston, South Carolina 29401-1899. The comments will be available for inspection and copying at 196 Tradd Street, Charleston, SC between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may also be hand delivered to this address.

FOR FURTHER INFORMATION CONTACT: CW04 R.M. Webber, Project Officer, Tel: (803) 724-7690.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this rulemaking by submitting written views, data or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD07-96-017) and the specific section of this proposal to which their comments apply, and give reasons for each comment. The regulations may be changed in the light of comments received. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal.

No public hearing is planned, but one may be held if written requests for a hearing are received, and it is determined that the opportunity to make oral presentations will aid the rulemaking process.

Discussion of Proposed Regulations

The City Marina Company and the City of Charleston have been granted, by the U.S. Army Corps of Engineers, a permit to build two 1000 foot piers on the south side of the Municipal Marina. These piers will cross an existing anchorage eliminating most of the anchorages within that area that have over six feet of water at mean low water. As the anchorage is extensively used by recreational vessels, two new anchorage areas are being proposed to

accommodate vessels that will be displaced when the new piers are built. The new anchorages are already being used by recreational vessels as overflow from the existing anchorage. To date, no problems have arisen from recreational vessels anchoring in these areas. Since the marina plans were published in the local newspaper, there has been considerable public interest in establishing new anchorages to replace the existing anchorage.

Proposed Ashley River Anchorage Number One would be located on the waters lying within an area across the Ashley River Channel from the George M. Lockwood Municipal Marina bounded by the southwest side of the channel beginning at latitude 32°46'43.7"N, longitude 079°57'19.3"W; thence to latitude 32°46'38.0"N, longitude 079°57'24.0"W; thence to latitude 32°46'32.0"N, longitude 079°57'15.5"W; thence to latitude 32°46'29.0"N, longitude 079°57'00.9"W; thence back to the beginning following the southwest boundary of the Ashley River Channel. All coordinates referenced use Datum: NAD 1983.

Proposed Ashley River Anchorage Number Two would be located on the waters lying within an area across the Ashley River Channel from the Ashley Marina bounded by the southwest side of the channel beginning latitude 32°46'53.0"N, longitude 079°57'34.5"W; thence to latitude 32°46'50.5"N, longitude 079°57'40.5"W; thence to latitude 32°46'46.0"N, longitude 079°57'34.5"W; thence to latitude 32°46'49.0"N, longitude 079°57'28.7"W; thence back to the beginning following the southwest boundary of the Ashley River Channel. All referenced coordinates use Datum: NAD 1983.

These proposed anchorage areas will provide that vessels no more than sixty-five feet in length, when anchored in the anchorage areas, shall not be required to carry or exhibit the white anchor lights required by the Navigation Rules.

Regulatory Evaluation

This proposal is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget 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 proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and

procedures of DOT is unnecessary. The proposed anchorage areas described in this notice are currently being used by recreational vessels as over flow from the existing anchorage.

Since the impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposed rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this proposal and has determined pursuant to Section 2.B.2. of Commandant Instruction M16475.1B, that this action is categorically excluded from further environmental documentation. A Categorical Exclusion Determination and Environmental Analysis Checklist are available in the docket for inspection or copying at the location listed in **ADDRESSES**.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to revise Part 110 of Title 33, Code of Federal Regulations, as follows:

PART 110—[AMENDED]

1. The authority citation for Part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 2030, 2035 and 2071; 49 CFR 1.46 and 33 CFR 1.05-1(g). Section 110.1a and each section listed in 110.1a are also issued under 33 U.S.C. 1223 and 1231.

2. Section 110.72d is revised to read as follows:

§ 110.72d Ashley River Anchorage Areas, SC.

The following locations are special anchorage areas:

(a) Ashley River Anchorage 1. The waters lying within an area across the Ashley River Channel from the George M. Lockwood Municipal Marina bounded by the southwest side of the channel beginning at latitude

33°46'43.7" N, longitude 079°57'19.3" W; thence to latitude 32°46'38.0" N, longitude 079°57'24.0" W; thence to latitude 32°46'32.0" N, longitude 079°57'15.5" W; thence to latitude 32°46'29.0" N, longitude 079°57'00.9" W; thence back to the beginning following the southwest boundary of the Ashley River Channel. All coordinates referenced use Datum: NAD 1983.

(b) Ashley River Anchorage 2. The waters lying within an area across the Ashley River Channel from the Ashley Marina bounded by the southwest side of the channel beginning at latitude 33°46'53.0" N, longitude 079°57'34.5" W; thence to latitude 32°46'50.5" N, longitude 079°57'40.5" W; thence to latitude 32°46'46.0" N, longitude 079°57'34.5" W; thence to latitude 32°46'49.0" N, longitude 079°57'28.7" W; thence back to the beginning following the southwest boundary of the Ashley River Channel. All coordinates referenced use Datum: NAD 1983.

Dated: April 10, 1996.

P.J. Cardaci,

*Captain, U.S. Coast Guard, Acting
Commander, Seventh Coast Guard District.*

[FR Doc. 96-9879 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-14-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 262, 264, 265, and 270

[IL-64-2-5807; FRL-5459-9]

Hazardous Waste Treatment, Storage, and Disposal Facilities and Hazardous Waste Generators; Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability.

SUMMARY: This notice announces the availability of additional data that are being considered by the EPA in amending the air emission standards for hazardous waste treatment, storage, and disposal facilities (TSDF) that were published December 6, 1994 under the authority of the Resource Conservation and Recovery Act (RCRA), as amended (59 FR 62896). This notice addresses the narrow issue of an Other Thermal Treatment Facility subject to regulation under subpart P of Part 265 (40 CFR 265.370 through 265.383) being eligible to receive spent activated carbon which is a hazardous waste. The additional data are available for public inspection at the EPA RCRA Docket Office.

DATES: Comments on these additional data will be accepted through May 7, 1996.

DOCKET: The information referenced by today's notice is available for public inspection and copying in the RCRA docket. The RCRA docket numbers pertaining to this rulemaking are F-91-CESP-FFFFF, F-92-CESA-FFFFF, F-94-CESF-FFFFF, F-94-CE2A-FFFFF, and F-95-CE3A-FFFFF. The RCRA docket is located at Crystal Gateway, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia. Hand delivery of items and review of docket materials are made at the Virginia address. The public must have an appointment to review docket materials. Appointments can be scheduled by calling the Docket Office at (703) 603-9230. The mailing address for the RCRA docket office is RCRA Information Center (5305W), U. S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

COMMENTS: Written comments regarding these data may be mailed to the Docket Clerk at the above-mentioned Washington, DC mailing address. Please send an original and two copies of all comments, and refer to Docket Number F-96-CE4A-FFFFF. The EPA will consider comments on the additional data that are received through May 7, 1996.

FOR FURTHER INFORMATION CONTACT: For information about this notice and the associated rulemaking contact the RCRA Hotline at (703) 412-9877 or toll-free at 1-800-424-9346.

SUPPLEMENTARY INFORMATION: This notice is available on the EPA's Clean-up Information Bulletin Board (CLU-IN). To access CLU-IN with a modem of up to 28,800 baud, dial (301) 589-8366. First time users will be asked to input some initial registration information. Next, select "D" (download) from the main menu. Input the file name "RCRA-NDA.496" to download this notice. Follow the on-line instructions to complete the download. More information about the download procedure is located in Bulletin 104; to read this type "B 104" from the main menu. For additional help with these instructions, telephone the CLU-IN help line at (301) 589-8368.

On December 6, 1994, the EPA published in the Federal Register (59 FR 62896) under authority of the RCRA standards requiring the use of air emission controls on certain tanks, surface impoundments, and containers at hazardous waste TSDF. These standards are codified in 40 CFR parts 264 and 265 under subpart CC (referred to as the "subpart CC standards").

This Notice of Data Availability addresses the appropriateness of an Other Thermal Treatment Facility subject to regulation under subpart P of Part 265 (40 CFR 265.370 through 265.383) being eligible to receive spent activated carbon which is a hazardous waste. In the December 6, 1994 final subpart CC standards (59 FR 62896), the EPA established a requirement that spent activated carbon removed from a control device had to be managed at particular types of facilities, namely regulated incinerators, regulated boilers or industrial furnaces, or "thermal treatment units that [are] permitted under subpart X of 40 CFR part 264 or subpart P of [Part 265]". See 40 CFR 265.1033(l)(1) as promulgated at 59 FR at 62935 (Dec. 6, 1994). A parallel requirement was contained in 40 CFR 264.1033(m), but no reference to subpart P was included (59 FR at 62927). In the February 9, 1996 technical correction notice, the EPA amended these provisions to clarify that they apply only to activated carbon which is a hazardous waste, and that interim status incinerators and boilers and industrial furnaces which had certified compliance could receive such activated carbon. See 61 FR at 4910, 4911, and 4913. In so doing, the EPA removed the reference to subpart P facilities in 265.1033(l)(1), thus removing such facilities from eligibility to receive hazardous waste spent activated carbon from interim status facilities, but did not provide any explanation for this omission.

The Response to Comment Background Information Document to the Final Rule does not completely clarify the EPA's intent. At one point the EPA mentioned subpart P facilities as potentially eligible to receive hazardous waste spent activated carbon (BID page 6-113 and 114), but at other points indicated that only other thermal treatment units permitted under subpart X would be eligible (BID at 6-116 and 117).

After publication of the February 9 notice, the EPA received a letter from a subpart P facility which reactivates spent activated carbon questioning the omission of subpart P facilities from amended 265.1033(l). The EPA is noticing this letter, along with memoranda documenting EPA's further contacts with the facility, for comment. The EPA is also seeking comment on the following issues. The subpart CC standards specify the types of facilities that can manage hazardous waste spent activated carbon so that EPA can ensure that any adsorbed hazardous organic

constituents released from the carbon are adequately controlled or destroyed, rather than emitted to the atmosphere (BID page 6-115). It is not clear that the subpart P standards, taken by themselves, provide this assurance, since subpart P standards do not contain substantive air emission controls. Thus, in addition to soliciting comment on the information in the docket, the EPA solicits comment on whether some further limitation should be necessary if subpart P facilities are to be eligible. For example, should eligibility be limited to facilities whose regeneration units provide adequate protection from the emission of desorbed organics? If so, is it appropriate to require compliance with subpart CC, or comparable controls to ensure such protection? The EPA will consider all comments on the new data received by the close of the comment period when making a final regulatory determination on the regulatory requirements for this regulation.

This notice does not represent the only provision of the final subpart CC standards which the EPA is considering revising. The EPA is planning to publish technical amendments to the rule within the next two months which will include revisions described in the August 14, 1995 Federal Register document entitled, "Proposed rule; data availability" (60 FR 41870), as well as a finding on the issue discussed in today's notice.

Dated: April 11, 1996.

Richard Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 96-9973 Filed 4-22-96; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MM Docket No. 96-90, FCC 96-169]

Telecommunications Act of 1996; Broadcast License Terms

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: We issue this Notice of Proposed Rule Making ("NPRM") to implement Section 203 of the Telecommunications Act of 1996 ("Telecom Act") (Broadcast License Terms). Section 203 eliminates the statutory distinction between the maximum allowable license terms for television stations and radio stations, and provides that such licenses may be

for terms "not to exceed 8 years." Amendment of the Commission's Rules is necessary to conform them to Section 203 of the Telecom Act. We seek comment on our proposal to amend our rules to extend broadcast license terms to 8 years, as well as on our proposal for implementing this change within the framework of existing license renewal cycles.

DATES: Comments are due on or before May 20, 1996, and reply comments are due on or before June 4, 1996. Written comments by the public on the proposed and/or modified information collections are due on or before May 20, 1996.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Robert Somers (202-418-2130), Mass Media Bureau.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Notice of Proposed Rule Making in MM Docket No. 96-90, FCC 96-169, adopted April 11, 1996 and released April 12, 1996. The complete text of this Notice of Proposed Rule Making is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street NW., Washington, D.C., and also may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, N.W., Suite 140, Washington, DC 20037.

Synopsis of Notice of Proposed Rule Making Extending License Terms for Broadcast Facilities

1. Section 307(c) of the Communications Act of 1934, as amended, 47 U.S.C. § 307(c), authorizes the Commission to establish the period or periods for which licenses shall be granted or renewed. Prior to the enactment of the Telecom Act, Section 307(c) provided that the licenses of television stations, including low power TV stations, could be issued for a term of no longer than 5 years. It further provided that license terms for radio stations, including auxiliary facilities, could be for a period not to exceed 7 years. These were the maximum allowable license terms and the Commission had the discretion to grant or renew a broadcast license for a shorter period if the public interest, convenience, and necessity would be served by such action. Consistent with these statutory provisions, Section 73.1020 of the Commission's Rules currently states that "[r]adio broadcasting stations will ordinarily be renewed for 7 years and TV broadcast stations will be renewed for 5 years.

However, if the FCC finds that the public interest, convenience and necessity will be served thereby, it may issue either an initial license or a renewal thereof for a lesser term." Section 73.1020 also sets forth a renewal schedule for broadcast stations based on the geographical region of the country in which each station is located.

2. Section 203 of the Telecom Act amends Section 307(c) of the Communications Act to read as follows:

Each license granted for the operation of a broadcasting station shall be for a term of not to exceed 8 years. Upon application therefor, a renewal of such license may be granted from time to time for a term of not to exceed 8 years from the date of expiration of the preceding license, if the Commission finds that public interest, convenience, and necessity would be served thereby. Consistent with the foregoing provisions of this subsection, the Commission may by rule prescribe the period or periods for which licenses shall be granted and renewed for particular classes of stations, but the Commission may not adopt or follow any rule which would preclude it, in any case involving a station of a particular class, from granting or renewing a license for a shorter period than that prescribed for stations of such class if, in its judgment, the public interest, convenience, or necessity would be served by such action.

3. Length of License Terms. Although the language of Section 203 of the Telecom Act lengthens the maximum permissible broadcast license term to 8 years for both television and radio stations, the statute does not require the Commission to extend license terms to 8 years as a matter of course. The statutory language provides that licenses are to have terms "not to exceed 8 years" and expressly states that the Commission "may" grant renewals for terms not to exceed 8 years if the public interest would be served thereby. Moreover, the language indicates that the Commission may, by rule, adopt different license terms for different classes of stations. Given this discretion under the statute regarding how we might amend our rules, we believe it is appropriate to determine through notice and comment rulemaking the proper length of broadcast license terms as a general matter.

4. For several reasons, we propose to amend our Rules to provide that broadcast licenses ordinarily have the maximum 8-year term authorized under the statute. First, the practice of ordinarily granting television and radio licenses for the maximum terms will reduce the burden to broadcasters of seeking the periodic renewal of their licenses and the associated burdens on the Commission. Second, it is consistent with past Commission practice; our

current rules provide for the maximum license terms in accordance with previous statutory maximum terms of 5 years for television stations and 7 years for radio stations. Finally, this approach is consistent with the legislative history of the Telecom Act. While the statutory language provides the Commission discretion in this area, the Conference Report indicates that Congress intended the Commission to adopt the maximum term, stating that Section 203 of the Telecom Act "extends the license term for broadcast licenses to eight years for both television and radio."

5. We seek comment on this proposal to amend Sections 73.1020 and 74.15 of our Rules to provide that the Commission will ordinarily grant licenses for the 8-year terms allowed by Section 203 of the Telecom Act. Irrespective of what the Commission ultimately determines to be an appropriate standard license term, we note that Section 203 of the Telecom Act explicitly reserves the Commission's authority to grant individual licenses for less than the statutory maximum if the public interest, convenience, and necessity would be served by such action.

6. Classes of Stations. Section 203 of the Telecom Act states in part:

"the Commission may by rule prescribe the period or periods for which licenses shall be granted and renewed for particular classes of stations. * * * While this provision provides us authority to designate different license terms for particular classes of stations (provided that they do not exceed 8 years), we propose to treat all but experimental broadcast stations uniformly.

7. With respect to television and radio stations the statute eliminates the current distinction between these services for purposes of establishing the maximum allowable license terms. In this regard, the legislative history states: "By applying a uniform license term * * * for all broadcast station licenses, the Committee simply recognizes that there is no reason for longer radio license terms than for television licenses. The Committee intends that applying a uniform license term * * * for radio and television licenses will enable the Commission to operate more efficiently in the awarding of new or renewed licenses for all broadcast licenses." H.R. Rep. No. 104-204, Section 304, 104th Cong., 1st Sess. 122 (1995).

8. Similarly, we propose to track the approach we take with full-service stations and adopt an 8-year license term for FM and TV translator facilities and low power TV stations, as well as for international broadcasting stations. This approach is consistent with our

previous decision to treat these different classes of stations uniformly. See Report and Order in MM Docket No. 92-168, 59 FR 63049, December 7, 1994. We further propose to continue our practice, set forth in Sections 74.15(b) and (c) of our Rules, of tying the license terms for auxiliary and booster facilities to the license terms of the broadcast stations with which they are associated. We seek comment on these proposals.

9. Finally, we propose to continue our practice, set forth in Section 74.15(a) of our Rules, of issuing licenses for experimental broadcast stations for a term of 1 year. We believe that a longer license term would not be warranted for this class of station and seek comment on this proposal.

10. Implementation of Amended License Term Provisions. Section 203 of the Telecom Act and the legislative history are silent as to whether existing broadcast station licenses may be modified immediately to conform to any new license terms that may be adopted.

11. The implementation issue is important because of the logistics involved in renewing broadcast licenses. Under Sections 73.1020 and 74.15 of the Commission's Rules, all of the licenses for a particular class of broadcast stations expire at fixed intervals over a 3-year period. To stagger the processing of renewal applications and thus perform this task more efficiently, the country is divided into 18 different regions containing 1 or more states for purposes of establishing synchronized schedules for radio and television license renewals. The radio renewal schedule and the television renewal schedule operate on separate and distinct cycles that do not run concurrently. Accordingly, once all radio licenses have been renewed as scheduled, there is a 50-month hiatus before the radio renewal cycle begins again. Similarly, once all television licenses have been renewed as scheduled, there is also a 26-month hiatus before the television renewal cycle begins again.

12. Because of the cyclical nature of this process, any change in the length of the license term implemented in the middle of a renewal cycle could adversely affect the synchronization of the whole process.

13. By the time the Telecom Act of 1996 was enacted in February 1996, the renewal cycle had already begun for radio stations in several regions of the country. The practical effect of this situation is that radio licenses that have already been renewed for the current maximum allowable 7-year term will have shorter terms than radio licenses renewed later in the renewal cycle, if we

adopt the 8-year term we now propose. When these previously granted licenses expire the radio renewal process will no longer be synchronized. We wish to maintain the efficiencies inherent in the existing synchronized schedule of renewal cycles. Should we ultimately adopt an 8-year license term, we therefore propose to implement it as follows. For broadcast renewal applications that are granted after the effective date of a decision in this proceeding, we propose to ordinarily grant the renewed license for the maximum proposed term of 8 years. For renewal applications that have been filed as part of the current renewal cycle (*i.e.*, the cycle beginning October 1, 1995 for radio stations) and that have been granted only the maximum 7-year license term provided under our current rules because they were processed prior to a decision in this proceeding, we propose to extend by rule the already renewed 7-year license term for such stations to the proposed 8-year term. These licenses will thus be modified by rule to have the new maximum term and will come up for renewal in synchronization with future radio renewal cycles. The Commission adopted a similar approach in 1983 when it extended existing common carrier and satellite licenses from 5 to 10 years. As noted in that decision, the Commission's authority to modify the provisions of existing licenses by rulemaking has been upheld on several occasions. This type of approach is also consistent with the discretion we are given by the Telecom Act to prescribe rules governing the period or periods for which licenses are granted for particular classes of stations. We solicit comment on this proposed approach for implementing the new maximum broadcast license terms authorized by the Telecom Act.

14. By this Notice of Proposed Rule Making we request comments on how to best implement the provisions of Section 203 of the Telecom Act. Specifically, we seek comment on whether we should amend Sections 73.1020, 73.733, and 74.15 of the Commission's Rules to provide that broadcast licenses ordinarily should have 8-year terms, the maximum provided under the Telecom Act. We also seek comment on the treatment of different classes of broadcast stations and how best to implement the transition to any amended license term in an equitable manner given that the renewal cycle has already begun.

15. This action is taken pursuant to authority found in Sections 4(i), 303(r), and 307(c) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i),

303(r), and 307(c), and Sections 0.204(b), 0.283 and 1.45 of the Commission's Rules, 47 CFR 0.204(b), 0.283 and 1.45.

List of Subjects

47 CFR Part 73

Radio broadcasting, Television broadcasting.

47 CFR Part 74

Radio broadcasting, Television broadcasting.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96-10051 Filed 4-22-96; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 040896C]

50 CFR Part 630

Atlantic Swordfish Fisheries; Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Additional public hearing; request for comments.

SUMMARY: On April 12, 1996, NMFS announced four public hearings to receive comments from fishery participants and other members of the public regarding proposed amendments to regulations governing the Atlantic swordfish fisheries. NMFS now announces one additional public hearing.

DATES: Comments on the proposed rule must be received on or before May 2, 1996. The hearing is scheduled for April 25, 1996, from 7-10 p.m.

ADDRESSES: Written comments should be sent to William Hogarth, Acting Chief, Highly Migratory Species Management Division, Office of Fisheries Conservation and Management (F/CM), National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. Clearly mark the outside of the envelope "Atlantic Swordfish Comments." The additional hearing will be held at the following location:

Pompano Beach Civic Center
1801 NE 6th Street
Pompano Beach, FL 32060

FOR FURTHER INFORMATION CONTACT: William Hogarth at 301-713-2339; Kevin Foster at 508-281-9260.

SUPPLEMENTARY INFORMATION: NMFS announces an additional public hearing on the Atlantic swordfish proposed rule (61 FR 15212, April 5, 1996). The announcement of the four original meetings was published April 12, 1996 (61 FR 16236) and included background information that is not repeated here.

Authority: 16 U.S.C. 1801 *et seq.* and 16 U.S.C. 971 *et seq.*

Dated: April 16, 1996.

Richard W. Surdi,

Acting Director, Office of Fisheries

Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96-9868 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-22-F

50 CFR Part 659

[Docket No. 960409106-6106-01; I.D. 031196A]

RIN 0648-AG26

Shrimp Fishery Off the Southern Atlantic States; Amendment 1

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement Amendment 1 to the Fishery Management Plan for the Shrimp Fishery of the South Atlantic Region (FMP). Amendment 1 would: add rock shrimp to the FMP's management unit; prohibit trawling for rock shrimp in an area off the Florida east coast; require permits for dealers, vessels, and vessel operators involved in the rock shrimp fishery; require dealers to report information needed to monitor the fishery; and require that the initial sale, trade, barter, or transfer of rock shrimp harvested from the exclusive economic zone (EEZ) occur only between permitted dealers and permitted vessels. Based on a preliminary evaluation of Amendment 1, NMFS disapproved the measure requiring a vessel operator permit. The proposed rule would implement the remaining measures in Amendment 1. The intended effect is to protect critical habitat and conserve and manage the rock shrimp fishery.

DATES: Written comments must be received on or before June 7, 1996.

ADDRESSES: Comments on the proposed rule must be sent to the Southeast

Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Requests for copies of Amendment 1, which includes a regulatory impact review, an initial regulatory flexibility analysis (IRFA), a social impact analysis, and an environmental assessment, should be sent to the South Atlantic Fishery Management Council, (South Atlantic Council) One Southpark Circle, Suite 306, Charleston, SC 29407-4699, telephone: 803-571-4366, FAX: 803-769-4520.

Comments regarding the collection-of-information requirements contained in this proposed rule should be sent to Edward E. Burgess, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: Peter J. Eldridge, 813-570-5305.

SUPPLEMENTARY INFORMATION: The FMP was prepared by the South Atlantic Council and is implemented through regulations at 50 CFR part 659 under the authority of the Magnuson Act. Add Rock Shrimp to the Management Unit

In the FMP, rock shrimp are included as part of the fishery, but they are not included in the management unit, because there are no management measures specific to rock shrimp. Amendment 1 contains management measures applicable to rock shrimp, including closing one area to trawling, and permitting and reporting requirements; therefore, rock shrimp would be included in the management unit.

Area Closed to Rock Shrimp Trawling

Amendment 1 proposes to prohibit trawling for rock shrimp between 27°30' N. lat. and 28°30' N. lat. in the area extending shoreward of the 100-fathom (183-m) depth contour (as shown on the latest edition of NOAA chart 11460) to 80°00' W. long. The Council is proposing this measure to minimize the impacts of rock shrimp trawling on important live-bottom habitat, including the slow-growing, fragile *Oculina* coral species in and adjacent to the *Oculina* Bank Habitat Area of Particular Concern (HAPC).

Oculina coral is fragile and particularly vulnerable to damage due to bottom trawling. The largest known concentrations of *Oculina* occur in a narrow band extending from Cape Canaveral, FL south through the HAPC. The *Oculina* formations provide

important habitat for rock shrimp, fishes in the snapper-grouper fishery, and numerous other species.

Testimony at public hearings indicated that some rock shrimp trawl activity has shifted south of Cape Canaveral since 1991, exposing the *Oculina* to trawl damage. Prohibition of rock shrimp trawling in the designated area would extend protection of the valuable *Oculina* habitat to the north and east of the existing HAPC, thereby preventing trawl damage to habitat that is currently unprotected and also enhancing the integrity of the existing HAPC.

Dealer Permit Requirement

Amendment 1 would require a dealer involved in the rock shrimp fishery to obtain an annual dealer permit. A dealer would be defined as the person who first receives rock shrimp harvested from the EEZ. To be eligible for a dealer permit, an applicant would be required to have a valid state wholesaler's license in the state where he or she operates if a license is required by that state, and have a physical facility for the receipt of rock shrimp at a fixed location in that state. A fee would be charged to cover the administrative cost of issuing the permit. A dealer permit would not be transferable and would expire upon change of ownership of the business.

Dealer permits are proposed to identify the universe of dealers involved in the rock shrimp fishery and to facilitate collection of data necessary to manage the fishery. The Council believes that this permit requirement would help ensure accurate dealer reporting, improve enforcement of the regulations by increasing dealer accountability, provide a means to improve communications among participants in the fishery management process, and improve understanding of the economic characteristics of the fishery.

Vessel Permit Requirement

For a person aboard a vessel to fish for or possess rock shrimp from the EEZ, an annual vessel permit would be required. A fee would be charged to cover the administrative costs associated with issuing the permit. The vessel permit requirement would identify the universe of participants in the harvesting sector of the fishery. The Council believes that the permit requirement would also help provide information necessary to assess impacts of fishing on the resource and associated habitats.

Vessel Operator Permit Requirement—Disapproved Measure

One measure in Amendment 1 would have required a vessel operator fishing for rock shrimp in the EEZ to obtain a vessel operator permit. An operator would have been defined as the master or other individual aboard who is in charge of the vessel. No performance or competency testing would be required to obtain a permit. A fee would have been charged to cover the administrative costs associated with issuing the permit.

The vessel operator permit requirement was proposed initially by the Council's Ad Hoc Rock Shrimp Advisory Panel and was subsequently adopted by the Council for inclusion in Amendment 1. The permit requirement was intended to instill vessel operators with greater responsibility and accountability regarding compliance with fishery regulations. The Council believes that revocation of an operator's permit would be more effective than existing penalties in deterring fishery violations.

NMFS has determined that the requirement for a vessel operator permit would not minimize costs and is inconsistent with the Magnuson Act's national standard 7 that requires conservation and management measures to minimize costs and avoid unnecessary duplication where practicable. NMFS believes that adequate regulatory compliance can be achieved via the existing penalty schedule without incurring the additional costs and public paperwork burden that would be associated with implementing a new class of permits. Accordingly, the Director, Southeast Region, NMFS (Regional Director) has disapproved this provision of Amendment 1, and it is not included in this proposed rule. The Regional Director has determined that this provision is not a matter of sufficient scope and substance warranting review under section 304(a)(1)(A) of the Magnuson Act.

Dealer Reporting

Permitted dealers would be required to maintain and submit basic information essential for proper management of the fishery. Additional data may be collected by authorized statistical reporting agents or authorized officers as necessary to address specific issues.

A permitted dealer who is selected by the Science and Research Director, Southeast Fisheries Center, NMFS (Science and Research Director) would be required to provide information on receipts and prices paid for rock shrimp

to the Science and Research Director in accordance with instructions provided on the reporting form. Such information would be submitted at monthly intervals, or more frequently if requested, postmarked not later than 5 days after the end of each month. The Council intends that, to the extent possible, the required information be provided through existing state/Federal cooperative agreements for data collection. To minimize duplication, the Science and Research Director would select a dealer to report only if the essential information were not otherwise available through the state/Federal cooperative data collection system.

Restrictions on Sale

Restrictions on sale of rock shrimp are proposed to ensure that the fishery is conducted only by properly permitted individuals and to assure that all landings are documented through the proposed data collection system. The proposed rule would require that rock shrimp harvested in the EEZ by a permitted vessel be sold, traded, bartered, or transferred only to a permitted dealer. Similarly, a permitted dealer would be allowed to purchase, barter, trade, or transfer rock shrimp harvested from the EEZ only from a permitted vessel.

Availability of Amendment 1

Additional background and rationale for the measures discussed above are contained in Amendment 1, the availability of which was announced in the Federal Register on March 19, 1996 (61 FR 11181).

Classification

Section 304(a)(1)(D) of the Magnuson Act requires publication of regulations proposed by a regional fishery management council within 15 days of receipt of an amendment and regulations. At this time, NMFS has not determined that Amendment 1 is consistent with the national standards, other provisions of the Magnuson Act, and other applicable laws, except for the provision of Amendment 1 specifically disapproved, as discussed above. NMFS, in making that determination with respect to the remaining parts of Amendment 1, will take into account the data, views, and comments received during the comment period.

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

The Council prepared an IRFA which describes the impacts this proposed rule would have on small entities, if adopted. The Council concluded that

the proposed measures in Amendment 1 would have a significant economic impact on a substantial number of small entities. These impacts, as assessed in the IRFA, may be summarized as follows. All of the commercial rock shrimp vessel owners and dealers are small entities that would be affected by one or more actions in the proposed rule. The south Atlantic rock shrimp fishery may have as many as 108 active vessels according to Florida's landings data, although industry representatives indicate that the number of vessels participating throughout the season may be closer to 65. The Council estimates that currently there are about 12 dealers actively buying rock shrimp from fishing vessels. It is noted that over 95 percent of rock shrimp harvested in the south Atlantic region occur in the EEZ off the east coast of Florida.

The IRFA identified the following impacts on small entities in terms of costs and revenues: (1) The addition of rock shrimp to the FMP management unit should not result in any changes in operating revenues or costs for individual vessels in the commercial fishery; (2) the prohibition of trawling for rock shrimp in the closed area off the Florida east coast may cause a reduction in annual gross revenues of current rock shrimp fishery participants by more than 5 percent. Although total annual rock shrimp catches by area are not available from NMFS or State sources, 34 participants in the fishery reported their 1994 landings by area fished during the public hearings process. These participants reported a catch of 1,128,624 pounds of rock shrimp from the area to be closed. This represents 25 percent of their total 1994 catch of rock shrimp from the South Atlantic and is 17 percent of the total 1994 catch of rock shrimp of all harvesters as reported in NMFS data. Using an average ex-vessel price of \$1.25 per pound, the value of the harvest by the 34 participants reporting catch by area is expected to decline \$1.41 million in the first year. These data do not indicate the total estimated catch or revenue effect from closing the area since, as indicated above, reliable data on catch locations for all fishery participants are not available. The IRFA indicates that many of the freezer-trawler vessels participating in the fishery in 1994 may show a reduction in harvest income somewhat in excess of \$40,000 per vessel during the first year of the area closure. Rock shrimp are known to move throughout the area off the east coast of Florida. Thus, it is likely that some of the shrimp initially located within the closed area may move to

other areas where they may be harvested. The impacted rock shrimp vessels are expected to shift fishing effort away from the closed area to open areas. The extent to which they can successfully shift effort will determine how well they can minimize adverse impacts. If vessels have to travel extra distances to the open fishing areas, they would incur additional operating costs. This may not result in a reduction in net revenue for vessels that can catch larger size shrimp yielding higher exvessel prices. Also, many vessels participate in other fisheries when they are not fishing for rock shrimp; it is likely that they may switch effort to these other fisheries during the time they would have been trawling for shrimp in the closed area. For these reasons, the above estimates of adverse economic impacts on small entities from the closed area should be considered maximum levels. Nevertheless, it is reasonable to assume that the 5 percent criterion for significant effects will be met for the small entities participating in the rock shrimp fishery in the U.S. South Atlantic. Finally, no small entities are expected to be forced to cease operations; (3) permit requirements for vessel owners, vessel operators, and dealers would increase costs for those sectors; (4) dealer reporting requirements would increase dealer costs marginally; and (5) restrictions on the sale of rock shrimp (i.e., permitted vessels may sell rock shrimp only to permitted dealers) would decrease revenues and increase costs marginally.

In deciding on its preferred management measures for this rule, the Council attempted to balance the competing objectives of providing protection for important habitat areas known to support important populations of juvenile rock shrimp and other valuable species, such as snappers, with the possible adverse economic effects on current fishery participants. The Council believes that Amendment 1 will reduce fishery related habitat damage and ensure successful recruitment of rock shrimp to the fishery over the long run as well as protecting the biological productivity of the snapper-grouper complex. The Council believes that without these conservation measures, the potential long-term, adverse economic effects on small entities would outweigh the short-term effects. A copy of the IRFA is available from the Council (see ADDRESSES).

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the

requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number.

This rule contains new collection-of-information requirements subject to the PRA—namely, vessel permit applications, dealer permit applications, dealer reports regarding rock shrimp receipts, and vessel identification requirements. These requirements have been submitted to OMB for approval. The public reporting burdens for these collections of information are estimated to average 20, 5, 10, and 45 minutes per response, respectively, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these reporting burden estimates or any other aspect of the collections of information, including suggestions for reducing the burdens, to NMFS and OMB (see ADDRESSES).

List of Subjects in 50 CFR Part 659

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: April 16, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 659 is proposed to be amended as follows:

PART 659—SHRIMP FISHERY OFF THE SOUTHERN ATLANTIC STATES

1. The authority citation for part 659 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 659.1 [Amended]

2. In § 659.1, paragraph (b) is amended by adding the phrase "rock shrimp," after "pink shrimp,".

3. In § 659.2, definitions for "Authorized statistical reporting agent", "Dealer", "Regional Director", "Rock shrimp", and "Science and Research Director" are added, in alphabetical order, to read as follows:

§ 659.2 Definitions.

* * * * *

Authorized statistical reporting agent means:

(1) Any person so designated by the Science and Research Director; or

(2) Any person so designated by the head of any Federal or state agency that has entered into an agreement with the Assistant Administrator to collect fishery data.

* * * * *

Dealer, for the purposes of this part 659, means the person who first receives rock shrimp harvested from the EEZ upon transfer ashore.

* * * * *

Regional Director means the Director, Southeast Region, NMFS, or a designee.

Rock shrimp means the species

Sicyonia brevirostris.

Science and Research Director means the Science and Research Director, Southeast Fisheries Science Center, NMFS, or a designee.

* * * * *

4. Section 659.3 is revised to read as follows:

§ 659.3 Relation to other laws.

(a) The relation of this part to other laws is set forth in § 620.3 of this chapter and paragraph (b) of this section.

(b) Regulations governing the taking of endangered and threatened marine mammals and sea turtles appear at 50 CFR parts 222 and 227.

§§ 659.4, 659.5, 659.6 [Redesignated as §§ 659.7, 659.8, 659.9]

5. In subpart A, §§ 659.4, 659.5, and 659.6 are redesignated as §§ 659.7, 659.8, and 659.9, respectively; new §§ 659.4, 659.5, and 659.6 are added; and newly redesignated § 659.7 is revised to read as follows:

§ 659.4 Permits and fees.

(a) *Applicability*—(1) *Annual vessel permit for rock shrimp*. For a person aboard a fishing vessel to fish for rock shrimp in the EEZ or possess rock shrimp in or from the EEZ, a vessel permit for rock shrimp must be issued for the vessel and be on board.

(2) *Annual dealer permit for rock shrimp*. A dealer who receives rock shrimp harvested from the EEZ must obtain an annual dealer permit for rock shrimp. To be eligible for such permit, an applicant must have a valid state wholesaler's license, if required in the state where the applicant operates, and must have a physical facility for receipt of rock shrimp at a fixed location in that state.

(b) *Application for an annual vessel permit for rock shrimp*. (1) Applications are available from the Regional Director. An application must be signed and submitted by the owner (in the case of a corporation, an officer or shareholder; in the case of a partnership, a general partner) or operator of the vessel. The application should be submitted to the Regional Director at least 30 days prior to the date the applicant desires the permit to be effective.

(2) A permit applicant must provide the following information:

(i) A copy of the vessel's valid U.S. Coast Guard certificate of documentation or, if not documented, a copy of its valid state registration certificate.

(ii) Vessel name and official number.

(iii) Name, address, telephone number, and other identifying information of the vessel owner and of the applicant, if other than the owner.

(iv) Any other information concerning the vessel, gear characteristics, principal fisheries engaged in, or fishing areas requested by the Regional Director.

(v) Any other information that may be necessary for the issuance or administration of the permit, as requested by the Regional Director and included on the application form.

(c) *Application for an annual dealer permit for rock shrimp*. (1) Applications are available from the Regional Director. An application for a dealer permit must be submitted and signed by the dealer or an officer of a corporation acting as a dealer. The application should be submitted to the Regional Director at least 30 days prior to the date the applicant desires the permit to be effective.

(2) A permit applicant must provide the following information:

(i) A copy of each state seafood wholesaler's license held by the dealer.

(ii) Business name; mailing address, including zip code, of the principal office of the business; telephone number; employer identification number, if one has been assigned by the Internal Revenue Service; and date the business was formed.

(iii) The address of each physical facility at a fixed location where the business receives rock shrimp.

(iv) Applicant's name; official capacity in the business; address; including zip code; telephone number; and identifying information specified on the application form.

(v) Any other information that may be necessary for the issuance or administration of the permit, as requested by the Regional Director and included on the application form.

(d) *Fees*. A fee is charged for each permit application submitted pursuant to this section. The amount of the fee is calculated in accordance with the procedures of the NOAA Finance Handbook for determining the administrative costs of each special product or service. The fee may not exceed such costs and is specified with each application form. The appropriate fee must accompany each application.

(e) *Initial issuance*. (1) The Regional Director will issue an initial permit at any time to an applicant if the application is complete and the specific

requirements for the requested permit have been met. An application is complete when all required forms, information, documentation, and fees have been received.

(2) Upon receipt of an incomplete application, the Regional Director will notify the applicant of the deficiency. If the applicant fails to correct the deficiency within 30 days of the date of the Regional Director's letter of notification, the application will be considered abandoned.

(f) *Duration*. A permit remains valid for the period for which it is issued unless revoked, suspended, or modified pursuant to subpart D of 15 CFR part 904.

(g) *Renewal*. (1) A permit required by this section will be effective for 1 year. Application for permit renewal is required only every 2 years. In the interim year, a permit will be renewed automatically (without application) if a vessel owner or a dealer has met the renewal requirements under paragraph (g)(2) of this section. The owner of a permitted vessel or a permitted dealer who does not meet the renewal requirements will be notified by the Regional Director approximately 2 months prior to the expiration of the current permit. The notification will specify the reasons the permit is not eligible for renewal and will provide an opportunity for correction of any deficiencies. For a year in which permit renewal application is required, the Regional Director will mail an application form to each owner of a permitted vessel or permitted dealer approximately 2 months prior to expiration of the current permit. A vessel owner or dealer who does not receive a renewal application in that time frame must contact the Regional Director to obtain a renewal application.

(2) The permit renewal requirements are:

(i) All reports required of an owner of a vessel or a dealer under the Magnuson Act have been submitted.

(ii) The permit has not been revoked, suspended, or denied under paragraph (j) of this section.

(h) *Transfer*. A vessel or dealer permit issued pursuant to this section is not transferable or assignable. A person obtaining a permitted vessel or dealership who desires to conduct activities for which a permit is required must apply for a permit in accordance with the provisions of paragraph (b) or (c) of this section, as appropriate.

(i) *Display*. A vessel permit issued pursuant to this section must be carried on board the vessel and such vessel must be identified as provided for in § 659.6. A dealer permit issued pursuant

to this section must be available on the dealer's premises. The operator of a vessel or a dealer must present the permit for inspection upon request of an authorized officer.

(j) *Sanctions and denials.* A permit issued pursuant to this section may be revoked, suspended, or modified, and a permit application may be denied, in accordance with the procedures governing enforcement-related permit sanctions and denials found at subpart D of 15 CFR part 904.

(k) *Alteration.* A permit that is altered, erased, or mutilated is invalid.

(l) *Replacement.* The Regional Director may issue a replacement permit. An application for a replacement permit will not be considered a new application. A fee, the amount of which is stated with the application form, must accompany each request for a replacement permit.

(m) *Change in application information.* The owner or operator of a vessel with a permit for rock shrimp or a dealer with a permit for rock shrimp must notify the Regional Director within 15 days after any change in the application information required by paragraph (b) or (c) of this section, respectively. The permit is void if any change in the information is not reported within 15 days.

§ 659.5 Recordkeeping and reporting.

(a) *Dealers.* A dealer who has been issued a permit required by § 659.4(a)(2) and who is selected by the Science and Research Director must provide information on receipts of rock shrimp and prices paid, to the Science and Research Director in accordance with instructions on the reporting form. The required information must be submitted at monthly intervals, or more frequently if requested, postmarked not later than 5 days after the end of each month.

(b) *Additional data and inspection.*
(1) Additional data will be collected by authorized statistical reporting agents or by authorized officers. A dealer is required, upon request, to make rock shrimp, or parts thereof, available for inspection by the Science and Research Director or an authorized officer.

(2) On demand, a dealer must make available to an authorized officer all records of off-loadings, purchases, barter, or sales of rock shrimp.

§ 659.6 Vessel identification.

(a) *Official number.* The owner and operator of a vessel with a valid permit, as required under § 659.4(a)(1) must ensure that the vessel's official number is displayed—

(1) On the port and starboard sides of the deckhouse or hull and on a weather

deck so as to be clearly visible from an enforcement vessel or aircraft;

(2) In block arabic numerals in contrasting color to the background;

(3) At least 18 inches (45.7 cm) in height for fishing vessels over 65 feet (19.8 m) in length and at least 10 inches (25.4 cm) in height for all other vessels; and

(4) Permanently affixed to or painted on the vessel.

(b) *Duties of operator.* The operator of each fishing vessel specified in paragraph (a) of this section must—

(1) Keep the official number clearly legible and in good repair; and

(2) Ensure that no part of the fishing vessel, its rigging, fishing gear, or any other material on board obstructs the view of the official number from an enforcement vessel or aircraft.

§ 659.7 Prohibitions.

In addition to the general prohibitions specified in § 620.7 of this chapter, it is unlawful for any person to do any of the following:

(a) Fish for rock shrimp in the EEZ or possess rock shrimp in or from the EEZ, on board a vessel that does not have a vessel permit for rock shrimp, as specified in § 659.4(a)(1).

(b) As a dealer, receive rock shrimp harvested from the EEZ without a dealer permit, as specified in § 659.4(a)(2).

(c) Falsify information specified in § 659.4(b)(2), or (c)(2) on an application for a permit.

(d) Fail to display a permit, as specified in § 659.4(h).

(e) Falsify or fail to maintain, submit, or provide information required to be maintained, submitted, or provided, as specified in § 659.5(a) or (b), or as may be required as a condition of an authorized activity under § 659.22.

(f) Fail to make rock shrimp, or parts thereof, available for inspection, as specified in § 659.5(b)(1).

(g) Falsify or fail to display and maintain vessel identification, as specified in § 659.6(a) and (b).

(h) Trawl for white shrimp, pink shrimp, or brown shrimp in a closed area or possess such shrimp in or from a closed area, as specified in § 659.20(a)(2)(i)(A), except possession authorized under § 659.20(a)(2)(ii).

(i) Use or have on board a vessel trawling in that part of a closed area specified under § 659.20(a)(1) that is within 25 nautical miles (46.30 km) of the baseline from which the territorial sea is measured, a trawl net with a mesh size less than 4 inches (10.2 cm), as specified in § 659.20(a)(2)(i)(B).

(j) Trawl for rock shrimp in the closed area specified in § 659.20(b) or possess on board a fishing vessel rock shrimp in or from that closed area.

(k) Transfer, receive, sell, purchase, barter, or trade, or attempt to transfer, receive, sell, purchase, barter, or trade a rock shrimp harvested from the EEZ from a vessel that does not have a valid permit, as specified in § 659.21(a).

(l) Transfer, sell, trade, or barter or attempt to transfer, sell, trade, or barter from a vessel rock shrimp harvested from the EEZ to a dealer who does not have a permit, as specified in § 659.21(b).

(m) As a permitted dealer, receive, purchase, barter, or trade or attempt to receive, purchase, barter, or trade rock shrimp harvested from the EEZ from a vessel that does not have a valid permit, as specified in § 659.21(c).

(n) Interfere with, obstruct, delay, or prevent by any means an investigation, search, seizure, or disposition of seized property in connection with enforcement of the Magnuson Act.

(o) Make any false statement, oral or written, to an authorized officer concerning the taking, catching, harvesting, landing, purchase, sale, possession, or transfer of brown shrimp, pink shrimp, rock shrimp, or white shrimp.

6. In § 659.20, paragraphs (a), (b), (b)(1), (b)(1)(i), (b)(1)(ii), and (b)(2) are redesignated as paragraphs (a)(1), (a)(2), (a)(2)(i), (a)(2)(i)(A), (a)(2)(i)(B), and (a)(2)(ii), respectively; in newly redesignated paragraph (a)(2)(i), introductory text, the reference "paragraph (a)" is removed and "paragraph (a)(1)" is added in its place; in newly redesignated paragraphs (a)(2)(i)(A) and (a)(2)(ii), the reference "paragraph (b)(2)" is removed and the reference "paragraph (a)(2)(ii)" is added in its place; and a new paragraph (a) heading and new paragraph (b) are added to read as follows:

§ 659.20 Closures.

(a) *Seasonal closures for brown, pink, and white shrimp.*

* * * * *

(b) *Area closure for rock shrimp.* No person may trawl for rock shrimp in the closed area east of 80°00' W. long, between 27°30' N. lat. and 28°30' N. lat. shoreward of the 100-fathom (183-m) contour, as shown on the latest edition of NOAA chart 11460; and no person may possess rock shrimp in or from this closed area on board a fishing vessel.

7. Section 659.21 is redesignated as § 659.22 and a new § 659.21 is added to read as follows:

§ 659.21 Restrictions on sale/purchase of rock shrimp.

(a) No person may transfer, receive, purchase, barter, trade, or sell, or attempt to transfer, receive, purchase,

barter, trade, or sell, rock shrimp harvested in the EEZ by a vessel for which a valid permit has not been issued under § 659.4(a)(1).

(b) No person may transfer, sell, trade, or barter or attempt to transfer, sell, trade, or barter, rock shrimp harvested in the EEZ by a vessel permitted under § 659.4(a)(1) to a dealer who does not have a valid permit issued under § 659.4(a)(2).

(c) No dealer who has a valid permit issued under § 659.4(a)(2) may receive, purchase, trade, or barter or attempt to receive, purchase, trade, or barter rock shrimp harvested in the EEZ from a vessel for which a valid permit has not been issued under § 659.4(a)(1).

[FR Doc. 96-9882 Filed 4-22-96; 8:45 am]

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Notices

Federal Register

Vol. 61, No. 79

Tuesday, April 23, 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

Forest Service

Transfer of Administrative Jurisdiction; Sam Rayburn Dam and Reservoir Project

AGENCY: Forest Service, USDA.

ACTION: Notice of joint interchange of lands.

SUMMARY: On October 10, 1995, and January 11, 1996, the Secretary of the Army and the Secretary of Agriculture respectively signed a joint interchange order agreeing to the transfer of administrative jurisdiction from the Department of Agriculture to the Department of the Army of 36.286 acres, more or less, lying within the Angelina National Forest in Jasper County, Texas, and from the Department of the Army to the department of Agriculture of 48.29 acres, more or less lying, within the exterior boundaries of the Sabine National Forest in Sabine County, Texas. As required by the Act of July 26, 1956, Congress has received 47 days advance notice of this action. A copy of the Joint Order, as signed, appears at the end of this notice.

EFFECTIVE DATE: The order is effective April 23, 1996.

FOR FURTHER INFORMATION CONTACT: David M. Sherman, Lands Staff, Forest Service, USDA, Telephone: (202) 205-1362.

Dated: April 12, 1996.

Jerry A. Sesco,
Acting Chief.

Department of the Army

Department of Agriculture

Sam Rayburn Reservoir, Texas

Joint Order Interchanging Administrative Jurisdiction of Department of the Army Lands and National Forest Lands

By Virtue of the authority vested in the Secretary of Agriculture and the Secretary of the Army by Public Law 804 dated July 26,

1956 (70 Stat. 656; 16 U.S.C. 505a, 505b) it is ordered as follows:

(1) The jurisdiction now held by the Secretary of the Army over the Army lands described in Exhibits A and A-1, attached hereto and made a part hereof, which lands are within the boundaries of the Sabine National Forest, Texas, is hereby transferred from the Secretary of the Army to the Secretary of Agriculture, subject to the Corps of Engineers' full, complete and perpetual right, power, privilege and easement occasionally to overflow, flood and submerge the land described in Exhibits A and A-1 lying below elevation 179' National Geodetic Vertical Datum (NGVD), and its right to maintain mosquito control as may be required in connection with the construction, operation and maintenance of the Sam Rayburn Reservoir Project, Texas, provided that no structures for human habitation shall be constructed or maintained on said land, and that no other structures shall be constructed or maintained on said land except as may be approved in writing by the representatives of the United States in charge of the Project, and that no excavation shall be conducted and no landfill placed on the land without such approval as to the location and method of excavation and/or placement of landfill, provided further that any use of the land shall be subject to Federal and State laws with respect to pollution.

(2) The jurisdiction now held by the Secretary of Agriculture over the National Forest lands described in Exhibits B and B-1, attached hereto and made a part hereof, which are a part of the Angelina National Forest, Texas, is hereby transferred from the Secretary of Agriculture to the Secretary of the Army, subject to continued access thereover by the Forest Service as may be necessary for National Forest purposes.

(3) Pursuant to Section 2 of the aforesaid Act of July 26, 1956, the National Forest lands transferred to the Secretary of the Army by this order are hereafter subject only to the laws applicable to the Department of the Army lands comprising the Sam Rayburn Reservoir Project, Texas. The Department of the Army lands transferred to the Secretary of Agriculture by this order are hereby subject to the laws applicable to lands acquired under the Act of March 1, 1911 (38 Stat. 961), as amended, in addition to the laws applicable to the Department of Army necessary to provide for flood control as specified in paragraph 1 of this Order. Pursuant to authority contained in section 11 of the Act of March 1, 1911, the Secretary of Agriculture hereby orders that those lands transferred to the Secretary of Agriculture shall be administered as a part of the Sabine National Forest, Texas.

This order will be effective as of date of publication in the Federal Register.

Dated: October 10, 1995.

Togo D. West, Jr.,
Secretary of the Army.

Dated: January 11, 1996.

Dan Glickman,
Secretary of Agriculture.

[FR Doc. 96-9865 Filed 4-22-96; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

Bureau of the Census

Current Population Survey (CPS) School Enrollment Supplement; Proposed Agency Information Collection Activity; Comment Request

SUMMARY: The Department of Commerce, 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)).

DATES: Submit written comments on or before June 24, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Bonnie Tarsia, Bureau of the Census, FOB 3, Room 3340, Washington, DC 20233-8400, (301) 457-3806.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau is requesting clearance for the collection of data concerning the School Enrollment Supplement to be conducted in conjunction with the October 1996 CPS, Title 13, United States Code, Section 182; and Title 29 United States Code, Sections 1-9, authorize the collection of CPS information. The Bureau of the Census and the Bureau of Labor Statistics (BLS) sponsor the basic annual school enrollment questions, which

have been collected annually in the CPS for over 25 years. The National Center for Education Statistics (NCES) sponsors the inclusion of the additional questions on summer school enrollment.

This survey provides information on public/private elementary and secondary school enrollment, and characteristics of private school students and their families, which is used for tracking historical trends and for policy planning and support. This year we will also ask questions about summer school enrollment and other organized activities in which the child participated during the previous summer. This survey is the only source of national data on the age distribution and family characteristics of college students, and the only source of demographic data on preprimary school enrollment. As part of the Federal Government's efforts to collect data and provide timely information to local governments for policymaking decisions, the survey provides national trends in employment and progress in school.

II. Method of Collection

The school enrollment information will be collected by both personal visit and telephone interviews in conjunction with the regular October CPS interviewing. All interviews are conducted using computer-assisted interviewing.

III. Data

OMB Number: 0607-0464.

Form Number: There are no forms. We conduct all interviewing on computers.

Type of Review: Regular.

Affected Public: Individuals or households.

Estimated Number of Respondents: 48,000 per month.

Estimated Time Per Response: 8 minutes.

Estimated Total Annual Burden Hours: 6,400.

Estimated Total Annual Cost: \$360,000.

IV. Request for Comments

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 (including hours and cost) of the proposed collection of information; (c) ways to enhance 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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 18, 1996.

Linda Engelmeier,

*Acting Department Forms Clearance Officer,
Office of Management and Organization.*

[FR Doc. 96-9981 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-07-P

1997 Economic Census Covering Trucks, Automobiles, and Buses; Proposed Agency Information Collection Activity, Comment Request

SUMMARY: The Department of Commerce, 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)).

DATES: Written comments must be submitted on or before June 24, 1996.

ADDRESSES: Direct all written comments to Linda Engelmeier, Acting Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Robert Crowther, Bureau of the Census, Room 2754, Building 3, Washington, DC 20233, (301) 457-2797.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau is the preeminent collector and provider of timely, relevant, and quality data about the people and economy of the United States. Economic data are the Census Bureau's primary program commitment during nondecennial census years. The economic census, conducted under authority of Title 13 U.S.C., is the primary source of facts about the structure and functioning of the Nation's economy and features unique industry and geographic detail. Economic census statistics serve as part of the framework for the national accounts and provide essential

information for government, business and the general public. The 1997 Economic Census will cover virtually every sector of the U.S. economy.

The 1997 Vehicle Inventory and Use Survey, a component of the Economic Census, will produce basic statistics on the physical and operational characteristics of the nation's trucks, automobiles, and buses. It also will yield a variety of subject statistics, including vehicles by annual miles, major use, fuel type, miles per gallon, and products carried. The Census Bureau will publish truck estimates at the state and national level, and automobile and bus estimates at the national level.

Primary strategies for reducing burden in the Vehicle Inventory and Use Survey data collections include employing a stratified random sample to use the least number of sampling units required to produce reliable statistics, separate vehicle-type specific questionnaires, check boxes with ranges in lieu of specific responses, accepting estimates, and utilizing a short form for light trucks with homogeneous characteristics.

II. Method of Collection

The Vehicle Inventory and Use Survey will survey a sample of private and commercial trucks, automobiles, and buses registered in the 50 States and the District of Columbia. Government vehicles will not be sampled. Trucks will be divided into 5 different groups: "pick-up," "van," "single-unit light," "single-unit heavy," and "truck tractors." Automobiles will be divided into 2 different groups: "station wagon" and "other automobiles." Buses will be divided into 4 different groups: "buses," "transit buses," "school buses," and "large van-type buses." All vehicles will be selected at random with equal probabilities of selection within a group. For each selected vehicle, a questionnaire will be mailed to the owner identified in the vehicle registration records. The owner will be asked to respond only for the vehicle identified by the registration information imprinted on the questionnaires, regardless of whether or not he still owns the vehicle.

Mail selection procedures will distinguish the following groups of vehicles:

A. Light Trucks

A sample of "pickups" and "vans" (including panel trucks, minivans, sport utility vehicles, and station wagons built on truck chassis) will be selected. We estimate that the census mail canvass for 1997 will include

approximately 35,000 light trucks of the estimated over 55 million privately and commercially registered light trucks.

B. Medium and Heavy Trucks

Selection procedures will assign all single-unit trucks (excluding those in the pickup and van strata) with a gross vehicle weight (GVW) of 26,000 pounds or less to the "single-unit light" stratum, the remaining single unit trucks to the "single-unit heavy" stratum, and truck tractors to the "truck tractor" stratum. We estimate that the census mail canvass for 1997 will include approximately 93,000 medium and heavy trucks of the estimated over 4 million privately and commercially registered medium and heavy trucks.

C. Automobiles

Selection procedures will assign automobiles to either the "station wagon" or "other automobiles" strata based on the vehicle's identification number (VIN). We estimate that the census mail canvass for 1997 will include approximately 3,100 automobiles of the estimated over 132 million automobiles.

D. Buses

Selection procedures will assign all non-government buses to one of the following groups: "intercity buses" consisting of tour/charter buses, "transit buses" consisting of public transportation buses, "school buses" consisting of privately-owned school buses, and "large van-type buses" consisting of all remaining buses. We estimate that the census mail canvass for 1997 will include approximately 710 of the estimated over 250,000 non-government buses.

III. Data

OMB Number: Not Available.

Form Number:

TC-9501: Light Trucks
TC-9502: Medium and Heavy Trucks
TC-9503: Automobiles
TC-9504: Buses

Type of Review: Regular Review.

Affected Public: Individuals, Farms, Businesses and Other For-profit, Non-profit Institutions, Small Businesses or Organizations.

Estimated Number of Respondents:

TC-9501: (Light Trucks): 35,190
TC-9502: (Medium and Heavy Trucks): 92,797
TC-9503: (Automobiles): 3,100
TC-9504: (Buses): 710

Total Number of Respondents—131,797

Estimated Time Per Response:

TC-9501: (Light Trucks): .5 hours
TC-9502: (Medium and Heavy

Trucks): .83 hours

TC-9503: (Automobiles): .5 hours

TC-9504: (Buses): .83 hours

Estimated Total Annual Burden Hours:

TC-9501: (Light Trucks): 17,595

TC-9502: (Medium and Heavy Trucks): 77,022

TC-9503: (Automobiles): 1,550

TC-9504: (Buses): 589

Total Annual Burden Hours—96,756

Estimated Total Annual Cost: The cost to the government for this work is included in the total cost of the 1997 Economic Census, estimated to be \$218 million.

IV. Request for Comments

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 (including hours and cost) of the proposed collection of information; (c) ways to enhance 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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 18, 1996.

Linda Engelmeier,

*Acting Departmental Forms Clearance Officer
Office of Management and Organization.*

[FR Doc. 96-9982 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-07-P

Foreign-Trade Zones Board

[Docket 26-96]

Foreign-Trade Zone 161—Sedgwick County, KS, Application for Subzone Status; Texaco Inc., (Oil Refinery Complex) Butler County, KS

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Board of Commissioners of Sedgwick County, Kansas, grantee of FTZ 161, requesting special-purpose subzone status for the oil refinery complex of Texaco Inc., located in Butler County, Kansas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR

part 400). It was formally filed on April 2, 1996.

The refinery complex (578 acres, 517 employees) consists of 2 sites and connecting pipelines in Butler County, 35 east of Wichita, Kansas: *Site 1* (460 acres)—main refinery complex (110,000 BPD) located at 1401 Douglas Road, just south of El Dorado; *Site 2* (118 acres)—crude oil storage facility (1.2 mil. barrel capacity) located at 3913 SW 10th Street, 3 miles west of the refinery.

The refinery complex is used to produce fuels and petrochemical feedstocks. Fuels produced include gasoline, jet fuel, distillates, diesel, and residual fuels. Petrochemical feedstocks and refinery by-products include methane, ethane, propane, butane, butylene, toluene, propylene, cumene, sulfur, carbon black and petroleum coke. About 46 percent of the crude oil (90 percent of inputs), and some feedstocks and motor fuel blendstocks used in producing fuel products are sourced abroad.

Zone procedures would exempt the operations involved from Customs duty payments on the foreign products used in its exports. On domestic sales, the company would be able to choose the finished product duty rate (nonprivileged foreign status—NPF) on certain petrochemical feedstocks and refinery by-products (duty-free) instead of the duty rates that would otherwise apply to the foreign-sourced inputs (e.g., crude oil). The duty rates on crude oil range from 5.25¢/barrel to 10.5¢/barrel. The application indicates that the savings from zone procedures would help improve the refinery's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 24, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to July 8, 1996).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce District Office, 151 N. Volusia, Wichita, Kansas 67214
Office of the Executive Secretary, Foreign-Trade Zones Board, Room 3716, U.S. Department of Commerce,

14th and Pennsylvania Avenue, NW.,
Washington, DC 20230.

Dated: April 9, 1996.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96-9983 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-DS-P

[Docket 28-96]

Foreign-Trade Zone 138—Columbus, OH, Application for Subzone Status; Abbott Manufacturing, Inc./Ross Products, Plant (Infant Formula, Adult Nutritional Products), Columbus, OH

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Rickenbacker Port Authority, grantee of FTZ 138, requesting special-purpose subzone status for export activity at the infant formula and adult nutritional products manufacturing plant of Abbott Manufacturing, Inc. (AMI) (a subsidiary of Abbott Laboratories, Inc.), located in Columbus, Ohio. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on April 9, 1996.

The plant (642,000 sq. ft. on 56 acres), known as the Ross Products facility, is located at 585 Cleveland Avenue in the City of Columbus (Franklin County), Ohio. The facility (560 employees) is used to produce milk and sugar-based infant formula and adult nutritional products for export and the domestic market; however, zone procedures would be used only for production for export. The production process involves blending foreign, ex-quota milk powder and foreign, ex-quota sugar with domestically-sourced oils, soy isolates, vitamins and minerals, and EZO ends. Other foreign-sourced items that may be used in the export-blending activity include: cocoa powder, pharmaceutical grade fat emulsions, vitamins and minerals, and caseinates (up to 14% of finished product value). All foreign-origin milk and sugar would be re-exported as finished blended products.

Zone procedures would exempt AMI from quota requirements and Customs duty payments on the foreign milk and sugar products used in the export activity and from Customs duty payments on the other foreign ingredients involved. The application indicates that subzone status would help improve the plant's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff

has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and three copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 24, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to July 8, 1996).

A copy of the application and the accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, District Office, 4th Floor, 37 North High Street, Columbus, OH 43215.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th Street & Pennsylvania Avenue, NW., Washington, DC 20230-0002.

Dated: April 12, 1996.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96-9985 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-DS-P

[Docket 27-96]

Foreign-Trade Zone 168—Dallas/Fort Worth, TX; Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Dallas/Fort Worth Maquila Trade Development Corporation (MTDC), grantee of FTZ 168, requesting authority to expand its zone in the Fort Worth, Texas, area, within the Dallas/Fort Worth Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on April 3, 1996.

FTZ 168 was approved on November 1, 1990 (Board Order 491, 55 FR 46974, 11/8/90) and reorganized in 1992 and 1994. The zone currently consists of three sites in the Fort Worth, Texas, area:

Site 1 (24 acres)—an industrial area at Alta Mesa and Will Rogers Boulevards, Fort Worth;

Site 2 (263 acres)—within the Centreport industrial development, south of DFW International Airport, Fort Worth;

Site 3 (195 acres)—within the Fossil Creek Business Park, I-35W and I-820, Fort Worth.

An application is currently pending (Doc. 77-95, 60 FR 61528, 11/30/95) for a fourth site located at the Regency Business Park, Post & Paddock Road, Grand Prairie, Texas, west of the City of Dallas.

The applicant is now applying for a fifth site (630 acres) within the 1,200-acre Mercantile Center, located at I-35 and Meacham Boulevard, Fort Worth, Texas. The site is owned by Mercantile Partners, L.P., a Texas Limited Partnership. Zone services will be provided by the FTZ Operating Company of Texas.

No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties.

Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 24, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to July 8, 1996).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, District Office, 2050 N. Stemmons Fwy., Suite 170, Dallas, Texas 75258

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th and Pennsylvania Avenue, NW., Washington, DC 20230

Dated: April 9, 1996.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 96-9984 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-DS-P

[Docket 29-96]

Foreign-Trade Zone 199—Texas City, TX, Application for Subzone Status, Basis Petroleum, Inc. (Oil Refinery Complex), Texas City, TX

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Texas City Foreign Trade Zone Corporation, grantee of FTZ 199, requesting special-purpose subzone

status for the oil refinery complex of Basis Petroleum, Inc. (Basis) (formerly Phibro Energy USA, Inc.), located in Texas City, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR part 400). It was formally filed on April 11, 1996.

The refinery complex (130,000 BPD, 310 acres) is located at 1301 Loop 197 South, Texas City (Galveston County), Texas, some 40 miles southeast of Houston. The refinery (400 employees) is used to produce fuels and petrochemical feedstocks. Fuels produced include gasoline, jet fuel, distillates, naphthas, and residual fuels. Petrochemical feedstocks and refinery by-products include methane, ethane, propane, butane, propylene and sulfur. About 85 percent of the crude oil (95 percent of inputs), and some feedstocks and motor fuel blendstocks used in producing fuel products are sourced abroad.

Zone procedures would exempt the operations involved from Customs duty payments on the foreign products used in its exports. On domestic sales, the company would be able to choose the finished product duty rate (nonprivileged foreign status—NPF) on certain petrochemical feedstocks and refinery by-products (duty-free). The duty on crude oil ranges from 5.25¢/barrel to 10.5¢/barrel. The application indicates that the savings from zone procedures would help improve the refinery's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 24, 1996. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to July 8, 1996).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce District Office, #1 Allen Center, Suite 1160, 500 Dallas, Houston, Texas 77002.
Office of the Executive Secretary, Foreign-Trade Zones Board, Room 3716, U.S. Department of Commerce, 14th & Pennsylvania Avenue, NW., Washington, DC 20230.

Dated: April 12, 1996.
John J. Da Ponte, Jr.,
Executive Secretary.
[FR Doc. 96-9986 Filed 4-22-96; 8:45 am]
BILLING CODE 3510-DS-P

National Institute of Standards and Technology

[Docket No. 960212025-6025-01]

RIN 0693-XX14

Approval of Federal Information Processing Standards Publication 177-1, Initial Graphics Exchange Specification (IGES)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce that the Secretary of Commerce has approved a revision of Federal Information Processing Standard (FIPS) 177, Initial Graphics Exchange Specification (IGES), which will be published as FIPS Publication 177-1. This revision adopts the American National Standard Digital Representation for Communication of Product Definition Data, ANSI/US PRO/IPO (United States Product Data Association/IGES PDES Organization)-100-1993, Version 5.2, and the specified application protocols. FIPS PUB 177-1 addresses IGES implementation and data file acquisition, interpretation, and conformance.

On April 12, 1995, notice was published in the Federal Register (60 FR 18583-18586) that a revision of Federal Information Processing Standard (FIPS) 177, Initial Graphics Exchange Specification (IGES), was being proposed for Federal use.

The written comments submitted by interested parties and other material available to the Department relevant to this standard were reviewed by NIST. On the basis of this review, NIST recommended that the Secretary approve the revised standard as Federal Information Processing Standards Publication (FIPS PUB) 177-1, and prepared a detailed justification document for the Secretary's review in support of that recommendation.

The detailed justification document which was presented to the Secretary, and which includes an analysis of the written comments received, is part of the public record and is available for inspection and copying in the Department's Central Reference and Records Inspection Facility, Room 6020, Herbert C. Hoover Building, 14th Street

between Pennsylvania and Constitution Avenues, NW, Washington, DC 20230.

This FIPS contains two sections: (1) an announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section, which deals with the technical requirements of the standard. Only the announcement section of the standard is provided in this notice.

EFFECTIVE DATE: This revised standard becomes effective November 1, 1996.

ADDRESSES: Interested parties may purchase copies of this revised standard, including the technical specifications section, from the National Technical Information Service (NTIS). Specific ordering information from NTIS for this standard is set out in the Where to Obtain Copies Section of the announcement section of the standard.

FOR FURTHER INFORMATION CONTACT: Ms Lynne Rosenthal, telephone (301) 975-3353, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Dated: April 16, 1996.
Samuel Kramer,
Associate Director.

Federal Information Processing Standards Publication 177-1

Announcing the Standard for Initial Graphics Exchange Specification (IGES)

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology (NIST) after approval by the Secretary of Commerce pursuant to Section 5131 of the Information Technology Management Reform Act of 1996 and the Computer Security Act of 1987, Public Law 104-106.

1. Name of Standard. Initial Graphics Exchange Specification (IGES) (FIPS PUB 177-1).

2. Category of Standard. Software Standard; Graphics and Information Interchange.

3. Explanation. This publication is a revision of the FIPS PUB 177 and supersedes FIPS PUB 177 in its entirety. It provides a substantial, upward-compatible enhancement of IGES Version 4.0. FIPS PUB 177-1 specifies new conformance requirements, the addition and use of application protocols (APs), and increased enhancement, correction, and clarification of the existing specification. It does not contain any new requirements that would make an

existing conforming implementation nonconforming.

FIPS PUB 177-1 adopts the American National Standard Digital Representation for Communication of Product Definition Data, ANSI/US PRO/IPO (United States Product Data Association/IGES PDES Organization)-100-1993, Version 5.2, and the specified application protocols. FIPS PUB 177-1 addresses IGES implementation and data file acquisition, interpretation, and conformance.

The purpose of the FIPS for IGES is to enable the compatible exchange of product definition data used by dissimilar computer-aided design and computer-aided manufacturing (CAD/CAM) systems. Utilizing a neutral database format the IGES processor can create or translate two-dimensional (2-D) or three-dimensional (3-D) vector-based digital product model data. The standard specifies file structure and syntactical definition, and defines the representation of geometric, topological, and nongeometric product definition data. The exact specification is in Section 10 of this standard.

4. Approving Authority. Secretary of Commerce.

5. Maintenance Agency. U.S. Department of Commerce, National Institute of Standards and Technology (NIST), Computer Systems Laboratory (CSL).

6. Cross Index.

a. American National Standard Digital Representation for Communication of Product Definition Data, ANSI/US PRO/IPO-100-1993, Version 5.2.

b. American Society of Mechanical Engineers/American National Standards Institute (ASME/ANSI) Y14.26M-1989, Digital Representation for Communication of Product Definition Data, IGES Version 4.0.

c. MIL-D-28000A, Continuous Acquisition and Life-Cycle Support Specification, Digital Representation for Communication of Product Definition Data: IGES Application Subsets and IGES Application Protocols, February 10, 1992.

d. American National Standard, 3-D Piping IGES Application Protocol, ANSI/US PRO/IPO-110-1994.

e. IGES Layered Electrical Product Application Protocol, Committee Draft SAND94-2375, December 1, 1994.

7. Related Documents.

a. Federal Information Resources Management Regulations (FIRMR) subpart 201.20.303, Standards, and subpart 201.39.1002, Federal Standards.

b. Federal ADP and Telecommunications Standards Index, U.S. General Services Administration, Information Technology Management

Service, October 1994 (updated periodically).

c. FIPS PUB 29-3, Interpretation Procedures for Federal Information Processing Standards for Software.

d. NISTIR 4379, IGES Technical Illustrations Application Guide.

e. NISTIR 4600, IGES 5.0 Recommended Practices Guide.

f. NISTIR 5541, Initial Graphics Exchange Specification (IGES): Procedures for the NIST IGES Validation Test Service.

g. MIL-T-31000, General Specification for Technical Data Packages.

8. Objectives. Federal standards for electronic interchange permit Federal departments and agencies to exercise more effective control over the production, management, and use of the government's information resources. The primary objectives specific to IGES are to:

—Reduce the overall life-cycle cost for digital systems by establishing a common exchange format that allows for the transfer of product definition data across organizational boundaries and independent of any particular CAD/CAM system.

—Exchange digital representations of product definition data in various forms: illustrations, 2-D drawings, 3-D edge-vertex models, surface models, solid models, and complete product models.

—Provide CAD/CAM implementation manufacturers with a guideline for identifying useful combinations of product definition data capabilities in any CAD/CAM system.

—Specify APs that can be used by Federal departments and agencies to support the exchange of product data when applicable.

9. Applicability.

9.1 This FIPS for IGES is intended for the computer-interpretable representation and exchange of CAD/CAM product definition data among applications and programs that are either developed or acquired or developed by a Federal agency shall include an IGES preprocessor and IGES postprocessor capability. FIPS for IGES is designed to support the exchange of 2-D or 3-D product definition data with rich attributable information. It provides a data format for describing product design and manufacturing information that has been created and stored in a computer-readable, device independent form.

9.2. The FIPS for IGES shall be used when one or more of the following situations exist:

—The product definition application or program is under constant review, and changes may result frequently.

—It is anticipated that the life of the data files will be longer than the life of the presently utilized CAD/CAM system.

—The application is being designed centrally for a decentralized system that may employ computers of different makes and models and different CAD/CAM devices.

—The product definition application may run on equipment other than that on which it was developed.

—The product definition data is to be used and maintained by other than the original designer.

—The product definition data is or is likely to be used by organizations outside the Federal Government.

—It is desired to have the design understood by multiple people, groups, or organizations.

For layered electrical product technology, three dimensional piping, and engineering drawing applications, the use of the appropriate AP or subset (as described below) is required for implementation of this FIPS IGES.

An AP or subset provides a means to improve the fidelity of the product data exchanged. APs are developed by domain experts for the purpose of defining the processes, information flows, and functional requirements of an application. An AP defines the scope, context, information requirements, representation of the application information, and conformance requirements. Initial release of this FIPS for IGES publication includes two APs and one application subset.

—Layered Electrical Product (LEP) Application Protocol: The LEP AP is used for the transference of 2-D electrical and electro-mechanical product models. This AP is required for layered electrical products technology applications, including specification control drawings, circuitry, fabrication and final assembly of a layered product system.

—3-D Piping Application Protocol: The 3-D Piping AP is used for the exchange of models from one piping modeling application to another. This AP is required for 3-D piping and related equipment models, including the fabrication and assembly of piping systems (e.g. pipe, pipe fittings, attached equipment, piping supports, and insulation).

—Engineering Drawing (Class II) Subset (MIL-D-28000A): The Class II subset is used for the exchange of the drawing model; including geometric and annotation entities, attributes

such as color and line fonts, and organization information such as levels and subfigures. This subset is required for the exchange of engineering drawings and product data following MIL-T-31000 (General Specification for Technical Data Packages).

10. Specifications. This FIPS adopts ANSI/US PRO/IPO-100-1993 and the specified APs: Layered Electrical Product (LEP) Application Protocol; 3-D Piping Application Protocol; and Engineering Drawing (Class II) Subset (MIL-D-28000A). The ANSI/US PRO/IPO-100-1993 standard for IGES, defines the communications file structure and format (i.e., a file of entities), language format, and the representation of product definition data.

New entities and constructs are added with each revision and are upwardly compatible. Thus, processor conforming to IGES Version 5.2 would be able to read and process an IGES Version 4.0 file, but the converse may not be true. The capabilities brought to the IGES user implementing the IGES Version 5.2 standard are:

- A new character set for the European Community;
- additional properties to the attribute table for Architecture/Engineering/Construction (AEC);
- the addition of a new form of the drawing entity; and
- the addition of a new class of entity use, termed construction information.

Conformance Requirements. Conformance is mandatory for this standard and is applicable to all Federal department and agency procurements. Conforming data files and processors must adhere to all the rules appropriate to specific features, such as entities, defines within ANSI/US PRO/IPO-100-1993 and when applicable, one of the APs or subset identified in this standard. Vendors of processors claiming conformance to this standard shall complete documentation which accurately indicates the processor's support of, and mapping between, native and IGES entities.

A conforming preprocessor shall create conforming IGES data files which represent the native database which was input to the preprocessor. File content shall represent the native entities according to the vendor's completed documentation. Unsupported native entities shall be reported.

A conforming postprocessor shall be capable of reading any complying data file without halting or aborting, including data files containing unprocessable entities. All

unprocessable entities shall be ignored. A conforming postprocessor shall translate conforming IGES data files into the native database form of a specific CAD/CAM system. It shall convert each supported entity into native constructs, which preserve the functionality and match the geometry, attributes, and relationships of the IGES entity in the file. The postprocessor shall report on any IGES entities or features which have been discarded.

Any visual presentation of supported, displayable entities that is produced by the processor, shall represent a visual appearance equivalent to the examples appearing in ANSI/US PRO/IPO-100-1993 and, if applicable, the AP or subset. The visual appearance shall depict the functional intent of the database.

Conformance Rules for Application Protocols and Subsets. An application protocol or subset which claims conformance to this standard, must satisfy the following rule:

- An implementation conforming to an AP shall satisfy the conformance requirements specified in the AP as well as the conformance requirements in the ANSI/US PRO/IPO-100-1993 specification.

11. Implementation. The implementation of this standard involves four areas of consideration: effective date, acquisition, interpretation, and validation.

11.1 Effective Date. This publication is effective November 1, 1996. A transition period of twelve (12) months, beginning on the effective date, allows industry to produce IGES implementations and data files conforming to this standard. Agencies are encouraged to use this standard for solicitation proposals during the transition period. This standard is mandatory for use in all solicitation proposals for IGES data files and implementations (i.e., computer-aided design and manufacturing systems) acquired twelve (12) months after the effective date.

11.2 Acquisition of IGES Implementations and Data Files. Conformance to this standard should be considered whether the CAD/CAM systems are developed internally, acquired as part of a system procurement, acquired by separate procurement, used under a leasing agreement, or specified for use in contracts for programming services. Recommended terminology for procurement of FIPS IGES is contained in the U.S. General Services Administration publication Federal ADP and Telecommunications Standards Index, Chapter 5, Part 1.

11.3 Interpretation of FIPS IGES. Resolutions of questions regarding this standard will be provided by NIST. Procedures for interpretations are specified in FIPS PUB 29-3. All questions concerning the specifications and content should be addressed to: Director, Computer Systems Laboratory, ATTN: FIPS IGES Interpretation, Building 820, Room 562, National Institute of Standards and Technology, Gaithersburg, MD 20899.

11.4 Validation of IGES Implementations. Validation of IGES implementations is not mandatory at this time. Testing of an implementation's conformance to this FIPS IGES will be optional by the agency. Government agencies acquiring implementations in accordance with this standard may wish to require testing for conformance, interoperability, and performance. The tests to be administered and the testing organization are at the discretion of the agency Acquisition Authority.

12. Waivers. Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may redelegate such authority only to a senior official designated pursuant to section 3506(b) of Title 44, U.S. Code. Waivers shall be granted only when:

- a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal computer system, or
- b. Cause a major adverse financial impact on the operator which is not offset by Governmentwide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written decision which explains the basis on which the agency head made the required finding(s). A copy of each such decision, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; ATTN: FIPS Waiver Decisions, Building 820, Room 509; Gaithersburg, MD 20899.

In addition, notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Governmental Affairs of the Senate and shall be published promptly in the Federal Register.

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the Commerce Business Daily as a part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment to such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any supporting and accompanying documents, with such deletions as the agency is authorized and decides to make under 5 U.S.C. Sec. 552(b), shall be part of the procurement documentation and retained by the agency.

13. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. (Sale of the included specifications document is by arrangement with the National Computer Graphics Association and the American National Standards Institute.) When ordering, refer to Federal Information Processing Standards Publication 177-1 (FIPSPUB177-1), and title. Payment may be made by check, money order, or NTIS deposit account.

[FR Doc. 96-9941 Filed 4-22-96; 8:45 am]
BILLING CODE 3510-CN-M

National Oceanic and Atmospheric Administration

Monterey Bay National Marine Sanctuary Advisory Council; Meeting

AGENCY: Sanctuaries and Reserves Division (SRD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Monterey Bay National Marine Sanctuary Advisory Council Open Meeting.

SUMMARY: The Advisory Council was established in December 1993 to advise NOAA's Sanctuaries and Reserves Division regarding the management of the Monterey Bay National Marine Sanctuary. The Advisory Council was convened under the National Marine Sanctuaries Act.

TIME AND PLACE: Friday, April 26, 1996, from 10:00 until 3:00. The meeting will be held at the Montaro Point Lighthouse, Highway #1, Montaro, California.

AGENDA: General issues related to the Monterey Bay National Marine

Sanctuary are expected to be discussed, including an update from the Sanctuary Manager, reports from the working groups, a discussion of Sanctuary management options, a report on the elephant seal population at Piedras Blancas, and a discussion of kelp harvesting in the Sanctuary.

PUBLIC PARTICIPATION: The meeting will be open to the public. Seats will be available on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Jane Delay at (408) 647-4246 or Elizabeth Moore at (301) 713-3141.

Federal Domestic Assistance Catalog Number 11.429

Marine Sanctuary Program

Dated: April 17, 1996.

David L. Evans,

Acting Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 96-9987 Filed 4-22-96; 8:45 am]

BILLING CODE 3510-08-M

[Docket No. 960412111-6111-01; I.D. 040596B]

RIN 0648-ZA20

West Coast Salmon Fisheries; Northwest Emergency Assistance Plan (NEAP)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: On August 2, 1995, the Secretary of Commerce (Secretary) declared that a fishery resource disaster still persists in the Pacific States of California (north of San Francisco), Oregon, and Washington (excluding Puget Sound). Pursuant to this declaration, the Secretary has provided an additional \$13 million in assistance to the affected fishermen in the Pacific Northwest. The additional funds will be used to continue funding the Northwest Emergency Assistance Plan (NEAP). The purpose of this action is to notify the public of new aspects of the NEAP and to solicit comments on proposed changes to the NEAP.

DATES: Written comments must be received by May 23, 1996.

ADDRESSES: Comments should be sent to Stephen P. Freese, Northwest Emergency Assistance Plan, Trade and Industry Services Division, Northwest Regional Office, National Marine Fisheries Service, BIN C15700, 7600 Sand Point Way NE, Seattle, WA 98115.

FOR FURTHER INFORMATION CONTACT: Stephen Freese, (206) 526-6113.

SUPPLEMENTARY INFORMATION:

Background

On May 26, 1994, the Secretary declared a fishery resource disaster, and authorized the expenditure of \$12 million in financial assistance for the NEAP, under the authority of section 308(d) of the Interjurisdictional Fisheries Act (IFA); (16 U.S.C. 1407(d)). Pursuant to the Secretary's declaration, NMFS established three NEAP programs: (1) A habitat restoration jobs program (\$6 million), administered by the U.S. Department of Agriculture's Natural Resources Conservation Service (USDA/NRCS); (2) a salmon fishing license buy out program (\$4 million), which has been completed by the Washington Department of Fish and Wildlife (WDFW); and (3) a data collection jobs program (\$2 million), administered by the Pacific States Marine Fisheries Commission (PSMFC). These programs provided financial assistance to the fishermen who suffered losses due to the fishery resource disaster that arose from factors that included drought, flooding, minimal snowpack, and an extreme El Niño ocean warming event.

On August 2, 1995, the Secretary declared that the fishery resource disaster continued in 1995 for the salmon fisheries of the Pacific States of California (north of San Francisco), Oregon, and Washington, excluding Puget Sound. In extending the disaster and determining its impacts, the Secretary considered the magnitude of the disaster in economic and social terms, in addition to the various natural factors causing the fishery resource disaster. Salmon stocks along the West Coast remain extremely depressed, and the fishery disaster has caused high levels of economic damage and social disruption. Therefore, NMFS will continue the NEAP to encompass the disaster period that extends from January 1, 1991 through December 31, 1995, and will continue to provide funding pursuant to the Federal Register notice that established the NEAP, published on October 11, 1994 (59 FR 51419), with subsequent minor amendments published on January 31, 1995, and June 22, 1995 (60 FR 3908, 60 FR 32507). The original NEAP terms and conditions will be in effect until the proposed revisions to the NEAP that are contained in this notice are finalized and implemented.

Of the \$13 million in additional NEAP funding, NMFS will transfer \$4.8 million to USDA/NRCS to continue its role as administrative intermediary for

the Habitat Restoration Jobs Program, and award \$2.65 million to the PSMFC for the 1996 phase of the Data Collection Jobs Program. Both the USDA/NRCS and the PSMFC will use the same criteria as those established in the NEAP and set forth in October 11, 1994, Federal Register notice (59 FR 51419). If the revised criteria proposed in this notice are adopted, NMFS will amend the agreement with USDA and the grant to PSMFC accordingly, and the revised criteria will be effective from the date of publication of the final Federal Register notice announcing this program. NMFS has also allocated \$5.25 million for the License Buy Out Program to continue to purchase licenses from fisheries that depend on chinook and coho salmon. NMFS proposes to implement this program through WDFW by June 1, 1996. NMFS proposes to maintain the same limitations in determining maximum bid amounts as currently employed in the NEAP. Reasons for using the same limitations include fairness to previous successful participants, reduced administrative costs, and reduced paperwork burden upon fishermen. NMFS is retaining \$300,000 for administrative costs.

Congress is currently considering amendments to the IFA. If such amendments are passed and can be applied retroactively, or if such amendments become law prior to publication of a final Federal Register notice announcing this program, the eligibility criteria may be subject to further change. Although NMFS may choose to maintain the current eligibility criteria to minimize disruption to the existing programs, or for other reasons, NMFS may change some or all of the eligibility limitations for certain programs. Such changes may mean that participation in the program would no longer be restricted to applicants with gross incomes under \$2 million, financial assistance would no longer be limited to \$100,000, and no calculation of uninsured loss would be necessary.

New Aspects to the NEAP Programs

NMFS has determined that changes are required to certain aspects of the NEAP programs in order to ensure effective implementation. This notice serves to notify the public of those changes.

The calculation of uninsured loss will change due to the expansion of the disaster period pursuant to the Secretary's 1995 disaster declaration and to new biological information on the state of the fishery in 1991. NMFS is extending the disaster period from 1992-1994 to 1991-1995 based on a

review of biological studies and on landings and ex-vessel revenue trends in ocean (Northern California, Oregon, and Washington) and Columbia River coho and chinook fisheries. Many, if not all, of the factors underlying the decline in the 1992-94 fisheries were present in 1991. The disaster period includes the year 1995 pursuant to the Secretary's 1995 disaster declaration.

Furthermore, as a result of the Secretary's expansion of the disaster and NMFS's efforts to improve the program, the term "loss", as defined in the NEAP published on January 31, 1994 (60 FR 5908), is redefined as a loss of income not subject to Federal or state compensation and determined by the following multi-step procedure. In Step 1, the applicant can select a base year from the years 1986 through 1991. In Step 2, the applicant can select a comparison year from the years 1991 through 1995. Step 3 will remain the same, i.e., the comparison year must be less than the base year in order to show a loss. Step 4 of this procedure is now different from the procedure set forth in the January 31, 1994, Federal Register notice due to the expansion of the disaster period to the years 1991 through 1995. The amount of annual loss is now multiplied by five, as opposed to three, to account for this expansion.

Finally, applicants can now use either their 1993, 1994, or 1995 gross income to determine whether they meet the \$25,000 or \$50,000 gross income cap.

Proposed Revisions to the NEAP Programs

NMFS proposes to revise some of the limitations, terms, and conditions to address the new disaster declaration for the continuation of the NEAP. The intent of these revisions is to increase the number of fishermen eligible to receive assistance under the NEAP, as well as continue the conservation work already begun. Section 308(d) of the IFA requires the Secretary to solicit public comment on the limitations, terms, and conditions that the Secretary has determined are necessary to administer the NEAP. Accordingly, the public is requested to comment on the items below.

(1) Proposed Change to Minimum Amount of Commercial Fishing Income Earning Requirement

An applicant must have earned at least \$2,500 in commercial fishing income in the base year selected in determining loss. The decrease to \$2,500 from \$5,000 would provide crew members with greater accessibility to

the program. The rest of the eligibility criteria would remain the same.

(2) Ability to Participate in All NEAP Programs

Participants in the License Buy Out Program would not be excluded from participation in the Habitat Restoration and Data Collection Jobs Program. Therefore, a fisherman who sold a license under the License Buy Out Program could be employed under either of the Jobs Programs, as long as the total compensation did not exceed 75 percent of the fisherman's uninsured loss. Compensation includes all compensation earned from NEAP.

(3) Requirement for Fishermen to Possess Same Licenses in 1995 as Were Possessed in 1994

NMFS proposes to exclude applicants from the License Buy Out Program who bought licenses in 1995. Such exclusion would limit applicants who speculated on the licenses in 1995 in anticipation of the revised License Buy Out program. Therefore, applicants to the License Buy Out Program who possessed one of the Washington State salmon licenses listed below in 1995 must also have possessed the same license(s) in 1994:

- (a) Salmon troll license
- (b) Salmon delivery license
- (c) Salmon gill net—Grays Harbor-Columbia River
- (d) Salmon gill net—Willapa Bay-Columbia River
- (e) Salmon charter

(4) Alternative Bidding Options for the License Buy Out Program

Option 1—According to gear group, all eligible fishermen would submit new bids or verify that they wish to maintain their previous bids. Offer packages would be ranked. Starting with the lowest offers in each license type, licenses would be accepted and retired by WDFW.

Option 2—WDFW would purchase licenses from the pool of applicants for the NEAP License Buy Out Program, beginning with the lowest unsuccessful 1995 offer. The WDFW would purchase licenses until the remaining funds are insufficient for the entire next offer amount.

Option 3—WDFW would purchase licenses beginning with the pool of applicants for the NEAP License Buy Out Program. Licensees who offered licenses in the NEAP, but were unsuccessful, would have an opportunity to sell their licenses for the last price paid per gear group. These amounts are: Salmon troll and delivery—\$24,984, Salmon gill net—\$38,000, and Salmon charter—\$21,300.

If any funds remain after purchase of licenses from the 1995 program applicants, 1996 program applications would be accepted as provided for in this section from persons who are eligible to participate, starting with the lowest offer. The WDFW would purchase licenses until the remaining funds are insufficient for the entire next offer amount.

Option 4—This option is modeled conceptually on NMFS's Fishing Capacity Reduction Demonstration Program (FCRDP) for Northeast groundfish vessels, published in the Federal Register, June 22, 1995 (60 FR 32504). Under the FCRDP, NMFS bought out both vessels and licenses, and bids were ranked by taking into consideration vessel performance. Under Option 4, WDFW would continue to buy out only licenses, but would establish a ranking system similar to that of the FCRDP. Bids would be ranked by license score, and the license score would be determined by dividing the bid by the applicant's uninsured loss, since the calculation of uninsured loss reflects vessel performance.

Using the same limitations employed in the 1995 NEAP buy out program, the applicant would submit a bid that can range from \$1.00 up to the maximum amount that the applicant can bid. The maximum amount that an applicant can bid is 2.25 times the difference between the highest gross income derived from salmon fishing during any calendar year 1986 through 1991 (which becomes the applicant's "base year"), and the least amount of gross income derived from salmon fishing activities during any calendar year from 1992 through 1994 (which becomes the applicant's "comparison year"). No bid can exceed \$100,000 minus any Federal unemployment or NEAP related income already received.

Using the definition of uninsured loss as defined by this notice, the applicant would also submit the amount of uninsured loss suffered as a result of the fishery disaster. Uninsured loss is 5 times the difference between the highest gross income derived from salmon fishing during any calendar year 1986 through 1991 (base year), and the least amount of gross income derived from salmon fishing activities during any calendar year from 1991 through 1995 (comparison year). The comparison year must be less than the base year. The applicant's bid amount would then be divided by the applicant's uninsured loss to determine the applicant's license score. The scores of all the applicants would be ranked from low to high with the lowest scores being purchased first.

Provided below are three examples of this scoring process:

Example 1

Step A. Applicant A submits a bid for \$18,500.

Step B. Applicant A has an uninsured loss of \$29,670.

Step C. The score for Applicant A is .6235 (\$18,500 divided by \$29,670).

Example 2

Applicant B submits the same bid as Applicant A (\$18,500). However, the uninsured loss for Applicant B is \$42,680.

Step A. Applicant B submits a bid for \$18,500.

Step B. Applicant B has an uninsured loss of \$42,680.

Step C. The score for Applicant B is .4335 (\$18,500 divided by \$42,680).

Example 3

Applicant C submits a bid for \$35,000. Applicant C's uninsured loss is \$81,860.

Step A. Applicant C submits a bid for \$35,000.

Step B. Applicant C has an uninsured loss of \$81,860.

Step C. The score for Applicant C is .4276 (\$35,000 divided by \$81,860).

Even though Applicant C's bid is higher than that of Applicants A and B, Applicant C's score is lower because of the greater uninsured loss. Consequently, Applicant C would be selected over Applicants A or B, and Applicant B would be selected before Applicant A. In the instances where a choice must be made between two or more equally scored bids, applicants with the lowest bid (Step A) will be given preference.

Catalogue of Federal Domestic Assistance

The NEAP is listed in the "Catalogue of Federal Domestic Assistance" under No.11.452, Unallied Industry Projects.

Classification

This action has been determined to be not significant for purposes of E.O. 12866.

Some of the activities mentioned in this notice are subject to the Paperwork Reduction Act (PRA). They have been approved by the Office of Management and Budget (OMB) under control number 0648-0288.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to, a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

Dated: April 17, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 96-9906 Filed 4-18-96; 3:09 pm]

BILLING CODE 3510-22-F

COMMODITY FUTURES TRADING COMMISSION

Agricultural Advisory Committee Meeting

This is to give notice, pursuant to Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, Section 10(a) and 41 CFR 101-6.1015(b), that the Commodity Futures Trading Commission's Agricultural Advisory Committee will conduct a public meeting on May 8, 1996 from 1:00 p.m. to 5:00 p.m. in the first floor hearing room of the Commodity Futures Trading Commission (Room 1000), Three Lafayette Centre, 1155 21st Street, N.W., Washington, D.C. 20581. The agenda will consist of:

Agenda

- I. Opening Remarks by Acting Chairman John E. Tull;
- II. Report from Dr. Wayne Purcell, of Virginia Tech, on "Needed Changes in Tax Treatment of Cattle Feeders' Activities in Cattle Futures;"
- III. Report on the FAIR Act Provisions for a USDA Office of Risk Management;
- IV. Report from the CBOT Regular Grain Storage Capacity Task Force;
- V. Report from the National Grain and Feed Association's Risk Evaluation Task Force;
- VI. Presentation by CBOT on the Project A Trading System;
- VII. Update on the CFTC-DEA Staff White Paper on the Agricultural Trade Option Prohibition;
- VIII. Report on the CME Proposal to Increase the Spot Month Speculative Position Limit on the Live Cattle Contract;
- IX. Other Committee Business;
- X. Closing Remarks by Commissioner Joseph Dial.

The purpose of this meeting is to solicit the views of the Committee on the above-listed agenda matters. The Advisory Committee was created by the Commodity Futures Trading Commission for the purpose of receiving advice and recommendations on agricultural issues. The purposes and objectives of the Advisory Committee are more fully set forth in the sixth renewal charter of the Advisory Committee.

The meeting is open to the public. The Chairman of the Advisory Committee, Commissioner Joseph B. Dial, is empowered to conduct the meeting in a fashion that will, in his

judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Advisory Committee should mail a copy of the statement to the attention of: the Commodity Futures Trading Commission Agricultural Advisory Committee c/o Kimberly Harter, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, N.W., Washington, D.C. 20581, before the meeting. Members of the public who wish to make oral statements should also inform Ms. Harter in writing at the foregoing address at least three business days before the meeting. Reasonable provision will be made, if time permits, for an oral presentation of no more than five minutes each in duration.

Issued by the Commission in Washington, D.C. on April 17, 1996.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96-9931 Filed 4-22-96; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF ENERGY

Low-Level Radioactive Waste Program, Idaho Operations Office; Notice of Intent

SUMMARY: The U.S. Department of Energy's (DOE) Office of Environmental Management through the Idaho Operations Office and pursuant to 10 CFR 600.6(c), intends to negotiate and award on a noncompetitive basis, a renewal of Grant No. DE-FG07-90ID13039 to the state of Washington's Department of Ecology (Washington) on behalf of the Low-Level Radioactive Waste Forum (Forum). The total estimated cost of the three year 100% DOE funded renewal award is \$1,972,002 or \$657,334 per year. The technical assistance proposed is the result of an unsolicited request from Washington for continued support of the Forum in maintaining an independent self-directed organization to promote an effective and efficient national system for the management and disposal of commercially generated low-level radioactive waste.

FOR FURTHER INFORMATION CONTACT: Dallas L. Hoffer, Contract Specialist, (208) 526-0014; U.S. Department of Energy, Idaho Operations Office, 850 Energy Drive, Mail Stop 1221, Idaho Falls, Idaho 83401-1563.

SUPPLEMENTARY INFORMATION: The anticipated award is justified in accordance with 10 CFR 600.6(c), as follows: The activity to be funded is necessary to the satisfactory completion

of an activity (a) that is presently being funded by DOE and (b) for which competition for support would have a significant adverse effect on continuity or completion of the activity.

The Statutory Authority for the renewal award can be found in Section 7(a) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (Pub. L. 99-240). In the Act, Congress has directed DOE to provide continuing technical assistance to states and compact commissions.

Procurement Request Number: 07-96ID13420.000.

Dated: April 10, 1996.

R. Jeffrey Hoyles,

Director, Procurement Services Division.

[FR Doc. 96-9939 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-M

Environmental Management Site-Specific Advisory Board, Idaho National Engineering Laboratory

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho National Engineering Laboratory (INEL)

DATES:

Site Tour: Monday, May 20, 1996 from 7:30 a.m. until 5:30 p.m. Mountain Savings Time (MST)

Meeting: Tuesday, May 21, 1996 from 8:00 a.m. until 6:00 p.m. MST. There will be a public comment availability session Tuesday, May 21, 1996 from 5:00 p.m. until 6:00 p.m. MST.

ADDRESSES: Holiday Inn Westbank, 475 Park Way, Idaho Falls, Idaho 83402.

FOR FURTHER INFORMATION CONTACT: Idaho National Engineering Laboratory Information 1-800-708-2680 or Marsha Hardy, Jason Associates Corporation Staff Support 1-208-522-1662.

SUPPLEMENTARY INFORMATION:

Purpose of the Board

The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Meeting Purpose

The EM SSAB, INEL will tour the Naval Reactors Facility, Radioactive Waste Management Complex, and some archeological sites at INEL. The Board

meeting features consensus training, a panel discussion on Health Effects issues, and presentations on informational topics including Integration of Federal Regulations and the Federal Facilities Compliance Act/Site Treatment Plan. Study issues for future recommendations include the Alternative Disposal Sites for Low-Level Waste and the INEL Spent Nuclear Fuel Strategic Plan.

Tentative Agenda

Tuesday, May 21, 1996

7:30 a.m.—*Sign-in and Registration*

8:00 a.m.—*Miscellaneous Business:*

Old Business

- Jerry Bowman—Deputy Designated Federal Official Report
- Chuck Rice (acting)—Chair Report

Standing Committee Reports

- Member Selection Committee—Dean Mahoney (chair), Chuck Rice, E.J. Smith

Member Reports

9:00 a.m.—*Health Effects Panel*

Discussion (speakers to be announced)

10:15 a.m.—Break

10:30 a.m.—*Health Effects Panel*

Discussion (continued)

12:00 p.m.—Lunch

1:00 p.m.—*Consensus Training*

- Peter Woodrow, CDR Associates

2:30 p.m.—Break

2:45 p.m.—*Consensus Training*

(continued)

5:00 p.m.—*Public Comment Availability*

6:00 p.m.—Adjourn

Wednesday, May 22, 1996

7:30 a.m.—*Sign-in and Registration*

8:00 a.m.—*Miscellaneous Business*

8:45 a.m.—*Alternate Disposal Sites for Low-Level Waste*

- Committee members—Terry Perez, Chuck Rice, Clarence Bellem; Speaker to be announced; Presentation and Discussion

10:30 a.m.—Break

10:45 a.m.—*DOE Presentation: Integration of Regulations*

- Speaker to be announced; Presentation and Discussion

12:00 p.m.—Lunch

1:00 p.m.—*INEL Spent Nuclear Fuel Strategic Plan*

- Committee members—Ben Collins, Clarence Bellem, E.J. Smith; Speaker to be announced; Presentation and Discussion

3:00 p.m.—Break

3:15 p.m.—*Federal Facilities*

Compliance Act/Site Treatment Plan Update

4:00 p.m.—Board Work
4:30 p.m.—Meeting Evaluation
5:00 p.m.—Adjourn

This agenda is subject to change as the Board meeting nears. For a most current copy of the agenda, contact Woody Russell, DOE-Idaho, (208) 526-0561, or Marsha Hardy, Jason Associates, (208) 522-1662. The final agenda will be available at the meeting.

Public Comment Availability

The two-day meeting is open to the public, with a Public Comment Availability session scheduled for Tuesday, September 19, 1995 from 5:00 p.m. to 6:00 p.m. MST. The Board will be available during this time period to hear verbal public comments or to review any written public comments. If there are no members of the public wishing to comment or no written comments to review, the board will continue with its current discussion. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact the Idaho National Engineering Laboratory Information line or Marsha Hardy, Jason Associates, at the addresses or telephone numbers listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday, except Federal holidays.

Issued at Washington, DC on April 15, 1996.

Gail Cephas,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96-9944 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site.

DATES AND TIMES: Monday, May 13, 1996: 6:00 p.m.—7:00 p.m. (public comment session); Tuesday, May 14, 1996: 8:30 a.m.—4:00 p.m.

ADDRESSES: Hyatt Regency Savannah, Two West Bay Street, Savannah, Georgia.

FOR FURTHER INFORMATION CONTACT: Tom Heenan, Manager, Environmental Restoration and Solid Waste, Department of Energy Savannah River Operations Office, P.O. Box A, Aiken, S.C. 29802 (803) 725-8074.

SUPPLEMENTARY INFORMATION:

Purpose of the Board

The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management and related activities.

Tentative Agenda

Monday, May 13, 1996

6:00 p.m.—Public Comment Session (5-minute rule)

7:00 p.m.—Adjourn

Subcommittee meetings will follow the public comment session.

Tuesday, May 14, 1996

8:30 a.m.—Approval of Minutes, Agency Updates (~ 15 minutes); Public Comment Session (5-minute rule) (~ 30 minutes); Nuclear Materials Management Subcommittee Report (~ 2 hours); Recommendation on plutonium disposition; Outreach Subcommittee Report (~ 15 minutes)

12:00 p.m.—Lunch

1:00 p.m.—Environmental Remediation & Waste Management Subcommittee Report (~ 1.5 hours) Risk Management & Future Use Subcommittee Report (~ 30 minutes) Subcommittee Participation (~ 15 minutes)

4:00 p.m.—Adjourn

If needed, time will be allotted after public comments for items added to the agenda, and administrative details. A final agenda will be available at the meeting Monday, May 13, 1996.

Public Participation

The meeting is open to the public. Written statements may be filed with the Committee either before or after the

meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Tom Heenan's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday except Federal holidays. Minutes will also be available by writing to Tom Heenan, Department of Energy Savannah River Operations Office, P.O. Box A, Aiken, S.C. 29802, or by calling him at (803) 725-8074.

Issued at Washington, DC on April 16, 1996.

Gail Cephas,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96-9945 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

Environmental Management Site-Specific Advisory Board, Hanford Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford Site.

DATES: Thursday, May 2, 1996: 9:00 a.m.—5:15 p.m.; Friday, May 3, 1996: 8:30 a.m.—4:00 p.m.

ADDRESSES: Shilo Inn, 50 Comstock, Richland, Washington.

FOR FURTHER INFORMATION CONTACT: Jon Yerxa, Public Participation Coordinator, Department of Energy Richland Operations Office, P.O. Box 550, Richland, WA 99352.

SUPPLEMENTARY INFORMATION:

Purpose of the Board

The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental

restoration, waste management, and related activities.

Tentative Agenda.

May Meeting Topics

The Hanford Advisory Board will receive information on and discuss issues related to: the Tri-Party Agreement (TPA) Community Relations Plan, DOE budget issues, the status of M-33 negotiations, strategic planning, the Tank Waste Remediation System (TWRS) Draft Environmental Impact Statement, the status of TWRS privatization, TWRS TPA change packet, and the TWRS request for proposal.

Public Participation

The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jon Yerxa's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments. Due to programmatic issues that had to be resolved, the Federal Register notice is being published less than fifteen days before the date of the meeting.

Minutes

The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available by writing to Jon Yerxa, Department of Energy Richland Operations Office, P.O. Box 550, Richland, WA 99352, or by calling him at (509) 376-9628.

Issued at Washington, DC on April 17, 1996.

Gail Cephas,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96-9946 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

Office of Fossil Energy

National Coal Council; Notice of Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: National Coal Council.
Date and Time: Thursday, May 16, 1996, 9:00 a.m.

Place: Ritz-Carlton Washington, 2100 Massachusetts Avenue, N.W., Washington, D.C.

Contact: Margie D. Biggerstaff, U.S. Department of Energy, Office of Fossil Energy (FE-5), Washington, D.C. 20585; Telephone: 202/586-3867.

Purpose of the Council: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to coal and coal industry issues.

Tentative Agenda

- Call to order and opening remarks by Joseph Craft III, Chairman of the National Coal Council.
- Approval of final agenda.
- Remarks by the Honorable Hazel R. O'Leary, Secretary of Energy.
- Remarks by the Honorable Elizabeth Ann Moler, Chairman, Federal Energy Regulatory Commission. (Invited)
- Remarks by the Honorable Bob Armstrong, Assistant Secretary for Land and Minerals Management, Department of the Interior. (Invited)
- Remarks by the Honorable Fred J. Hansen, Deputy Administrator, Environmental Protection Agency. (Invited)
- Report of the Coal Policy Committee.
- Administrative matters.
- Election of 1996-97 Officers.
- Discussion of any other business properly brought before the Council.
- Public comment—10-minute rule.
- Adjournment.

Public Participation: The meeting is open to the public. The Chairman of the Council is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Council will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Margie D. Biggerstaff at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provisions will be made to include the presentation on the agenda.

Transcript: Available for public review and copying at the Public Reading Room, Room 1E-190, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C., between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, D.C., on April 17, 1996.

Gail Cephas,

Acting Deputy Advisory Committee Management Officer.

[FR Doc. 96-9942 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

PLD Advanced Automatic Systems, Inc.

AGENCY: Department of Energy, Office of the General Counsel.

ACTION: Notice of Intent to Grant Exclusive Patent License.

SUMMARY: Notice is hereby given of an intent to grant to PLD Advanced Automation Systems, Inc., of Rockledge, Florida, an exclusive license to practice the invention described in U.S. Patent No. 4,942,339, entitled "Intense, Steady State, Electron Beam Generator." The invention is owned by the United States of America, as represented by the Department of Energy (DOE). The proposed license will be exclusive for a specified duration, subject to a license and other rights retained by the U.S. Government, and other terms and conditions to be negotiated. DOE intends to grant the license, upon a final determination in accordance with 35 U.S.C. § 209(c), unless within 60 days of this notice the Assistant General Counsel for Technology Transfer and Intellectual Property, Department of Energy, Washington, D.C. 20585, receives in writing any of the following, together with supporting documents:

- (i) A statement from any person setting forth reasons why it would not be in the best interests of the United States to grant the proposed license; or
- (ii) An application for a nonexclusive license to the invention, in which applicant states that he has already brought the invention to practical application or is likely to bring the invention to practical application expeditiously.

DATES: Written comments or nonexclusive license applications are to be received at the address listed below no later than June 24, 1996.

ADDRESSES: Office of Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585.

FOR FURTHER INFORMATION: Robert J. Marchick, Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, Forrestal Building, Room 6F-067, 1000 Independence Avenue, Washington, D.C. 20585; Telephone (202) 586-4792.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 309(c) provides the Department with authority to grant exclusive or partially exclusive licenses in Department-owned inventions, where a determination can be made, among other things, that the desired practical application of the invention has not been achieved, or is not likely expeditiously to be achieved, under a nonexclusive license. The statute and implementing regulations (37 C.F.R. 404) require that the necessary determinations be made after public notice and opportunity for filing written objections.

PLD Advanced Automation Systems, Inc., of Rockledge, Florida, has applied for an exclusive license to practice the invention embodied in U.S. Patent No. 4,942,339, and has a plan for commercialization of the invention.

The proposed license will be exclusive as defined above, subject to a license and other rights retained by the U.S. Government, and subject to a negotiated royalty. The Department will review all timely written responses to this notice, and will grant the license if, after expiration of the 60-day notice period, and after consideration of written responses to this notice, a determination is made, in accordance with 35 U.S.C. 209(c), that the license grant is in the public interest.

Issued in Washington, D.C., on April 16, 1996.

Agnes P. Dover,

Deputy General Counsel for Technology Transfer and Procurement.

[FR Doc. 96-9943 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

Office of Energy Efficiency and Renewable Energy

[Case No. DH-005]

Energy Conservation Program for Consumer Products: Decision and Order Granting a Waiver From the Vented Home Heating Equipment Test Procedure to Superior Fireplace Company

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Decision and order.

SUMMARY: Notice is given of the Decision and Order (Case No. DH-005) granting a Waiver to Superior Fireplace Company (Superior) from the existing Department of Energy (DOE or Department) test procedure for vented home heating equipment. The Department is granting Superior's Petition for Waiver regarding pilot light

energy consumption for manually controlled heaters in the calculation of Annual Fuel Utilization Efficiency (AFUE), and calculation procedure for weighted average steady state efficiency for manually controlled heaters with various input rates for its models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters.

FOR FURTHER INFORMATION CONTACT:

William W. Hui, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Mail Station EE-431, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0121, (202) 586-9145

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-72, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0103, (202) 586-9507.

SUPPLEMENTARY INFORMATION: In accordance with Title 10 CFR 430.27(j), notice is hereby given of the issuance of the Decision and Order as set out below. In the Decision and Order, Superior has been granted a Waiver for its models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters, permitting the company to use an alternate test method in determining AFUE.

Issued in Washington, DC, on April 4, 1996.

Christine A. Ervin,

Assistant Secretary, Energy Efficiency and Renewable Energy.

Decision and Order, Department of Energy, Office of Energy Efficiency and Renewable Energy

In the Matter of: Superior Fireplace Company (Case No. DH-005)

Background

The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act, Public Law 94-163, 89 Stat. 917, as amended (EPCA), which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer products, including vented home heating equipment. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at Title 10 CFR Part 430, Subpart B.

The Department amended the prescribed test procedures by adding

Title 10 CFR 430.27 to create a waiver process. 45 FR 64108, September 26, 1980. Thereafter, DOE further amended its appliance test procedure waiver process to allow the Assistant Secretary for Energy Efficiency and Renewable Energy (Assistant Secretary) to grant an Interim Waiver from test procedure requirements to manufacturers that have petitioned DOE for a waiver of such prescribed test procedures. 51 FR 42823, November 26, 1986.

The waiver process allows the Assistant Secretary to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing according to the prescribed test procedures or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until final test procedure amendments become effective, resolving the problem that is the subject of the waiver.

Superior filed a "Petition for Waiver" dated August 30, 1995, a second letter, dated November 30, 1995, which requested modification to the minimum fuel input rate of the vented heaters previously submitted for consideration, and a third letter dated January 12, 1996, which provided a list of companies that make similar products, confidential product performance data, and amending the list of models submitted for consideration in the August 30, 1995, Waiver request, in accordance with section 430.27 of Title 10 CFR Part 430. The Department published in the Federal Register on February 14, 1996, Superior's Petition and solicited comments, data and information respecting the Petition. 61 FR 5755, February 14, 1996. Superior also filed an "Application for Interim Waiver" under section 430.27(b)(2), which DOE granted on February 1, 1996. 61 FR 5755, February 14, 1996.

No comments were received concerning either the "Petition for Waiver" or the "Interim Waiver." The Department consulted with The Federal Trade Commission (FTC) concerning the Superior Petition. The FTC did not have any objections to the issuance of the waiver to Superior.

Assertions and Determinations

Superior's Petition seeks a waiver from the DOE test provisions regarding (a) pilot light energy consumption for manually controlled heaters in the calculation of AFUE and (b) calculation procedure for weighted average steady

state efficiency for manually controlled heaters with various input rates. The DOE test provisions in section 3.5 of Title 10 CFR Part 430, Subpart B, Appendix O requires measurement of energy input rate to the pilot light (Q_p) with an error no greater than 3 percent for vented heaters, and use of this data in section 4.2.6 for the calculation of AFUE using the formula: $AFUE = [4400\eta_{ss}\eta_u Q_{in-max}] / [4400\eta_{ss}Q_{in-max} + 2.5(4600)\eta_u Q_p]$. Superior requests the allowance to delete the $[2.5(4600)\eta_u Q_p]$ term in the denominator in the calculation of AFUE when testing its models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters. Superior states that its models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters are designed with a transient pilot which is to be turned off by the user when the heater is not in use. The control knob on the combination gas control in these heaters has three positions: "OFF," "PILOT" and "ON". Gas flow to the pilot is obtained by rotating the control knob from "OFF" to "PILOT," depressing the knob, holding in, pressing the piezo igniter. When the pilot heats a thermocouple element, sufficient voltage is supplied to the combination gas control for the pilot to remain lit when the knob is released and turned to the "ON" position. The main burner can then be ignited by moving an ON/OFF switch to the "ON" position. Instructions to instruct users to turn the gas control knob to the "OFF" position when the heater is not in use, which automatically turns off the pilot, are provided in the User's Instruction Manual and on a label adjacent to the gas control knob. If the manufacturer's instructions are observed by the user, the pilot light will not be left on. This will result in a lower energy consumption, and in turn a higher efficiency than calculated by the current DOE test procedure. Since the current DOE test procedure does not address this issue, Superior asks that the Waiver be granted.

Based on DOE's review of how Superior's models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters operate and the fact that if the manufacturer's instructions are followed, the pilot light will not be left on, DOE grants Superior a Petition for Waiver to exclude the assumed pilot light energy input term in the calculation of AFUE.

This decision is subject to the condition that the heaters shall have an easily read label near the gas control

knob instructing the user to turn the valve to the off-position when the heaters are not in use be maintained.

Superior also seeks a Waiver from the DOE test provisions in section 3.1.1 of Title 10 CFR Part 430, Subpart B, Appendix O that require steady state efficiency for manually controlled heaters with various flow rates to be determined at a fuel input rate that is within ± 5 percent of 50 percent of the maximum fuel input rate, and the use of this data in section 4.2.4 to determine the weighted average steady state efficiency in the calculation of AFUE.

Superior states that its manually controlled heaters utilize a gas control with a variable pressure regulator control that allows the user to select various fuel input rates by varying the range of pressures of the heaters, and request that it be allowed to determine steady state efficiency and weighted average steady state efficiency in the calculation of AFUE at a minimum fuel input rate of no greater than two-thirds of the maximum fuel input rate instead of the specified ± 5 percent of 50 percent of the maximum fuel input rate. Also, previous Petitions for Waiver to exclude the pilot light energy input term in the calculation of AFUE for home heating equipment with a manual transient pilot control and allowance to determine steady state efficiency and weighted average steady state efficiency used in the calculation of AFUE at a minimum fuel input rate of 65.3 percent of the maximum fuel input rate have been granted by DOE to Appalachian Stove and Fabricators, Inc., 56 FR 51711, October 15, 1991, and Valor Inc., 56 FR 51714, October 15, 1991.

Based on DOE having granted similar waivers in the past to heaters utilizing a variable pressure regulator control that allows a user to set various fuel input rates, DOE agrees that a waiver should be granted to allow the determination of steady state efficiency and weighted average steady state efficiency used in the calculation of AFUE at a minimum fuel input rate of no greater than two-thirds of the maximum fuel input rate instead of the specified ± 5 percent of 50 percent of the maximum fuel input rate for Superior models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters.

It is therefore, ordered that:

(1) The "Petition for Waiver" filed by Superior Fireplace Company (Case No. DH-005) is hereby granted as set forth in paragraph (2) below, subject to the provisions of paragraphs (3), (4), and (5).

(2) Notwithstanding any contrary provisions of Appendix O of Title 10 CFR Part 430, Subpart B, Superior

Fireplace Company shall be permitted to test its models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters on the basis of the test procedure specified in Title 10 CFR Part 430, with modifications set forth below:

(i) Delete paragraph 3.5 of Appendix O.

(ii) The last paragraph of 3.1.1 of Appendix O is revised to read as follows:

3.1.1 (a) For manually controlled gas fueled vented heaters, with various input rates determine the steady-state efficiency at:

(1) A fuel input rate within ± 5 percent of 50 percent of the maximum fuel input rate or,

(2) The minimum fuel input rate if the design of the heater is such that ± 5 percent of 50 percent of the maximum fuel input rate can not be set, provided this minimum input rate is no greater than two-thirds of the maximum input rate of the heater.

(b) If the heater is designed to use a control that precludes operation at other than maximum output (single firing rate) determine the steady state efficiency at the maximum input rate only.

(iii) Delete paragraph 4.2.4 of Appendix O and replace with the following paragraph:

4.2.4 Weighted Average Steady-State Efficiency. (a) For manually controlled heaters with various input rates, the weighted average steady-state efficiency (η_{ss-wr}) is:

(1) At ± 5 percent of 50 percent of the maximum fuel input rate as measured in either section 3.1.1 to this appendix for manually controlled gas vented heaters or section 3.1.2 to this appendix for manually controlled oil vented heaters, or

(2) At the minimum fuel input rate as measured in either section 3.1.1 to this appendix for manually controlled gas vented heaters or section 3.1.2 to this appendix for manually controlled oil vented heaters if the design of the heater is such that ± 5 percent of 50 percent of the maximum fuel input rate can not be set, provided the tested input rate is no greater than two-thirds of maximum input rate of the heater.

(b) For manually controlled heater with one single firing rate, the weighted average steady-state efficiency is the steady-state efficiency measured at the single firing rate.

(iv) Delete paragraph 4.2.6 of Appendix O and replace with the following paragraph:

4.2.6 Annual Fuel Utilization Efficiency. For manually controlled vented heaters, calculate the Annual

Fuel Utilization Efficiency (AFUE) as a percent and defined as:

$$AFUE = \eta_u$$

where:

η_u = as defined in section 4.2.5 of this appendix.

(v) With the exception of the modification set forth above, Superior Fireplace Company shall comply in all respects with the test procedures specified in Appendix O of Title 10 CFR Part 430, Subpart B.

(3) The Waiver shall remain in effect from the date of issuance of this Order until DOE prescribes final test procedures appropriate to models GI-3821, DSH-36T, DVH-33R, DVH-33T, DVA-33R, and DVA-33T manually controlled vented heaters manufactured by Superior Fireplace Company.

(4) This Waiver is based upon the presumed validity of statements, allegations, and documentary materials submitted by the petitioner. This Waiver may be revoked or modified at any time upon a determination that a factual basis underlying the Petition is incorrect.

(5) Effective April 14, 1996, this Waiver supersedes the Interim Waiver granted Superior Fireplace Company on February 1, 1996. 61 FR 5755, February 14, 1996. (Case No. DH-005).

Issued in Washington, D.C., on April 4, 1996.

Christine A. Ervin,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 96-9948 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

FOR FURTHER INFORMATION CONTACT:

Cyrus H. Nasser, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Mail Station EE-431, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0121 (202) 586-9138

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC-72, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0103, (202) 586-9507.

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 430.27(j), notice is hereby given of the issuance of the Decision and Order as set out below. In the Decision and Order, Thermo has been granted a Waiver for its CHA-upflow and CGA-downflow series of condensing gas furnaces permitting the company to use an alternate test method in determining AFUE.

Issued in Washington, DC, on April 4, 1996.

Christine A. Ervin,

Assistant Secretary, Energy Efficiency and Renewable Energy.

Decision and Order, Department of Energy, Office of Energy Efficiency and Renewable Energy

In the matter of: Thermo Products Inc. (Case No. F-083).

Background

The Energy Conservation Program for Consumer Products (other than automobiles) was established pursuant to the Energy Policy and Conservation Act, Public Law 94-163, 89 Stat. 917, as amended (EPCA), which requires DOE to prescribe standardized test procedures to measure the energy consumption of certain consumer products, including furnaces. The intent of the test procedures is to provide a comparable measure of energy consumption that will assist consumers in making purchasing decisions. These test procedures appear at 10 CFR Part 430, Subpart B.

The Department amended the prescribed test procedures by adding 10 CFR 430.27 to create a waiver process. 45 FR 64108, September 26, 1980. Thereafter, DOE further amended its appliance test procedure waiver process to allow the Assistant Secretary for Energy Efficiency and Renewable Energy (Assistant Secretary) to grant an Interim Waiver from test procedure requirements to manufacturers that have petitioned DOE for a waiver of such prescribed test procedures. 51 FR 42823, November 26, 1986.

The waiver process allows the Assistant Secretary to waive temporarily test procedures for a particular basic model when a petitioner shows that the basic model contains one or more design characteristics which prevent testing according to the prescribed test procedures or when the prescribed test procedures may evaluate the basic model in a manner so unrepresentative of its true energy consumption as to provide materially inaccurate comparative data. Waivers generally remain in effect until test procedure amendments become effective, resolving the problem that is the subject of the waiver.

Thermo filed a "Petition for Waiver," dated November 29, 1995, in accordance with section 430.27 of 10 CFR Part 430. The Department published in the Federal Register on January 30, 1996. Thermo's Petition and solicited comments, data and information respecting the Petition. 61 FR 3023, January 30, 1996. Thermo also filed an "Application for Interim Waiver" under section 430.27(b)(2), which DOE granted on January 24, 1996. 61 FR 3023, January 30, 1996.

No Comments were received concerning either the "Petition for Waiver" or the "Application for Interim Waiver." The Department consulted with The Federal Trade Commission (FTC) concerning the Thermo Petition. The FTC did not have any objections to the issuance of the waiver to Thermo.

Assertions and Determinations

Thermo's Petition seeks a waiver from the DOE test provisions that require a 1.5-minute time delay between the ignition of the burner and the starting of the circulating air blower. Thermo requests the allowance to test using a 45-second blower time delay when testing its CHA-upflow and CGA-downflow series of condensing gas furnaces. Thermo states that since the 45-second delay is indicative of how these models actually operate, and since such a delay results in an increase in AFUE improvement of up to 2.0 percent, the Petition should be granted.

Under specific circumstances, the DOE test procedure contains exceptions which allow testing with blower delay times of less than the prescribed 1.5-minute delay. Thermo indicates that it is unable to take advantage of any of these exceptions for its CHA-upflow and CGA-downflow series of condensing gas furnaces.

Since the blower controls incorporated on the Thermo furnaces are designed to impose a 45-second blower delay in every instance of start up, and since the current test procedure

[Case No. F-083]

Energy Conservation Program for Consumer Products: Decision and Order Granting a Waiver From the Furnace Test Procedure to Thermo Products Inc.

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Decision and order.

SUMMARY: Notice is given of the Decision and Order (Case No. F-083) granting a Waiver to Thermo Products Inc. (Thermo) from the existing Department of Energy (DOE or Department) test procedure for furnaces. The Department is granting Thermo's Petition for Waiver regarding blower time delay in calculation of Annual Fuel Utilization Efficiency (AFUE) for its CHA-upflow and CGA-downflow series of condensing gas furnaces.

provisions do not specifically address this type of control, DOE agrees that a waiver should be granted to allow the 45-second blower time delay when testing the Thermo CHA-upflow and CGA-downflow series of condensing gas furnaces. Accordingly, with regard to testing the CHA-upflow and CGA-downflow series of condensing gas furnaces, today's Decision and Order exempts Thermo from the existing test procedure provisions regarding blower control and allows testing with the 45-second delay.

It is, therefore, ordered that:

(1) The "Petition for Waiver" filed by Thermo Products Inc. (Case No. F-083) is hereby granted as set forth in paragraph (2) below, subject to the provisions of paragraph (3), (4), and (5).

(2) Notwithstanding any contrary provisions of Appendix N of 10 CFR Part 430, Subpart B, Thermo Products Inc., shall be permitted to test its CHA-upflow and CGA-downflow series of condensing gas furnaces on the basis of the test procedure specified in 10 CFR Part 430, with modifications set forth below.

(I) Section 3.0 of Appendix N is deleted and replaced with the following paragraph:

3.0 Test Procedure. Testing and measurements shall be as specified in section 9 in ANSI/ASHRAE Standard 103-82 with the exception of section 9.2.2, 9.3.1, and 9.3.2, and the inclusion of the following additional procedures:

(ii) Add a new paragraph 3.10 to Appendix N as follows:

3.10 Gas- and Oil-Fueled Central Furnaces. The following paragraph is in lieu of the requirement specified in section 9.3.1. of ANSI/ASHRAE Standard 103-82. After equilibrium conditions are achieved following the cool-down test and the required measurements performed, turn on the furnace and measure the flue gas temperature, using the thermocouple grid described above, at 0.5 and 2.5 minutes after the main burner(s) comes on. After the burner start-up, delay the blower start-up by 1.5 minutes (t-), unless: (1) the furnace employs a single motor to drive the power burner and the indoor air circulating blower, in which case the burner and blower shall be started together; or (2) the furnace is designed to operate using an unvarying delay time that is other than 1.5 minutes, in which case the fan control shall be permitted to start the blower; or (3) the delay time results in the activation of a temperature safety device which shuts off the burner, in which case the fan control shall be permitted to start the blower. In the latter case, if the fan control is adjustable, set it to

start the blower at the highest temperature. If the fan control is permitted to start the blower, measure time delay, (t-), using a stopwatch. Record the measured temperatures. During the heat-up test for oil-fueled furnaces, maintain the draft in the flue pipe within ± 0.01 inch of water column of the manufacturer's recommended on-period draft.

(iii) With the exception of the modifications set forth above, Thermo Products Inc. shall comply in all respects with the test procedures specified in Appendix N of 10 CFR Part 430, Subpart B.

(3) The Waiver shall remain in effect from the date of issuance of this Order until DOE prescribes final test procedures appropriate to the CHA-upflow and CGA-downflow series of condensing gas furnaces manufactured by Thermo Products Inc.

(4) This Waiver is based upon the presumed validity of statements, allegations, and documentary materials submitted by the petitioner. This Waiver may be revoked or modified at any time upon a determination that the factual basis underlying the Petition is incorrect.

(5) Effective April 14, 1996, this Waiver supersedes the Interim Waiver granted Thermo Products Inc. on January 24, 1996. 61 FR 3023, January 30, 1996 (Case No. F-083).

Issued In Washington, DC, on April 4, 1996.

Christine A. Ervin,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 96-9949 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-M

Energy-Efficiency and Renewable Energy Office

Energy-Efficient Product Commercialization Study

AGENCY: Office of Energy Efficiency and Renewable Energy, DOE.

ACTION: Notice.

SUMMARY: The Department of Energy (DOE) is investigating the potential use of the purchasing power of the Federal government to promote the commercialization of energy-efficient products that incorporate new, value-added technologies for federal buyers. The Energy Policy Act directs the Secretary of Energy to conduct a study to identify energy-efficient, renewable energy, and water conserving products for which there is a high potential for federal purchasing power to substantially promote their

development and commercialization, and to identify barriers to federal procurement of such products. The principal product focus of the study is on those which are beyond the prototype stage, but are not commercially available or in widespread use. These products must also be potentially cost-effective to federal and non-federal buyers, with increased production and sales volume. DOE is soliciting information from interested parties concerning products which offer this potential, recommendations on how federal procurement actions could facilitate product commercialization, and existing barriers to such procurement actions.

DATES: Written information on products which meet the criteria listed below, barriers to federal procurement of such products, and recommended federal procurement actions and programs to promote commercialization of such products (1 copy) must be received on or before May 13, 1996, to be included for consideration in this study. A public meeting will be held on June 5, 1996; requests to present information at this public meeting on recommended federal actions and programs must be received by May 13, 1996.

ADDRESSES: All written comments (1 copy), as well as requests to speak at the public meeting, are to be submitted to: U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE-90, Energy-Efficient Product Commercialization Study, 1000 Independence Avenue SW., Washington, DC 20585-0121, 202-586-8287. FAXed comments may be sent to 202-586-3000. The public meeting will be held at the U.S. Department of Energy, Main Auditorium, 1000 Independence Avenue, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Rick Klimkos, EE-90, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585-0121, 202-586-8287.

SUPPLEMENTARY INFORMATION: The Federal government is the largest customer in the world for many energy-related products. The Department of Energy (DOE) is investigating the potential use of the purchasing power of the Federal government to promote the development and commercialization of energy-efficient products that incorporate new, value-added technologies for federal buyers. The objective of this study is to identify energy-efficient, renewable energy, and water conserving products for which there is a high potential for federal purchasing power to substantially

promote their commercialization, and to identify barriers to federal procurement of such products. It is anticipated that Government procurement of energy efficient products will stimulate industry to introduce energy-efficient products which enhance national competitiveness both domestically and internationally, to achieve a production scale which improves the cost-effectiveness of new technologies to government and non-government purchasers, and create new job opportunities throughout these industries. This notice requests information from interested parties on how the government can most effectively use its buying power to create or expand the market for energy-efficient products.

Section 152(h) of the Energy Policy Act of 1992 (Pub. L. 102-486) amends the National Energy Conservation Policy Act (NECPA) by inserting section 549, subsection (e). This section directs the Secretary of Energy to conduct this study, which is the responsibility of the Federal Energy Management Programs Office within the DOE Office of Energy Efficiency and Renewable Energy. DOE is soliciting information from interested parties to identify and recommend energy-saving, renewable energy, and water-conserving products which offer high potential for federal purchasing power to substantially promote their commercialization.

The product component of this study is focused on products which meet certain criteria for technical and commercial viability and which are, or could be, purchased in significant quantities by federal agencies. These criteria include products:

- Which meet applicable performance, safety, and reliability requirements;
- For which the prototype development stage has been completed or is near completion;
- Which offer the potential for minimizing life-cycle cost for the application;
- For which commercial production is practical and economically feasible;
- For which initial market analysis has demonstrated a sufficiently large potential market to warrant commercial production and sales; and
- Which are not yet in production at commercial levels or which have just reached commercial availability.

These criteria do not include products at earlier stages of development—ranging from concept development through engineering prototype testing and field demonstrations—for which the technical and economic feasibility of commercial production have not yet

been established. For products, technologies, or concepts in these earlier stages, programs such as the DOE/National Institute for Standards and Technology (NIST) Energy-Related Inventions Program (ERIP) and the DOE Innovative Concepts Program (InnCon) are available. For information concerning the ERIP program, contact the Office of Technology Evaluation and Assessment, National Institute of Standards and Technology, Gaithersburg, MD 20899. For information concerning the InnCon program contact Mr. E. Levine, U.S., Department of Energy, Forrestal Building, EE-521, 1000 Independence Ave., SW, Washington, DC 20585-0121, 202-586-1605.

Interested parties are requested to submit information to DOE on products which meet the above criteria for commercial viability and relevance to the federal market, on federal procurement actions which could promote commercialization of these products, and on potential barriers to such procurement actions, including:

- The product's energy efficiency and other performance characteristics;
- The product's current state of commercial development, including manufacturing capacity and sales;
- Results of market analyses which indicate the potential market—both within the federal government and the non-federal market, domestically and internationally;
- The potential for energy and dollar savings, both per unit and for potential total sales to federal and non-federal customers;
- Assessment of the life-cycle cost of the product, including projected capital cost and operating and maintenance costs, based upon projected costs at commercially viable levels of production;
- The total level of sales, including federal and non-federal sectors, considered necessary to justify undertaking commercial production;
- Concepts for federal policies and programs which would facilitate commercialization of energy-efficient products;
- Concepts for federal procurement actions which, combined with other market opportunities, could be used to implement these policies and programs;
- Barriers to the rapid penetration of products in federal, other governmental, and commercial markets (e.g. sole-source, lowest first-cost, no history of performance); and
- Recommendations for actions which DOE, other federal agencies, or Congress could take to reduce or eliminate these barriers.

An information packet which provides further definition of the types of information desired, outlines preliminary concepts being considered for such federal policies and programs, and provides information on the March public meeting will be sent to those responding to this Notice.

Only non-proprietary technical or market information should be submitted in response to this request. DOE reserves the right to publish or use any information submitted.

The Federal Energy Management Programs Office will conduct the public meeting on June 5, 1996, to solicit public comment on how federal procurement actions and related information programs, technology demonstrations, or other actions could facilitate commercialization of products meeting the criteria of this study. Responses may be in written form and/or may be presented verbally at the meeting. Verbal presentations must be limited to no more than five minutes. Verbal presentations will be limited to comments on barriers, opportunities, and recommended policies and programs; information on specific products will not be accepted in verbal comments at the hearings but should be submitted in writing.

Issued in Washington, DC on April 16, 1996.

Christine A. Ervin,
Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 96-9947 Filed 4-22-96; 8:45 am]

BILLING CODE 6450-01-P

Federal Energy Regulatory Commission

[Docket No. CP96-298-000]

CNG Transmission Corporation; Notice of Application

April 17, 1996.

Take notice that on April 4, 1996, CNG Transmission Corporation (CNG), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP96-298-000 an application pursuant to Section 7(c)¹ of the Natural Gas Act for authorization to amend an existing service agreement applicable to the storage of natural gas under Rate Schedule GSS between CNG and Long Island Lighting Company (LILCO) to add, on a secondary basis, a new storage receipt point, all as more fully set forth

¹ CNG filed its request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211), however, CNG's request is being treated as a Section 7(c) application.

in the application on file with the Commission and open to public inspection.

CNG states that LILCO, a local distribution company, has requested, and CNG has agreed to add, on a secondary basis, a new storage injection receipt point at an existing interconnection between CNG and Iroquois Pipeline Company, known as Canajoharie, to the existing GSS Service Agreement between CNG and LILCO dated January 1, 1996.

CNG states that the utilization of the Canajoharie receipt point as a storage injection receipt point will only be used as operating conditions permit, and that since the interconnect already exists, no new facilities are required.

CNG states that the addition of this secondary receipt point will not disadvantage any existing CNG customer and does not change LILCO's GSS Storage injection quantities.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 29, 1996, file with the Federal Energy Regulatory Commission, Washington, D.C. 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 the 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 a grant of the certificate 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 CNG to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96-9886 Filed 4-22-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. RP94-367-007 and RP95-31-014]

National Fuel Gas Supply Corporation; Notice of Tariff Filing

April 17, 1996.

Take notice that on April 12, 1996, National Fuel Gas Supply Corporation (National) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets proposed to be effective April 1, 1996:

2nd Sub. Sixth Revised Sheet No. 2

Fourth Revised Sheet No. 17

Second Revised Sheet No. 17A

Third Revised Sheet No. 159

3rd Sub. Fifth Revised Sheet Nos. 236 and 237

National states that on March 22, 1996, National submitted its compliance filing in the above-captioned proceedings. On April 1, 1996 and April 5, 1996, National submitted corrections to the Compliance Filing. The above-listed sheets correct pagination and typographical errors in National's previous filings.

National further states that copies of this filing were served upon the company's jurisdictional customers and upon the Regulatory Commissions of the States of New York, Ohio, Pennsylvania, Delaware, Massachusetts, and New Jersey.

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 Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). 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 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. 96-9888 Filed 4-22-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM96-13-29-000]

Transcontinental Gas Pipe Line Corporation; Notice of Proposed Changes in FERC Gas Tariff

April 17, 1996.

Take notice that on April 12, 1996 Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing certain revised tariff sheets to its FERC Gas Tariff, Third Revised Volume No. 1 which tariff sheets are enumerated in Appendix A attached to the filing.

Transco states that the purpose of the instant filing is to track rate changes attributable to a) storage service purchased from CNG Transmission Corporation (CNG) under its Rate Schedule GSS the costs of which are included in the rates and charges payable under Transco's Rate Schedules LSS and GSS and b) transportation service purchased from Texas Gas Transmission Corporation (Texas Gas) under its rate schedule FT the costs of which are included in the rates and charges payable under Transco's Rate Schedule FT-NT. This tracking filing is being made pursuant to Section 4 of Transco's Rate Schedule LSS, Section 3 of Transco's Rate Schedule GSS and Section 4 of Transco's Rate Schedule FT-NT.

Transco states that included in Appendices B and C attached to the filing are explanations of the rate changes and details regarding the computation of the revised Rate Schedule LSS, GSS and FT-NT rates.

Transco states that copies of the filing are being mailed to each of its LSS, GSS and FT-NT 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, Washington, D.C. 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 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. 96-9889 Filed 4-22-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP96-311-000]

Williams Natural Gas Company; Notice of Application To Amend Certificate

April 17, 1996.

Take notice that, on April 11, 1996, Williams Natural Gas Company (Williams), P.O. Box 3288, Tulsa, Oklahoma 74101, filed an abbreviated application, pursuant to section 7 of the Natural Gas Act, to amend the certificate issued on September 24, 1958, in Docket No. G-10956 (20 FPC 390) by expanding the storage area of its Elk City Storage Field, all as more fully set forth in the application, which is on file with the Commission and open to public inspection.

The certificate issued in Docket No. G-10956 authorized Williams (formerly: Cities Service Gas Company) to construct and operate the Elk City Storage Field, in Elk, Chautauqua, and Montgomery Counties, Kansas, as an underground gas storage field. Williams now requests the Commission to authorize it to extend the Elk City Storage Field's buffer zone north and west of its current location, by acquiring gas storage rights under approximately 2,740 acres of land in Elk and Montgomery Counties, Kansas. As proposed, the extension would add the following parcels of land to the storage area:

Montgomery County, Kansas

The west half of Section 2 in T31S, R13E.

Elk County, Kansas

All of Section 3 in T31S, R13E.

The east half of Section 4 in T31S, R13E.

The east half of Section 9 in T31S, R13E.

All of Section 10 in T31S, R13E.

The north half of the north half of Section 15 in T31S, R13E.

The south half of the southwest quarter of the northwest quarter of Section 15 in T31S, R13E.

The east half of Section 16 in T31S, R13E.

Williams would acquire the subject acreage by lease, purchase, or through the exercise of eminent domain under the Natural Gas Act. Williams states that the gas wells located on the property to be acquired will be converted into observation wells. Williams also states that it believes the extension will increase the effectiveness of the storage area, enhance the overall efficiency of its storage operations, and reduce the risk of storage gas migrating to producing wells outside the present storage area boundary. Williams further asserts that extending the storage area boundary, as proposed, is both reasonable and required by the present and future public convenience and necessity.

Any person desiring to be heard, or to make any protest with reference to said application should, on or before May 8, 1996, file with the Federal Energy Regulatory Commission, Washington, D.C., 20426, a motion to intervene or 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 the 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 the 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 same required herein, or if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or 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 Williams to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 96-9887 Filed 4-22-96; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5460-6]

National Environmental Education and Training Foundation, Inc.; Announcement of a New Appointment to the Board of Directors

The National Environmental Education and Training Foundation (NEETF) was created by Public Law 101-619, the National Environmental Education Act of 1990. It is a private 501(c)(3) non-profit organization established to promote and support education and training as necessary

tools to further environmental protection and sustainable, environmentally sound development. NEETF provides the common ground upon which leaders from business and industry, all levels of government, public interest groups, and others can work cooperatively to expand the reach of environmental education and training programs beyond the traditional classroom. The Foundation operates a grant program that promotes innovative environmental education and training programs; it also develops partnerships with government and other organizations to administer projects that promote the development of an environmentally literate public.

The Administrator of the U.S. Environmental Protection Agency, as required by the terms of the Act, announces the appointment of Walter M. Higgins to the NEETF Board of Directors. Walter Higgins is President and Chief Executive Officer of Sierra Pacific Power Company and Sierra Pacific Resources, a diversified utility holding company in Reno, Nevada. Prior to 1993 when he joined Sierra Pacific Resources, Mr. Higgins was the President of the Louisville Gas and Electric Company in Kentucky, and prior to that he was with the Portland General Electric Company (PGE) in Oregon for 14 years. In the mid-1980's he was President of PGE's first non-utility subsidiary, an energy conservation and cogeneration company.

Education: Mr. Higgins graduated with distinction from the U.S. Naval Academy with a degree in Nuclear Science; two years of Navy postgraduate nuclear engineering training; George Washington University graduate business studies; Public Utility Executive Course at the University of Idaho; and Stanford University Graduate School of Business Executive Program.

Organizations: Mr. Higgins has a great deal of experience with a number of organization including the following—Board of Trustees of the Nature Conservancy of Nevada; Board of Directors of the Reno United Way; Edison Electric Institute Board of Directors; Pacific Coast Gas Association Board of Directors; Western Energy and Communication Association Board of Directors and Executive Board of Nevada Area Council Boy Scouts of America.

Mr. Higgins appointment to the NEETF Board of Directors will be for a 4-year term. Great care is taken to assure that each new appointee to the thirteen-member NEETF Board has the highest degree of expertise and commitment, and also brings to the Board diverse

points of view relating to environmental education and training.

Dated: April 15, 1996.

Carol M. Browner,
Administrator.

[FR Doc. 96-9977 Filed 4-22-96; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5460-8]

Public Water System Supervision Program Revisions for the State of Hawaii Lead and Copper Rule

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of decision and opportunity for hearing.

SUMMARY: Notice is hereby given that the State of Hawaii is revising its approved State Public Water System Supervision Program. Hawaii has adopted regulations for controlling lead and copper in drinking water. The Hawaii State regulations correspond to the National Primary Drinking Water Regulations promulgated by EPA on June 7, 1991 [56 FR 26460], also known as the Lead and Copper Rule; and correcting amendments appearing on July 15, 1991 [56 FR 32112]; June 29, 1992 [57 FR 28785]; and June 30, 1994 [59 FR 33860]. EPA has determined that the State program revisions are no less stringent than the corresponding federal regulations. Therefore, EPA has tentatively decided to approve the State program revision.

All interested parties are invited to request a public hearing on EPA's decision to approve the State program revisions. A request for a public hearing must be submitted by May 23, 1996, to the Regional Administrator at the address shown below. Insubstantial requests for a hearing may be denied by the Regional Administrator. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his/her own motion, this determination shall become effective May 23, 1996.

Any request for a public hearing shall include the following: [1] the name, address, and telephone number of the individual, organization, or other entity requesting a hearing; [2] a brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such hearing; and [3] the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday, at the following offices: Hawaii Department of Health, Five Waterfront Plaza, Suite 250, 500 Ala Moana Blvd., Honolulu, Hawaii 96813; and EPA, Region IX, Water Management Division, Drinking Water Section (W-6-1), 75 Hawthorne Street, San Francisco, California 94105.

FOR FURTHER INFORMATION CONTACT: Barry Pollock, EPA, Region IX, at the San Francisco address given above or by telephone at (415) 744-1854.

(Sec. 1413 of the Safe Drinking Water Act as amended [1986]; and 40 CFR 142.10 of the National Primary Drinking Water Regulations)

Dated: April 10, 1996.

Felicia Marcus,

Regional Administrator.

[FR Doc. 96-9847 Filed 4-22-96; 8:45 am]

BILLING CODE 6560-50-P

[FRL-5462-3]

Annual Conference on Analysis of Pollutants in the Environment

AGENCY: United States Environmental Protection Agency (EPA).

ACTION: Notice of conference.

SUMMARY: The Office of Science and Technology and the Water Environment Federation, co-sponsors, will hold the "19th Annual Conference on Analysis of Pollutants in the Environment" to discuss all aspects of environmental measurement. The conference is open to the public. The Water Environment Federation is sponsoring a Preconference Workshop on Quality Based Laboratory Performance.

DATES: The conference will be held on May 15-16, 1996. On May 15, 1996, the conference will begin at 8:30 am and last until 5:30 pm. On May 16, 1996, the conference will begin at 8:30 am and adjourn at 5:30 pm. The Preconference Workshop on Quality Based Laboratory Performance will be held on May 14, 1996, from 9:00 am to 5:00 pm.

ADDRESSES: The conference will be held at the Omni Waterside Hotel, Norfolk, Virginia. The Preconference Workshop on Quality Based Laboratory Performance will be held at the Norfolk Waterside Marriott.

FOR FURTHER INFORMATION CONTACT: Conference and workshop arrangements are being conducted by the Water Environment Federation. For information on registration, hotel rates, transportation, social events, and

reservations call the Water Environment Federation at (800) 666-0206. If you have technical questions regarding the conference program, please contact William Telliard, Office of Science and Technology (Mail Code 4303), telephone (202) 260-7120, fax (202) 260-7185.

SUPPLEMENTARY INFORMATION: EPA's 19th Annual Conference on Analysis of Pollutants in the Environment is designed to bring together representatives of regulated industries, commercial environmental laboratories, state and Federal regulators, and environmental consultants and contractors to discuss all aspects of environmental measurement with a particular focus on analytical methods and related issues.

A Preconference Workshop on Quality Based Laboratory Performance will be presented by the Water Environment Federation's Laboratory Practices Committee on Tuesday, May 14, 1996, at the Norfolk Waterside Marriott, Norfolk, Virginia.

The program for the conference follows:

19th Annual Conference on Analysis of Pollutants in the Environment

Wednesday, May 15, 1996

8:30 a.m.—Opening Remarks

William Telliard, Director,

Engineering and Analysis Division, Analytical Methods Staff, Office of Science and Technology, Office of Water, USEPA

8:40 a.m.—Introductory Remarks

Lenore Clesceri, Water Environment Federation

8:50 a.m.—Welcome

James Hanlon, Deputy Office Director, Office of Science and Technology, USEPA

Regulatory Initiatives

9:00 a.m.—Streamlining Promulgation of Methods at 40 CFR Parts 136 and 141 Under Section 304(h) of the Clean Water Act and Section 1401(1)(D) of the Safe Drinking Water Act

William Telliard, Director, Engineering and Analysis Division, Analytical Methods Staff, Office of Science and Technology, Office of Water, USEPA

Toxicity Testing

9:30 a.m.—The Acute Whole Effluent Toxicity of Storm Water From an International Airport

Daniel Fisher, University of Maryland WREC

10:00 a.m.—Break

10:15 a.m.—West Coast WET Tests—Different Strokes for Different Folks

Gary Chapman, Paladin Water Quality Consulting

Microwave Assisted Solvent Extraction
10:45 a.m.—Abbreviated Microwave Assisted Extraction of Pesticides and PCBs in Soils
Rick McMillan, USEPA Region 6 Laboratory

Solid Phase Extraction
11:15 a.m.—Optimizing Solid Phase Extraction for Oil and Grease and Particulate Laden Samples
Margaret Raisglid, University of Arizona
11:45 a.m.—Lunch

Method Detection Limit Issues
1:00 p.m.—Alternative Minimum Level (AML): A Scientifically Sound and Practical Approach to Compliance Limits
Ray Maddalone, TRW
1:30 p.m.—Application of an Alternative Minimum Level Determination for Volatile Water Soluble Compounds in Pulp Mill Effluent using Microdistillation (SW-846 Method 5031)
Alex Gholson, NCASI
2:00 p.m.—Evaluation of Alternative Detection Limit Concepts Using a Common Database
Barry Eynon, SRI International

Field Studies
2:30 p.m.—Field Analysis: Effective Approach to Site Assessment and Remediation
Ileana Rhodes, Shell Development Company
3:00 p.m.—Break

Biomarkers
3:15 p.m.—Use of a Human Cell Line Biomarker to Assess the Risk of Dioxin-like Compounds
Jack Anderson, Columbia Analytical Services, Inc.
3:45 p.m.—Biomarkers of Environmental Contamination
Scott Steinert, Computer Sciences Corporation

Cyanide
4:15 p.m.—A Method Comparison and Evaluation for the Analysis of Weak Acid Dissociable Cyanide
John Sebroski, Bayer Corporation

Great Lakes
4:45 p.m.—The Lake Michigan Mass Balance Study: Amalgam, Resin and Dramamine
Marcia Kuehl, Grace Analytical
5:15 p.m.—Adjourn

Thursday, May 16, 1996

Organics
8:30 a.m.—The Semipermeable Membrane Device (SPMD)—Sampling Dissolved Organic Contaminants
Carl Orazio, National Biological Service
9:00 a.m.—Determination of CDDs and CDFs at Part-per-quintillion Levels Using a Cubic Meter Sample
Dale Rushneck, Interface, Inc.
9:30 a.m.—A Quantitative Immunoassay for Triazine Herbicides in Drinking Water
Harry McCarty, SAIC
10:00 a.m.—Break
10:15 a.m.—Equilibrium Headspace: An Alternative to Purge and Trap for Industrial Wastewater Analyses
Elaine Lemoine, The Perkin Elmer Corporation
10:45 a.m.—Toxaphene, and Its Occurrence in Large Lakes
John Kucklick, National Marine Fisheries Service
11:15 a.m.—Initial Validation of Method 1668: Toxic PCBs by HRGC/HRMS
Bruce Colby, Pacific Analytical, Inc.
11:45 a.m.—Lunch
1:00 p.m.—Analysis of Phenolic Acid Compounds in Calcareous Soils by SW-846 Method 8270
Cary Jackson, Support Systems, Inc./Global Environmental Services

Trace Metals
1:30 p.m.—Expedited Delineation of Elemental Mercury (Hg) in Soils at an Industrial Facility in South America
Thomas Lusardi, Keating Environmental Management, Inc.
2:00 p.m.—Analysis of Trace Metals in Complex Matrices
Howard Weinberg, University of North Carolina
2:30 p.m.—Applying Clean Metal Techniques to Real World Situations
Paul Boothe, Albion Environmental and TERL at Texas A&M University
3:00 p.m.—Break
3:15 p.m.—How Dirty Can an Acid Bath be and Still Meet "Clean Metal" Requirements
Eric Crecelius, Battelle Marine Sciences Laboratory
3:45 p.m.—Application of Clean Metals Techniques to Wastewater Monitoring
Paula Hogg, Hampton Roads Sanitation District
4:15 p.m.—A Practical Approach to Permit-based Trace Metals Monitoring
Roger Stewart, Virginia DEQ
4:45 p.m.—A Common Sense Approach to Turning Your Metals Laboratory

into an Environment Where Clean Metals Analysis Can be Performed Reliably
Jim Anderson, Commonwealth of Virginia/Division of Consolidated Laboratories
5:15 p.m.—Adjourn.
Dated: April 17, 1996.

Tudor Davies,
Director, Office of Science and Technology.
[FR Doc. 96-9978 Filed 4-22-96; 8:45 am]
BILLING CODE 6560-50-P

[FRL-5462-4]

Workshop Announcement; Call for Papers: Analysis of Issues Related to Next Steps on Climate Change

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Negotiations under the Framework Convention on Climate Change (FCCC) are underway to address possible actions under the Berlin Mandate. These discussions are scheduled to reach a conclusion at the Third Meeting of the Parties which is planned for Fall of 1997. To provide input on a wide range of analytical issues related to these negotiations, the Departments of Agriculture, Commerce, Energy, and State, and the Environmental Protection Agency are hosting a workshop on June 6-7 in the Washington, D.C. area.

The purpose of the workshop is to provide a forum to share and discuss information on analytical issues to help inform U.S. policymakers and the interested public as we move forward in negotiations concerning possible next steps under the Berlin Mandate.

The workshop will focus on analysis of the key issues identified in the Berlin Mandate. These issues are:

- the elaboration of policies and measures,
- the setting of quantified emissions limitation and reduction objectives, and
- actions to advance the implementation of existing commitments under Article 4.1 for Parties not included in Annex 1.

This workshop provides an opportunity for federal agencies to present the interim results of their ongoing analyses related to the economic and environmental impacts of issues arising in the context of these negotiations.

The workshop also offers an opportunity for other interested individuals and organizations to present analytical studies that contribute to an improved understanding of the issues described above.

People interested in presenting papers at the workshop should submit an abstract of no more than one page to the conference organizer identified below. Abstracts should be received by April 29th and submitters will be notified if their paper has been accepted for presentation by May 6th. All papers should focus on analytical issues related to the issues described above. Papers will be selected on the basis of their relevance to the workshop topics, the availability of time, and the need for presentations in each of the three areas identified in the mandate.

For information about attending the workshop or submitting an abstract of a paper for the meeting, please call (703) 934-3870.

DATES: The conference will be held June 6-7, 1996.

FOR FURTHER INFORMATION CONTACT: Jeremy Symons, U.S. Environmental Protection Agency, 401 M Street, NW, Mail Code 6202J, Washington, DC 20460.

Dated: April 17, 1996.

Mary D. Nichols,
Assistant Administrator for Air and Radiation.

[FR Doc. 96-10088 Filed 4-22-96; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Approved by Office of Management and Budget

April 17, 1996.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1995, Pub. L. 96-511. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Notwithstanding any other provisions of law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Questions concerning the OMB control numbers and expiration dates should be directed to Dorothy Conway, Federal Communications Commission, (202) 418-0217.

Federal Communications Commission

OMB Control No.: 3060-0054.

Expiration Date: 2/28/99.

Title: Application for Exemption from Ship Radio Station Requirements FCC Form 820.

Estimated Annual Burden: 233 hours annual burden; average 1 hour and 10 minutes per respondent; 200 respondents.

Description: FCC Rules require this collection of information when exemptions from radio provisions of statute; treaty or international agreement are requested. The data is used by the examiners to determine the applicants qualifications for the requested exemption.

OMB Control No.: 3060-0541.

Expiration Date: 2/28/99.

Title: Transmittal Sheet for Phase 2 Cellular Applications for Unserved Areas.

Form: FCC Form 464-A.

Estimated Annual Burden: 1,660 total annual hours; average 10 minutes per respondent; 10,000 respondents.

Description: The information is used by the Commission to determine whether the applicant is qualified legally, technically, and financially to be licensed as a cellular operator. Without the information the Commission could not determine whether to issue licenses to the applicants that provide telecommunications services to the public. The transmittal sheet facilitates application intake and other processing functions. The applicant must certify on the form that the application is complete in every respect and contains all the required information.

OMB Control No.: 3060-0321.

Expiration Date: 2/28/99.

Title: Sampling systems for Antenna Monitors - Section 73.68.

Estimated Annual Burden: 200 total annual hours; average 2 hours per respondent; 100 respondents.

Description: Section 73.68(b) requires that licensees of existing AM broadcast stations with antenna monitor sampling systems, meeting the performance standards specified in the rules may file informal request for approval of their sampling systems. Section 73.68(d) requires that a request for modification of the station license be submitted by the FCC when the antenna sampling system is modified or components of the the sampling system are replaced. The data is used by staff to maintain complete technical information regarding licensees to insure that the sampling system is in full compliance with the rules and will not cause interference to other facilities.

OMB Control No.: 3060-0175.

Expiration Date: 2/28/99.

Title: Station Main Studio Location Section 73.1125.

Estimated Annual Burden: 68 total annual hours; average 30 minutes per respondent; 135 respondents.

Description: Section 73.1125 requires AM, FM or TV licensees to locate their main studio at any point within the station's principal community contours. If the station relocates its main studio the licensee is required to notify the Commission. This notice assures that the station is located within the principal community contours and notifies FCC of the change in mailing address.

OMB Control No.: 3060-0160.

Expiration Date: 2/28/99.

Title: Directional Antenna Monitoring Points - Section 73.158.

Form: N/A.

Estimated Annual Burden: 320 total annual hours; average 4 hours per respondent; 80 respondents.

Description: Section 73.158 requires licensees of AM radio stations using a directional antenna system to file an informal application to modify their station license for changes in field monitoring point and for routing description to each. It also requires licensees to file a request for a corrected station license when the descriptive routing to reach any of the monitoring points is no longer correct. The data is used by FCC staff to alleviate electro magnetic interference and issue a new license.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 96-9930 Filed 4-22-96; 8:45 am]

BILLING CODE 6712-01-F

FEDERAL MARITIME COMMISSION

[Docket No. 96-09]

Southern Pacific Transportation Co. and the Atchison, Topeka & Santa Fe Railway Co. v. Port of Long Beach; Filing of Complaint and Assignment

Notice is given that a complaint filed by Southern Pacific Transportation Company and The Atchison, Topeka and Santa Fe Railway Company ("Complainants") against Port of Long Beach ("Respondent") was served April 17, 1996. Complainants allege that Respondent has violated section 10(d)(1) of the Shipping Act of 1984, 46 U.S.C. app 1709(d)(1), in connection with a new item in Respondent's tariff that imposes an access charge for use of Port owned rail tracks, contrary to provisions of existing agreements between Complainants and the City of Long Beach.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by April 17, 1997, and the final decision of the Commission shall be issued by August 15, 1997.

Joseph C. Polking,

Secretary.

[FR Doc. 96-9885 Filed 4-22-96; 8:45 am]

BILLING CODE 6730-01-M

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, D.C. 20573.

RMG International Inc., 755 Bradfield, Houston, TX 77060, Officers: Robert M. Goodsir, President, Michael K. Freeman, Vice President

Smile Enterprises Co., 500 Carson Plaza Drive, #125, Carson, CA 90746, Se Il Cha, Sole Proprietor

Dated: April 18, 1996.

Joseph C. Polking,

Secretary.

[FR Doc. 96-9956 Filed 4-22-96; 8:45 am]

BILLING CODE 67301-01-M

[Docket No. 96-08]

Longrow Shipping Limited; Possible Violations of Sections 8 and 10(b)(1) of the Shipping Act of 1984 and Commission Rule 514.1(e)(1); Order of Investigation and Hearing

This proceeding is instituted pursuant to sections 3, 8, 10, 11 and 13 of the Shipping Act of 1984 ("1984 Act"), 46 USC app. 1702, 1707, 1709, 1710 and 1712, and the Federal Maritime Commission's ("Commission") regulations governing the tariffing of non-vessel-operating common carriers, 46 CFR Part 514.

Longrow Shipping Limited ("Longrow") is a non-vessel-operating common carrier ("NVOCC") incorporated in Hong Kong in 1991. Its receiving agent in the United States and agent for service of process is Pan-Pacific Express Corporation in California. Longrow currently maintains a tariff, effective July 17, 1994, in the Commission's Automated Tariff Filing and Information System. It holds an NVOCC surety bond, issued on May 26, 1994, in the amount of \$50,000.

It appears that between May 30 and July 16, 1994, Longrow may have operated as a NVOCC without an effective tariff. During this time, Longrow held itself out as a NVOCC providing ocean transportation from Hong Kong to the United States in its dealings with at least five shippers and one ocean common carrier. Section 8 of the 1984 Act, 46 USC app. 1707, provides that no common carrier may provide service in the United States foreign trade unless the carrier first has filed a tariff with the Commission showing all of its rates, charges and practices. Section 8 also states that no new rates may become effective earlier than 30 days after filing at the Commission. In promulgating this statutory provision, Commission rule 514.9(b)(9)(i)(A), 46 CFR 514.9(b)(9)(i)(A), explains that "[n]ew tariffs * * * shall * * * be filed to become effective not earlier than 30 days after the date of filing." According to the records maintained by the Commission's Bureau of Tariffs, Certification and Licensing, Longrow did not have an effective tariff until July 17, 1994. Commission rule 514.1(e)(1), 46 CFR 514.1(e)(1), provides that "[o]perating without an effective tariff on file with the Commission * * * is unlawful." Therefore, it would appear and Longrow, by providing and holding out to the public to provide transportation by water of cargo for compensation and by contracting as a shipper in relation to a common carrier

for the transportation of cargo of other persons, may have acted as a NVOCC without an effective tariff, in violation of section 8 of the 1984 Act and Commission rule 514.1(e)(1).

After Longrow's tariff became effective, Longrow transported between July 17, 1994 and February 21, 1995, at least twenty (20) shipments from Hong Kong to the United States. For those shipments, Longrow appears to have charged rates other than those shown in Longrow's tariff. Pursuant to section 10(b)(1), 46 USC app. 1709(b)(1), the 1984 Act maintains that a common carrier is prohibited from charging, demanding, collecting or receiving greater, less or different compensation for transportation of property than the rates shown in its tariffs or service contracts. This prohibition is reiterated in Commission rule 514.1(e)(1) which states that "charging rates not in conformance with such a tariff is lawful." Therefore, Longrow may have violated section 10(b)(1) of the 1984 Act and Commission rule 514.1(e)(1) by charging rates other than those shown in its tariff between July 17, 1994 and February 21, 1995.

Section 11 of the 1984 Act, 46 USC app. 1710, sets forth the Commission's authority to investigate any conduct that may be in violation of the 1984 Act. In the event violations are found, section 13 of the 1984 Act, 46 USC app. 1712, provides that the Commission may assess civil penalties for violations of the 1984 Act and the regulations issued thereunder.

Now therefore it is ordered, That pursuant to sections 3, 8, 10, 11, and 13 of the 1984 Act, 46 USC app. 1702, 1707, 1709, 1710, and 1712, an investigation is hereby instituted to determine:

(1) Whether Longrow Shipping Limited violated section 8 of the 1984 Act and Commission rule 514.1(e)(1), by providing common carrier services without an effective tariff filed at the Commission between May 30, 1994 and July 16, 1994;

(2) Whether Longrow Shipping Limited violated section 10(b) of the 1984 Act and Commission rule 514.1(e)(1), by failing to charge the rates shown in its tariff between July 17, 1994 and February 21, 1995;

(3) Whether, in the event Longrow Shipping Limited violated sections 8 and 10(b) of the 1984 Act and Commission rule 514.1(e)(1), civil penalties should be assessed and, if so, the amount of such penalties;

It is further ordered, That a public hearing be held in this proceeding and that this matter be assigned for hearing before an Administrative Law Judge of

the Commission's Office of Administrative Law Judges in compliance with Rule 61 of the Commission's Rules of Practice and Procedure, 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Administrative Law Judge only upon a proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matters in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record;

It is further ordered, That Longrow Shipping Limited is designated Respondent in this proceeding;

It is further ordered, That the Commission's Bureau of Enforcement is designated a party to this proceeding;

It is further ordered, That notice of this Order be published in the Federal Register, and a copy be served on parties of record;

It is further ordered, That other persons having an interest in participating in this proceeding may file petitions for leave to intervene in accordance with Rule 72 of the Commission's Rules of Practice and Procedure, 46 CFR 502.72;

It is further ordered, That all further notices, orders, and/or decisions issued by or on behalf of the Commission in this proceeding, including notice of the time and place of hearing or prehearing conference, shall be served on parties of record;

It is further ordered, That all documents submitted by any party of record in this proceeding shall be directed to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, in accordance with Rule 118 of the Commission's Rules of Practice and Procedure, 46 CFR 502.118, and shall be served on parties of record;

It is further ordered, That in accordance with Rule 61 of the Commission's Rules of Practice and Procedure, the initial decision of the Administrative Law Judge shall be issued by April 16, 1997, and the final decision of the Commission shall be issued by August 14, 1997.

By the Commission.
Joseph C. Polking,
Secretary.
[FR Doc. 96-9873 Filed 4-22-96; 8:45 am]
BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

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 May 14, 1996.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Boscobel Bancorp, Inc.*, Boscobel, Wisconsin; to engage *de novo* in making and servicing loans, pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 17, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96-9920 Filed 4-22-96; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 614]

Surveillance of the Complications of Hemophilia

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds to continue a cooperative agreement program to conduct active surveillance for hemophilia A and B (henceforth referred to as hemophilia) and their complications. The international classification of diseases (ICD) code definition of hemophilia A is congenital factor VIII disorder and hemophilia B is congenital factor IX disorder. Applicant's programs must be targeted to individuals with hemophilia who receive their care both within and outside hemophilia treatment centers and comprehensive care centers. Such individuals should include: persons who do not access traditional hemophilia treatment services and may receive inadequate care (and are possibly over-represented by persons who are economically disadvantaged), persons who live in rural areas or inner cities; or, persons who are members of one of four federally recognized minority groups: (1) Black; African-American or Caribbean; (2) Hispanic; Central American, South American, Mexican American, Dominican, Cuban, or Puerto Rican; (3) Asian/Pacific Islander, or (4) American Indian or Alaskan Native.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Diabetes and Chronic Disabling Conditions. (For ordering a copy of Healthy People 2000, see the Section Where to Obtain Additional Information.)

Authority

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act, as amended

[42 U.S.C. 241(a) and 247b(k)(2)]. Applicable program regulations are found in 42 CFR Part 51b - Project Grants for Preventive Health Services.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Assistance will be provided only to the official public health agencies of States or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

The low prevalence of hemophilia limits competition to the official public health agencies of States. This project requires experience in conducting statewide, active surveillance programs for hemophilia, and experience in collaboration with organizations having the ability to reach a wide variety of demographically distinct populations, including traditionally underserved populations. Since only State health agencies can perform the required project activities, competition is limited accordingly.

Funding preference will be given to competitive continuation applications of States who have currently established statewide hemophilia surveillance systems (HSS); and, who have demonstrated collaboration between health departments, hemophilia treatment centers, and/or university schools of public health, in hemophilia surveillance activities.

Availability of Funds

Approximately \$2,500,000 is available in FY 1996 to fund approximately 6 awards. The average award will be \$350,000, ranging from \$250,000 to \$450,000. It is expected that the funds will be awarded on or about September 30, 1996, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory programmatic progress and the availability of funds.

Purpose

The purpose of the hemophilia cooperative agreement program is to assist recipients in characterizing the statewide epidemiology of hemophilia and its complications, and determining its impact among three populations: (1) Those who access traditional hemophilia treatment and comprehensive care services, (2) those who receive care outside traditional hemophilia care centers, and (3) those who receive inadequate care. The latter population category may be over-represented by persons who are economically disadvantaged, or who live in rural areas, or inner cities. Inadequate care would include less than prompt treatment, treatment from improperly trained personnel, or poor access to comprehensive care. The data collected through a Hemophilia Surveillance System (HSS) can assist hemophilia treatment providers and States in developing, implementing, and evaluating education and prevention programs to reduce the morbidity, mortality, and costs of hemophilia and its complications.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. below, and CDC will be responsible for conducting the activities under B. below:

A. Recipient Activities

All recipients must conduct activities in collaboration and coordination with the CDC.

Required Activities for All Recipients

1. Meet with representatives from CDC to: (a) Assure continuation of optimal surveillance methods, such as the use of standardized HSS protocols and data collection form, and (b) amend previous HSS protocols with any new activities or procedures.

2. Use standard surveillance protocols as a basis to design, implement, and evaluate statewide surveillance programs for adult, adolescent, and pediatric cases of hemophilia and its complications.

3. Update data abstractors, as necessary, in methods of active surveillance, use of the HSS data abstraction form, techniques of reviewing medical records, and other methods of surveillance as appropriate and provided for in the HSS Manual.

4. Maintain appropriate management and evaluation systems that ensure data abstractors conduct active surveillance, and use data collection methods according to the HSS Manual.

5. Maintain secure databases of all reported cases of hemophilia and its complications.

6. Maintain strict policies on protecting the confidentiality of persons with hemophilia, and ensure the security of databases and other records through controlled access to areas with confidential information, database password protection, locking file cabinets, and other security features.

7. Using the standardized format, prepare and submit progress reports on a quarterly basis that address the achievements of HSS activities, program goals and objectives for the previous quarter.

8. Upon request, assist State or regional programs in the use of data to develop or improve hemophilia care programs.

Surveillance of Hemophilia: Specific Required Activities

1. Promote and maintain liaison with potential reporting sources both within and outside of the traditional hemophilia treatment system. These potential reporting sources include, but are not limited to, State or regional hemophilia chapters or associations, hospitals, emergency care centers, hematology clinics, private physicians, organizations that provide home-infusion therapy, distributors of home-infusion factor concentrates, and others.

2. In accordance with HSS protocols, implement active hemophilia surveillance among reporting sources outside of the traditional hemophilia care system, and in the collaborative network of hemophilia treatment centers to determine the statewide prevalence of hemophilia.

3. In accordance with standard HSS protocols, redirect current surveillance activities as indicated through critical review of data and evaluation of yield from various surveillance activities. Initiate additional methods of surveillance for hemophilia, as appropriate.

4. Augment surveillance through the use of at least one alternate database (e.g., death certificates, State hospital-discharge summaries, State reimbursement programs). Document these methods, results, and if appropriate, the redirection of surveillance activities in the quarterly progress report.

5. Through death certificate review and active surveillance, collect data on deaths attributed to hemophilia to calculate State hemophilia-specific mortality rates. Collect epidemiologic data that could be used to determine the sensitivity of death certificates in

documenting deaths attributed to hemophilia.

6. Collect Universal Data Collection (UDC) forms from designated hemophilia treatment centers, and enter into the CDC-provided UDC software for transmission to the CDC on a regular basis. Document this activity in the quarterly progress report.

Surveillance of Hemophilia-Related Complications: Specific Required Activities

1. Through medical record review or other methods proposed by the applicant, describe the source, frequency, and type of preventive and medical care among persons with hemophilia, and determine the prevalence of the following hemophilia-related complications:

Joint disease
Liver disease
Inhibitors
HIV/AIDS
Blood-borne infections

Sampling methods, if used, will be developed in collaboration with CDC to insure sufficient representation of persons of different race/ethnicity, age, HIV status, severity of hemophilia, and source of care.

2. Conduct longitudinal follow-up of persons with hemophilia-related joint disease to relate the source, frequency, and type of preventive and medical care to health outcome (e.g., severity of joint disease, degree of disability). In addition to joint disease, applicants are encouraged to propose and conduct longitudinal follow-up of persons with other hemophilia-related complications.

B. CDC Activities

1. Provide programmatic consultation, scientific and technical assistance in planning, implementing, and evaluating hemophilia surveillance activities.

Assistance includes the implementation of standardized HSS protocols, and the use of the HSS data abstraction form, progress report forms, and HSS database software.

2. Plan, coordinate, and facilitate periodic meetings with recipients to exchange operational experiences, and to provide consultation and assistance in the modification of standard surveillance protocols as needed.

3. Provide programmatic coordination of surveillance initiatives among the recipients.

4. Assist with the analysis and reporting of aggregate surveillance data collected from funded initiatives by coordinating and consolidating the transfer of tabulated data, analyses, and conclusions from the recipients.

5. Assist National, State, or regional programs in the use of data to develop or improve hemophilia care programs.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria: (Total 100 points)

A. Capacity

1. The capacity of the applicant to access the medical records of hemophilia patients who receive care both within and outside of the traditional hemophilia treatment system. The capacity to access these records is measured by (a) the extent that the applicant incorporates shared responsibility between hemophilia treatment centers and State health departments as delineated in letters of agreement, and (b) the extent of collaboration among these entities and with other organizations involved in the delivery of care to persons with hemophilia. (25 points)

2. The scope and magnitude of previous cooperative efforts between regional or State hemophilia treatment centers and State or local health departments that propose to collaborate in this application. (5 points)

3. The allocation of time, number, and qualifications of proposed staff to meet stated objectives and goals, and the availability of facilities to be used during the project period. (5 points)

B. Goals and Objectives

The extent to which the applicant's proposed goals and objectives meet the required activities specified under Program Requirements section A. *Recipient Activities* of this announcement, and that are measurable, specific, time-phased, and realistic. (20 points)

C. Methods and Activities

1. The quality of the applicant's plan for conducting program activities and the extent to which surveillance methods proposed are: (a) Appropriate to accomplish stated goals and objectives; (b) adaptable to a variety of health care settings, multiple complications of hemophilia, and the collection of longitudinal data; (c) accurate to produce valid and reliable data, and (d) feasible within programmatic and fiscal restrictions. (25 points)

2. The applicant's documented ability to (a) identify optimal surveillance methods, (b) develop standardized HSS protocols, HSS data collection instruments, progress report forms, and HSS database software, (c) modify proposed methods and activities to

conform to standardized protocols, and (d) ensure that women and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. (10 points)

D. Program Management and Evaluation

The extent to which the proposed management system, including the type, frequency, and methods of evaluation, will be used to assure valid and reliable data. (10 points)

E. Budget

The extent to which the budget is reasonable and consistent with the intended use of the cooperative agreement funds. (not scored)

F. Human Subjects Research

Whether or not exempt from DHHS regulations, are the procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, or (2) protections appear adequate, but there are comments regarding the protocol, or (3) protections appear inadequate and the objective review group (ORG) has concerns related to human subjects; or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable. (not scored)

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372, which sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their state Single Point of Contact (SPOC) early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. Indian tribes are strongly encouraged to request tribal government review of the approved application. A current list of SPOCs is included in the application kit. If SPOCs (or tribal governments) have any State (or tribal) process recommendations on applications submitted to CDC, they should reference this announcement number (614) and forward recommendations to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers

for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-18, Atlanta, Georgia 30305, no later than 60 days after the application deadline date. CDC does not guarantee to "accommodate or explain" State process recommendations it receives after that date.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirement.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283, Centers for Disease Control and Prevention (CDC)—Investigations and Technical Assistance.

Other Requirements

Paperwork Reduction Act

Projects that involve collection of information from 10 or more individuals and funded by cooperative agreements will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Confidentiality

All information obtained in connection with this surveillance program shall not, without such individual's consent, be disclosed except as may be necessary to provide services to him or her or as may be required by a law of a State or political subdivision of a State. Information derived from any such program may be disclosed: (1) in summary, statistical, or

other form, or (2) for clinical or research purposes, but only if the identity of the individual under such program is not disclosed.

HIV/AIDS Requirement

Recipients must comply with the document entitled "Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions" (June 1992), a copy of which is included in the application kit. To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a government health department consistent with the content guidelines. The names of the review panel members must be listed on the Assurance of Compliance form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved, including conference agendas.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947-47951.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (Revised 7/92, OMB number 0937-0189) must be

submitted to Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-18, Atlanta, Georgia 30305, on or before June 24, 1996.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either: a. Received on or before the deadline date; or b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-18, Atlanta, Georgia 30305, telephone (404) 842-6595, or by Internet or CDC WONDER electronic mail at LXT1@OPSPGO1.EM.CDC.GOV. Programmatic technical assistance may be obtained from Robert Cicatello, Public Health Advisor, telephone (404) 639-4034, or by Internet or CDC WONDER electronic mail at RAC3@CIDDAS1.EM.CDC.GOV, Hematologic Diseases Branch, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop D-02, Atlanta, Georgia 30333.

Please refer to Announcement Number 614 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office,

Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: April 17, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-9936 Filed 4-22-96; 8:45 am]

BILLING CODE 4163-18-P

Food and Drug Administration

[Docket No. 96N-0066]

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 a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements implementing the Federal Import Milk Act.

DATES: Submit written comments on the collections of information by June 24, 1996.

ADDRESSES: Submit written comments on the collections 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.

Part 1210 *Regulations Under the Federal Import Milk Act* (21 CFR Part 1210) (OMB Control Number 0910-0212—Extension)

Under the regulations implementing the Federal Import Milk Act (21 U.S.C. 141-149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F. In addition, the regulations require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22).

FDA estimates the burden of complying with the information collection provisions of these regulations as follows:

Estimated Annual Reporting Burden

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	1	1	1	0.5	0.5
FDA 1993/Application of permit	1210.20	1	1	1	0.5	0.5
FDA 1994/Tuberculin test	1210.13	0	0	0	N/A	0
FDA 1995/Physical examination of cows	1210.12	0	0	0	N/A	0
FDA 1996/Sanitary inspection of dairy farms	1210.11	1	300	300	1.5	450
FDA 1997/Sanitary inspections of plants	1210.14	1	1	1	2.0	2.0
Total						453

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
21 CFR 1210.15	1	1	1	.05	0.05

There are no capital or operating and maintenance costs associated with this collection.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for Forms FD 1994 and 1995 because they are not currently being used. The Secretary of Health and Human Services has the discretion to allow Form FD 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FD 1994 and 1995. To date, Form FD-1815 has been submitted in lieu of these forms.

Dated: April 11, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-9869 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96F-0107]

**Dainippon Ink and Chemicals, Inc.;
Filing of Food Additive Petition**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dainippon Ink and Chemicals, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aliphatic polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by May 23, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4496) has been filed by Dainippon Ink and Chemicals, Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 22091. The petition proposes to amend the food additive regulations in § 177.1390 *Laminate structures for use at temperatures of 250° F and above* (21 CFR 177.1390) to permit the safe use of aliphatic polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before May 23, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: April 4, 1996.

George H. Pauli,
Acting Director, Office of Premarket
Approval, Center for Food Safety and Applied
Nutrition.

[FR Doc. 96-9915 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96N-0126]

**Drug Export; Migramist™
(dihydroergotamine mesylate, USP) 4
Milligrams(mg)/Milliliters(mL) Nasal
Spray**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sandoz Pharmaceuticals Corp. has filed an application requesting conditional approval for the export of the human drug Migramist™ (dihydroergotamine mesylate, USP) 4 mg/mL Nasal Spray to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Sandoz Pharmaceuticals Corp., 59 Rt. 10, East Hanover, NJ 07936-1080, has filed an application requesting conditional approval for the export of the human drug Migramist™ (dihydroergotamine mesylate, USP) 4 mg/mL Nasal Spray to Canada. This product is indicated for the treatment of migraine headaches. The application was received and filed in the Center for Drug Evaluation and Research on

October 19, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 3, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 5, 1996.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 96-9896 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96N-0124]

Drug Export; Differin™ (Adapalene) 0.1% Topical Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Galderma Laboratories, Inc., has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520

Standish Pl., Rockville, MD 20855, 301-594-3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Galderma Laboratories, Inc., 3000 Alta Mesa Blvd., Forth Worth, TX 76133, has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel to Canada. This product is indicated for the topical treatment of acne vulgaris. The application was received and filed in the Center for Drug Evaluation and Research on October 16, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 3, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 5, 1996.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 96-9897 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96N-0124]

Drug Export; Differin™ (Adapalene) 0.1% Topical Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Galderma Laboratories, Inc., has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Galderma Laboratories, Inc., 3000 Alta Mesa Blvd., Forth Worth, TX 76133, has filed an application requesting approval for the export of the human drug Differin™ (Adapalene) 0.1% Topical Gel to Canada. This product is indicated for the topical treatment of acne vulgaris. The application was received and filed in the Center for Drug Evaluation and Research on October 16, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application

to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 3, 1996, and to provide an additional copy of the submission directly to the contract person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: April 5, 1996.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 96-9897 Filed 4-22-96; 8:45 am]

BILLING CODE 4160-01-F

Indian Health Service

Proposed Information Collection Activities Available for Public Comment and Recommendations

In accordance with Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995, the Indian Health Service (IHS) is requesting public comment on the following proposed agency information collection activities. Your comments are invited on: (a) Whether the information collection activity is necessary to carry out an agency function and whether the IHS processes the information collected in a useful and timely fashion; (b) the accuracy of the public burden estimate (this is the amount of time needed for individual respondents to provide the requested information) and the methodology and assumptions used to determine the estimate; (c) ways to enhance the quality, utility, and clarity of the information being collected; and (d) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Activity #1: The IHS Contract Health Service (CHS) seeks (A) approval for a 1 year reinstatement with no change of previously approved information collection activity, 0917-0002, "Indian Health Service, Hospital, Dental and Other Contract Health Service Reports"; and (B) a 1 year approval for a new CHS form (IHS-843-1A, "Purchase-Delivery Order for Health Services") which is currently being pilot tested and is expected to be completed by September 1996.

The 1 year reinstatement of the current CHS forms and the 1 year approval of the new form will provide

for a transition and implementation period for the new form and will allow the IHS to provide education and training in the use of the new single form; make any necessary adjustments in the protocol for the use of the new single form; and, make computer programming corrections as may be needed during the implementation period. The IHS-wide implementation of the new form is expected to be completed by the end of fiscal year 1997.

The new streamlined, user friendly CHS form IHS-843-1A combines the three current CHS forms (the IHS 43-1A used for hospital inpatient services, the IHS-57-1A used for dental services, and, the IHS-64-1A used for health care services other than hospital inpatient or dental) into one single form which reduces public response burden. The CHS forms are completed by CHS Providers and used to certify that the health care services request and authorized by the IHS have been performed by the CHS provider(s); process payments for health care services performed by such providers; and serve as a legal document for health and medical care authorized by the IHS and rendered by health care providers under contract with the IHS. The burden estimate for this information collection activity follows:

Information collection activity	Number of respondents	Responses per respondent	Average burden per response (hours)*
IHS-43-1A	580	148	0.17 (10 mins).
IHS-57-1A	532	22	0.42 (25 mins).
IHS-64-1A	7,688	32	0.17 (10 mins).
New form: IHS-843-1A	13,215	41	0.05 (3 mins).
Inpatient Discharge Summary	85,988	1	1.37 (82 mins).

* Burden estimate is based on data provided by the IHS Fiscal Intermediary (FI) contractor and feedback from CHS Providers (respondents) who have completed the forms (current or new) for at least one year. For FY-1994, the FI processed approximately 360,000 forms for some 8,800 respondents; and, the IHS CHS staff processed approximately 180,000 forms for some 4,400 respondents. The number of responses per respondent is based on the average number of forms processed for each Provider.

The inpatient discharge summary was overlooked as an information collection activity in prior approval requests and is added accordingly.

Proposed Activity #2: The IHS Loan Repayment Program (LRP) seeks a 3 year approval for reinstatement with minor change of previously approved information collection activity, 0917-0014, "Indian Health Service Loan Repayment Program". The IHS LRP recruits highly qualified health care professionals to meet agency health care staffing needs. The information collection forms used for this activity are contained in the IHS LRP Information and Application Booklet.

The booklet provides an overview of the LRP, instructions regarding application procedures and potential employment opportunities, and tear-out application forms. The application form collects the following data from each applicant: Name, address, work and home telephone numbers, education and degree(s) obtained, work experience, and an accounting of financial (tuition) loans to be considered for payback. The instructions and forms contained in the LRP information and application

booklet were updated, revised and clarified to improve applicant understanding and ease the response burden. The information collected is used to verify and evaluate applications to determine eligibility for the IHS LRP; award and authorize applicant payments; and, provide statistical program data. The burden estimate for this information collection activity follows:

Information collection activity	Number of respondents	Responses per respondent	Average burden/response (hours)*
Section I	350	1	0.25 (15 mins).
Section II	350	1	0.50 (30 mins).
Section III	350	4	0.25 (15 mins).
Contract	350	1	0.34 (20 mins).
Affidavit	350	1	0.17 (10 mins).
Lender Cert	1400	1	0.25 (15 mins).

* Burden estimate is based on feedback from applicants or lenders who have completed these forms over the past year.

To request more information on any of the proposed information collection activities or to obtain a copy of the collection of information form(s) and/or instructions, you may call the IHS Reports Clearance Officer on (301) 443-0461. This is not a toll free number. Please send your written comments regarding any or all of the proposed information collection activities to Mr. Lance Hodahkwen, Sr., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20857. Comments may also be sent via facsimile to: (301) 443-1522, or Internet: Lhodahkwen@ihs.ssw.dhhs.gov. Written comments should be received within 60 days of this notice.

Dated: April 16, 1996,
 Michael H. Trujillo,
Assistant Surgeon General, Director.
 [FR Doc. 96-9871 Filed 4-22-96; 8:45 am]
BILLING CODE 4160-16-M

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of a 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 Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Growth and Differentiation of Smooth Muscle Cells.
Date: May 22-23, 1996.
Time: 8:30 p.m.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland.
Contact Person: Louis M. Ouellette, Ph.D., Two Rockledge Center, Room 7216, 6701 Rockledge Drive, Bethesda, MD 20892-7924 (301) 435-0310.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 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. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: April 17, 1996.
 Susan K. Feldman,
Committee Management Officer, NIH.
 [FR Doc. 96-9952 Filed 4-22-96; 8:45 am]
BILLING CODE 4140-01-M

National Heart, Lung, and Blood Institute; Notice of Meetings

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Panel: Cardiovascular Disease Community Surveillance.
Dates of Meeting: May 7, 1996.
Time of Meeting: 8:00 a.m.
Place of Meeting: Two Rockledge Center, Room 7111 6701 Rockledge Drive, Bethesda, MD.
Agenda: To provide concept review for cardiovascular disease community surveillance.
Contact Person: Lawton S. Cooper, M.D., M.P.H., NIH/NHLBI/DECA, Rockledge Center Two, Room 8166, 6701 Rockledge Drive, Bethesda, Maryland 20892-7934, (301) 435-0444.

Name of Panel: Heart Failure Research.
Dates of Meeting: May 20, 1996.
Time of Meeting: 8:00 a.m.
Place of Meeting: Two Rockledge Center, Conference Room 9B1 6701 Rockledge Drive, Bethesda, MD.

Agenda: Prioritize needs and future directions for research to advance understanding, prevention, and treatment of heart failure.

Contact Person: Leslie Reinlib, Ph.D., NIH/NHLBI/DHVD, Rockledge Center Two, Rm. 9188, 6701 Rockledge Drive, Bethesda, Maryland 20892-7940, (301) 435-0504.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institute of Health)

Dated: April 17, 1996.
 Susan K. Feldman,
Committee Management Officer, NIH.
 [FR Doc. 96-9954 Filed 4-22-96; 8:45 am]
BILLING CODE 4140-01-M

National Institute of Dental Research; 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 of Dental Research Special Emphasis Panel (SEP) meetings:

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of RO3 grants 96-22.

Dates: May 16, 1996.
Time: 12:00 pm.
Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Review of RO3 grants 96-23.

Dates: May 17, 1996.
Time: 3:00 pm.
Place: Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).

Contact person: Dr. George Hausch, Chief, Grants Review Section, 4500 Center Drive, Natcher Building, Room 4AN-44F, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

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/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 Program No. 93.121, Oral Diseases and Disorders Research)

Dated: April 17, 1996.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 96-9953 Filed 4-22-96; 8:45 am]
BILLING CODE 4140-01-M

Division of Research Grants; Notice of Meeting of the Division of Research Grants Advisory Committee

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Division of Research Grants Advisory Committee, May 20-21, 1996, Natcher Building (Building 45) Conference Room F, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. on May 20 to adjournment on May 21. The meeting will include, among other topics, a discussion of some recent experiences and experiments in streamlining the

peer review system. Attendance by the public will be limited to space available.

The Office of Committee Management, Division of Research Grants, Rockledge 2 Building, Suite 3016, National Institutes of Health, Bethesda, Maryland 20892-7778, telephone (301) 435-1124, will furnish a summary of the meeting and a roster of the committee members.

Dr. Samuel Joseloff, Executive Secretary of the Committee, Rockledge 2 Building, Suite 3176, National Institutes of Health, Bethesda, Maryland 20892-7762, phone (301) 435-0691, will provide substantive program information upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary at least two weeks in advance of the meeting.

Dated: April 17, 1996.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 96-9955 Filed 4-22-96; 8:45 am]
BILLING CODE 4140-01-M

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Submission for OMB Review, Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-0525.

Substance Abuse Prevention and Treatment Block Grant—45 CFR Part 96—Extension of a currently approved collection—This interim final rule provides guidance to States regarding the Substance Abuse Prevention and Treatment Block Grant legislation. The rule implements the reporting and recordkeeping requirements of 42 U.S.C. 300x 21-35 & 51-64 by specifying the content of the The annual reporting and recordkeeping burden estimate is shown below:

REPORTING BURDEN

Section	Number of respondents	Number of responses per year	Number hours per response	Total hours
Standard Form and Content: 96.122(c)				
Annual Report: 96.122(f)	60	1	152	9,120
96.134(d)	60	1	16	960
State Plan: 96.122(g)	60	1	162	9,720
96.124(c)(1)	60	1	40	2,400
96.127(b)	60	1	8	480
96.131(f)	60	8	480
96.133(a)	60	1	80	4,800
Waivers: 96.132(d)*	60	1	16	960
96.134(b)*	60	1	40	2,400
96.135(d)*	60	1	8	480
Total	60	1	530	** 31,800

* For the purpose of calculating burden in this OMB submission, it is assumed that all States would apply for each waiver. In reality it expected that only a small number would apply.

** This is the burden for the annual application for the Substance Abuse Prevention and Treatment Block Grant, not including the reporting burden associated with the Tobacco Regulation for the Substance Abuse and Treatment Block Grants Final Rule. OMB approval for the actual application is under control number 0930-0080.

RECORDKEEPING BURDEN—45 CFR 96

Section	Number of record-keepers	Number hours per respondent	Total hours
96.129(a)(13)	60	16	960
Total	60	16	960

TOTAL COMBINED BURDEN—45 CFR 96

	No. hours per respondent	total hours
	546	32,760

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, D.C. 20503.

Dated: April 15, 1996.
Richard Kopanda,
Executive Officer, SAMHSA.
[FR Doc. 96-9935 Filed 4-22-96; 8:45 am]
BILLING CODE 4162-20-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4049-N-02]

Office of Lead-Based Paint Abatement and Poisoning Prevention; Notice of Proposed Information Collection for Public Comment Submission for OMB Review: Comment Request

AGENCY: Office of Lead-Based Paint Abatement and Poisoning Prevention, HUD.

ACTION: Notice for emergency processing.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency processing, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: April 30, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven days from the date of this Notice. Comments should refer to the proposal by name and/or OMB Control Number (2539-0005) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, D.C., 20503.

FOR FURTHER INFORMATION CONTACT:

Kay Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th St., SW., Washington, DC 20410, Tel. (202) 708-0050.

This is not a toll-free number. Copies of the proposed forms and/or other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for emergency processing, as required by the Paperwork Reduction Act of 1995 (44 U.S.C., Chapter 35, as amended.) April 25, 1996 is the requested date for OMB approval.

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to:

(1) evaluate whether the proposed collection of information is necessary for the proper performance of the functions 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;

(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 through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Notice of Funding Availability for 1996—HUD's Grant Program for Lead-Based Paint Hazard Reduction in Priority Housing (FR-4049).

Description of the Need for the Information and Proposed Use: This information collection is required in connection with the anticipated issuance of a Notice of Funding Availability that will announce the availability of \$50 million for grants for lead-based paint hazard reduction in private priority housing, pursuant to Title X of the Housing and Community Development Act of 1992.

Form Number: None.

Members of Affected Public: State and local governments.

Estimation of the Total Number of Hours Needed to Prepare the Information Collection including Number of Respondents, Frequency of Response, and Hours of Response:

	Number of respondents	×	Frequency of responses	=	Hours per response	=	Burden hours
Application Development	75		1		120		9,000

Total Estimated Burden Hours: 9,000.

Status of the Proposed Information Collection: Emergency Processing.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: April 17, 1996.

David S. Cristy,
Director, IRM Policy and Management Division.

[FR Doc. 96-9968 Filed 4-22-96; 8:45 am]
BILLING CODE 4210-01-M

[Docket Nos. FR-4005-N-02; FR-4014-N-02; FR-3961-N-04; FR-4042-N-02]

Office of the Assistant Secretary for Community Planning and Development; Supplemental Notice Concerning Notices of Funding Availability

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Supplemental and Amendatory Notice Concerning Notices of Funding Availability (NOFAs) of the Office of Community Planning and Development: NOFA for the Youthbuild Program, NOFA for the Historically Black Colleges and Universities Program, NOFA for the Early Childhood Development Program, and NOFA for Continuum of Care Homeless Assistance.

SUMMARY: This notice advises of additional information and amendments concerning the Department's NOFAs issued to date by the Office of Community Planning and Development. The additional information and amendments relate to the submission of applications in response to the NOFAs; the review, rating, and selection of these applications; and the funding available under the NOFAs.

DATES: *For the Historically Black Colleges and Universities (HBCU) NOFA:* For the HBCU NOFA, published in the Federal Register on March 7, 1996 (61 FR 9258), completed applications are due before midnight eastern time on July 11, 1996.

For the Continuum of Care Homeless Assistance NOFA: For the Continuum of Care Homeless Assistance NOFA, published in the Federal Register on March 15, 1996 (61 FR 10866), applications that are mailed before June 12, 1996, but received within ten (10) days after that date, will be deemed to have been received by that date if postmarked by the United States Postal Service by no later than June 11, 1996.

All other application due dates and any other dates, if applicable, remain as set forth in the individual NOFAs, or as set forth in any extension notices, that the Department has published.

FOR FURTHER INFORMATION CONTACT:

Applicants should contact the individual or office listed in the "For Further Information Contact" section of the individual NOFAs for which the applicant has a question. Hearing- or speech-impaired persons may access the telephone numbers via TTY by calling the Federal Information Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

NOFA for the Youthbuild Program

The Department published the Notice of Funding Availability (NOFA) for the Youthbuild Program in the Federal Register on March 4, 1996 (61 FR 8442). This notice advises the public that the NOFA for the Youthbuild Program is amended in the following ways:

1. The Department is amending the NOFA for the Youthbuild Program to

include the following language: "The Department may establish panels including persons not currently employed by the Department to obtain certain expertise and outside points of view, including views from other Federal agencies."

2. The Department is amending the NOFA for the Youthbuild Program regarding the estimated amount of funds available. The March 4, 1996 NOFA announced the expected availability of \$37.5 million for Fiscal Year (FY) 1996. However, this notice amends that NOFA to announce the availability of approximately \$20 million for FY 1996 under the Youthbuild Program.

NOFA for the Historically Black Colleges and Universities Program

The Department published the NOFA for the Historically Black Colleges and Universities (HBCU) Program in the Federal Register on March 7, 1996 (61 FR 9258). This notice advises the public that the NOFA for the HBCU Program is amended in the following ways:

1. The Department is amending the NOFA for the Historically Black Colleges and Universities Program to include the following language: "The Department may establish panels including persons not currently employed by the Department to obtain certain expertise and outside points of view, including views from other Federal agencies."

2. The Department is changing the submission deadline for applications under the Historically Black Colleges and Universities Program. The March 7, 1996 NOFA announced an application submission deadline of May 23, 1996. However, this notice extends the deadline for applications under this NOFA to be July 11, 1996.

NOFA for the Early Childhood Development Program

The Department published the NOFA for the Early Childhood Development Program in the Federal Register on March 28, 1996 (61 FR 13950). This notice advises the public that the NOFA for the Early Childhood Development Program is amended to include the following language: "The Department may establish panels including persons not currently employed by the Department to obtain certain expertise and outside points of view, including views from other Federal agencies."

NOFA for Continuum of Care Homeless Assistance

The Department published the NOFA for Continuum of Care Homeless Assistance in the Federal Register on March 15, 1996 (61 FR 10866). This

notice advises the public that the NOFA for Continuum of Care Homeless Assistance is amended in the following ways:

1. The Department is changing the application submission information for the Continuum of Care Homeless Assistance NOFA in order to make the deadline for using the Postal Service the same as the deadline for using an overnight delivery service.

On page 10873 of the NOFA, in the first column, this notice amends the first sentence of the paragraph under the heading "Submissions" to provide that: "Applications that are mailed before June 12, 1996, but received within ten (10) days after that date will be deemed to have been received by that date if postmarked by the United States Postal Service by no later than June 11, 1996."

2. This notice also provides information on additional selection considerations under the NOFA for Continuum of Care Homeless Assistance (61 FR 10866). These considerations are based on statutorily required funding limitations, and are described in section III.(a)(7) of the NOFA (61 FR 10870).

On page 10871, in the first column, in section III.(a)(7), under the heading "Additional selection considerations", the first two paragraphs are corrected to read as follows:

In accordance with section 455(b) of the McKinney Act, no more than 10 percent of the assistance made available for Shelter Plus Care in any fiscal year may be used for programs located within any one unit of general local government.

In accordance with section 441(c) of the McKinney Act, no city or urban county may have Section 8 SRO projects receiving a total of more than 10 percent of the assistance made available under this program.

On page 10871, in the first column, in section III.(a)(7), under the heading "Additional selection consideration", new paragraph is added after the second paragraph, to read as follows:

This year's NOFA does not set-aside specific amounts to be awarded under the Shelter Plus Care, Supportive Housing or the Section 8/SRO Moderate Rehabilitation programs. Instead, the distribution will be demand-driven. However, potential applicants need to be able to plan for their project proposals. Therefore, in accordance with the requirements of section 455(b) and section 441(c) of the McKinney Act, restricting awards to any one unit of general local government (for purposes of Shelter plus Care) or city or urban county (for purposes of the SRO program) in any fiscal year to no more than 10 percent of the assistance made available under each of these two programs. HUD is defining 10 percent this fiscal year as \$10 million for each of these two programs. This \$10 million number is based on past experience of the distribution of the total funds made available

for HUD homeless assistance programs. However, if the amount awarded under either of these two programs exceeds \$100 million, then the amount awarded to any one unit of general local government (for purposes of the Shelter Plus Care program) and or city or urban county (for the purposes of the SRO program) may not exceed 10 percent of the actual total amount awarded for that program.

In addition, if the Administration budget request is enacted as the final appropriation as referred to earlier in the NOFA, the 10% number for each of the 2 programs would increase proportionately.

Dated: April 18, 1996.

Mark C. Gordon,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 96-9969 Filed 4-18-96; 3:03 pm]

BILLING CODE 4210-29-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Tribal Self-Governance Notice of Availability of Self-Governance Negotiation/Planning Grants

AGENCY: Office of Self-Governance, Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: In this notice, the Office of Self-Governance (OSG) announces the availability of fiscal year 1996 (1) negotiation grants (up to 20 grants of \$40,000 each); (2) advance planning grants (up to 10 grants of \$50,000 each); and (3) negotiation/planning grants to negotiate for DOI non-BIA programs (up to 10 grants of no more than \$40,000 each). The timeframes for application and selection vary with each type of grant and are specified in this announcement.

DATES: Applications must be submitted in accordance with the table below:

Type of grant	Deadline for submitting application
Negotiation	May 10, 1996.
Advance Planning	July 31, 1996.
Negotiation/Planning	May 15, 1996.

ADDRESSES: Completed applications for grants should be sent to the Director, Office of Self-Governance, U.S. Department of the Interior, Mail Stop 2548, 1849 C Street NW, Washington DC 20240.

FOR FURTHER INFORMATION CONTACT:

Dr. Kenneth D. Reinfeld, U.S. Department of the Interior, Office of Self-Governance, 1849 C Street NW, Mail Stop 2548, Washington DC 20240, 202-219-0240.

SUPPLEMENTARY INFORMATION: The tribal self-governance program is designed to promote self determination by allowing tribes to assume more control through negotiated agreements of programs operated by the Department of the Interior. The new law allows for negotiations to be conducted for programs operated by BIA and for programs operated by other bureaus and offices within the Department that are available to Indians or when there is an historical cultural, or geographic connection to an Indian tribe.

One of the criteria for entry into self-governance negotiations is the completion of a self-governance planning activity. For this purpose, the Congress has provided funding for planning and negotiation grants.

The purpose of this notice is to announce the availability of planning and negotiation grants in accordance with the self-governance interim rule published elsewhere in today's Federal Register.

The following types of grants are available to tribes in 1996 with the deadlines as stated below:

(1) *Negotiation Grants:* Up to 20 grants of \$40,000 are available. As announced in the Federal Register on February 1, 1996, the closing date for submitting completed applications to begin participation in tribal self-governance in fiscal year 1996 or calendar year 1996 is April 29, 1996. Applications requesting to be included in the applicant pool to begin participation in tribal self-governance may be submitted at any time. Subject to the availability of funds, all tribes/consortia selected from the applicant pool to begin participation in tribal self-governance in fiscal year 1996 or calendar year 1997, will be eligible to receive a negotiation grant. Selected tribes/consortia will be notified by May 3, 1996, and must submit written applications for a negotiation grant no later than May 10, 1996, by indicating their intention to negotiate and annual funding agreement with any bureau within DOI for 1997.

(2) *Advance Planning Grants:* Up to 10 grants of \$50,000 are available. The closing date for submitting applications to receive a grant to plan for future participation in the tribal self-governance program is July 31, 1996.

(3) *Negotiation/Planning Grants to Negotiate Non-BIA Programs:* Up to 10 grants of no more than \$40,000 are available. The closing date for submitting applications to receive a negotiation/planning grant for existing self-governance tribes to negotiate for DOI non-BIA programs is May 15, 1996.

In order to provide sufficient time for tribes to effectively use the planning and negotiation grants, the following dates have been identified for the awarding of grants:

(1) *Negotiation Grants:* Since agreements for the 1997 fiscal year need to be signed and submitted by July 1, 1996, to allow sufficient time to prepare for negotiations, new participating tribes will be selected and awarded negotiation grants by May 15, 1996.

(2) *Advance Planning Grants:* In order to avoid delays in planning activity and future participation in tribal self-governance, advance planning grants must be awarded to tribes/consortia by August 30, 1996.

(3) *Negotiation/Planning Grants to Negotiate Non-BIA Programs:* Since agreements for the 1997 fiscal year need to be signed and submitted by July 1, 1996, to allow sufficient time to prepare for negotiation of DOI non-BIA programs, negotiation/planning grants for existing self-governance tribes to negotiate non-BIA programs must be awarded by May 22, 1996.

Submitting Applications

(1) Applications must be submitted in accordance with the interim rule published elsewhere today in the Federal Register and by the deadlines identified in this announcement.

(2) Applications may be mailed or hand-delivered.

(3) Applications which are mailed must be postmarked no later than the date given in this notice for the particular type of grant being applied for.

Dated: April 4, 1996.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96-9739 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-02-M

Bureau of Land Management

[UT-020-03-1430-01; U-72442]

Salt Lake District, Temporary Closure of Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary closure of lands to motorized vehicles in Tooele County, Utah.

SUMMARY: Notice is hereby given that under the provisions of 43 CFR 8364.1 the public lands listed below are hereby closed to motorized vehicles for a period not to exceed 5 years from the date this notice is published. This temporary closure affects all public lands within the following description:

Salt Lake Meridian

T. 2 S., R. 3 W.,
Sections 5, 7, 8, 16, 17, 20, 21, 28–34
inclusive;

T. 2 S., R. 4 W.,
Section 1, E $\frac{1}{2}$ SE $\frac{1}{4}$;
Section 12, E $\frac{1}{2}$ E $\frac{1}{2}$;
Tract 37;

T. 3 S., R. 3 W.,
Sections 4–9 inclusive.

T. 3 S., R. 4 W.,
Section 1;
Section 11, 12.
Containing 15,553 acres more or less.

T. 2 S., R. 6 W.,
Sections 19, 20, 21, 29, 30;

T. 2 S., R. 7 W.,
Sections 24, 25, 26.
Containing 1,235 acres more or less.

T. 9 S., R. 3 W.,
Sections 5, 8, 9.
Containing 987 acres more or less.

This closure order does not restrict use by the Bureau of Land Management and their grazing permittees or maintenance crews from the following organizations:

Utah Power and Light Company
Lincoln Water Users Association

The Bureau of Land Management has recently acquired the above described lands through land exchange with private parties. Detailed land use planning for these lands are not covered under the existing Pony Express Resource Management Plan of 1990. The lands contain important wildlife habitat, watershed, and safety hazards relating to historic mining activity. The closure is necessary to protect the public and the resources that exist on these lands until the BLM Salt Lake District has developed and implemented land use planning for these areas and has mitigated the safety concerns that exist.

FOR FURTHER INFORMATION CONTACT: Michael Nelson, BLM Salt Lake District Office, (801) 977-4300.

Dated: April 10, 1996.

Joseph L. Jewkes,

Acting Salt Lake District Manager.

[FR Doc. 96-9878 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-DQ-M

[ES-030-06-1310-01]

Notice of Intent To Prepare a Planning Analysis/Environmental Assessment for the Leasing of Federal Minerals

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: The Milwaukee District Office, Eastern States, in cooperation with the U.S. Army Corps of Engineers (COE), Pittsburgh District, will prepare

a Planning Analysis/Environmental Assessment (PA/EA) to assist in the decision-making process related to the leasing of Federal oil and gas resources administered by the Bureau of Land Management (BLM) at the COE Mosquito Creek Lake (MCL) Project, Trumbull County, Ohio. In addition to those Federal oil and gas resources found within the COE administrative boundary, 32.46 acres of Federal oil and gas rights are located under one non-COE tract located in the southwestern corner adjacent to the MCL Project. This tract is owned by the Lakeview Local School District.

This notice is issued pursuant to Title 43 CFR 1610.8(b) and 1610.2(c). The PA/EA will follow the procedures set forth in 43 CFR 1610.5–5.

The public is invited to review and provide comments on issues, concerns and related agency resource objectives as outlined in this notice, or identify additional issues or concerns, if appropriate.

DATES: Comments relating to issues, concerns, and agency resource objectives will be accepted through May 23, 1996.

ADDRESSES: Comments and requests to be included on the mailing list for this project should be sent to: Bureau of Land Management, Milwaukee District, P.O. Box 631, Milwaukee, WI 53201-0631.

FOR FURTHER INFORMATION CONTACT: Ms. Terry Saarela, PA/EA Team Leader, Milwaukee District, (414) 297-4437.

SUPPLEMENTARY INFORMATION: Mosquito Creek Lake is located on Mosquito Creek in Trumbull County, northeastern Ohio about 4.5 miles north-northeast of the City of Warren and 14 miles north-northwest of the City of Youngstown. The majority of the COE administered property is either leased or licensed to the Ohio Department of Natural Resources (ODNR) and managed for parks/recreation and wildlife purposes (of the 11,180.62 acres owned in fee, 5,635 acres are leased to the ODNR Division of Parks and Recreation and 5,370 acres are licensed to the ODNR Division of Wildlife).

There are public-use sites scattered around the lake.

The PA/EA will aid in making decisions related to the leasing of the Federal oil and gas resources in the vicinity of the MCL Project. Decisions relating to Federal oil and gas leasing will be made within the context of existing land use planning documents developed by the COE and the ODNR. Existing management decisions will not be changed or modified by the PA/EA.

The leasing of the Federal oil and gas resources and subsequent development will be carried out in accordance with Federal and State laws, regulations, and orders. The PA/EA will assess the impacts of foreseeable Federal oil and gas development on these lands. Most oil and gas drilling would occur on the southern two-thirds of the MCL Project and vicinity, because this area has the highest development potential. BLM's preliminary estimate indicates that approximately 84 wells could be drilled to develop the Federal oil and gas resources. Drilling would occur over a 9 to 12 year period with 7 to 9 wells drilled per year. The primary drilling target would be the Clinton sandstone. Natural gas with some oil and brine would be produced.

Mosquito Creek Lake, developed areas, sensitive biological habitats, and other special uses greatly reduce the available surface for locating oil and gas operations within the MCL Project and school district property boundaries. This would require the use of directional drilling technology to develop Federal oil and gas beneath areas where the surface cannot be occupied. Therefore, most of the surface disturbance associated with drilling wells to develop the Federal leases would be shifted to private land adjacent to the MCL Project and school district property. However, surface locations for some vertical and directional wells would be on the MCL Project, and one surface location might be on the school district property.

The BLM, COE and ODNR have identified the following preliminary issues in relation to oil and gas development: (1) Potential impacts to the aesthetic qualities for residents and users; (2) Potential impacts to surface and ground water quality in the watersheds of Mosquito Creek Lake; (3) Potential impacts to wetlands and associated resources; (4) Potential impacts to historic, archaeological and traditional cultural properties; (5) Potential impacts to Special Status Species and habitat; (6) Potential impacts to cooperative (ODNR and local farmers) farming leasees; (7) Potential impacts to outdoor recreation opportunities; (8) Effect of fluctuating pool elevation of Mosquito Creek Lake on location of oil and gas operations; (9) Safety concerns for recreational users and residents; and (10) Potential impact to current and future uses of Lakeview Local School District property. Two issues were identified as being beyond the scope of the document. These included: (1) Oil and gas leasing and subsequent operations may affect property values in the Mosquito Creek

Lake area; and (2) traffic associated with oil and gas operations may impact road conditions in the Mosquito Creek Lake vicinity. These issues will be addressed in the analysis process, but no decisions resulting from the PA/EA will be specific to these two issues.

Resource objectives were developed to address specific issues or concerns. Management actions developed through the planning process will strive to meet the outlined resource objectives. The specific objectives, as they relate to oil and gas leasing and development, are:

- Maintain or minimize the impacts to the aesthetic values present at the Mosquito Creek Lake area.
- Sustain and/or improve current safety levels for recreational users and residents.
- Maintain or enhance wetland values in the Mosquito Creek Lake watersheds.
- Maintain existing surface and ground water quality in the Mosquito Creek Lake watersheds.
- Maintain or enhance the historical, archaeological, and traditional cultural resource values.
- Maintain and enhance special status species populations and suitable habitat.
- Minimize impact to farm cooperative leases and associated forage area.
- Maintain current outdoor recreational opportunities and facilities and minimize impacts to future opportunities and facilities.
- Maintain the assigned visual resource management class as determined through the planning process.
- Maintain the integrity of the reservoir pool zones.
- Maintain and/or enhance current and future uses of the Lakeview Local School District property.

Additional issues and resource objectives may be identified as a result of public input.

The PA/EA will be developed by an interdisciplinary team (IDT) composed of specialists in air quality, archaeology, forestry, geographic information systems, hazardous and solid waste, minerals, paleontology, recreation, socio-economics, soils, visual resources, water resources, and wildlife and special status species. Additional technical support will be provided by other specialists as needed.

Public participation will be an important part of the PA/EA process. It is intended that all interested or affected parties be involved. The IDT will seek input by direct mailings, media coverage, person to person contacts, and coordination with local, State, and other Federal agencies throughout the

process. Written and oral comments will be accepted at an open house and public meeting to be held in the multi purpose room of the Cortland Elementary School, 264 Park Avenue in Cortland, Ohio on May 8, 1996. An informal open house will be held from 3:30 p.m. to 5:30 p.m. Resource specialists will be available to discuss specific areas of interest with the public. A formal meeting will be held from 7:00 p.m. to 9:00 p.m. with registration beginning at 6:30 p.m. Agency personnel will accept oral or written comments on the preliminary issues and resource objectives.

Complete records of all phases of the planning process will be available for public review at the Milwaukee District Office. The draft, proposed, and the final PA/EA will be available upon request.

Dated: April 17, 1996.
James W. Dryden,
District Manager.
[FR Doc. 96-9908 Filed 4-22-96; 8:45 am]
BILLING CODE 4310-GJ-P

[ES-020-1310-00]

Notice of Intent for Planning Analyses

AGENCY: Bureau of Land Management (BLM), Interior.

SUMMARY: The Jackson District Office, Eastern States, will prepare Planning Analyses (PA) for consideration of leasing ten scattered tracts of Federal mineral estate for oil and gas exploration and development. The PAs will be prepared in concert with Environmental Analyses (EA).

This notice is issued pursuant to Title 40 Code of Federal Regulations (CFR) 1501.7 and Title 43 CFR 1610.2(c). The planning effort will follow the procedures set forth in 43 CFR Part 1600.

The public is invited to participate in this planning process, beginning with the identification of planning issues and criteria.

DATES: Comments relating to the identification of planning issues and criteria will be accepted through May 30, 1996.

ADDRESSES: Send comments to Bureau of Land Management, Jackson District, 411 Briarwood Drive, Suite 404, Jackson, Mississippi 39206.

FOR FURTHER INFORMATION CONTACT: Sid Vogelpohl, Assistant District Manager for Mineral Resources, Jackson District, (601) 977-5400.

SUPPLEMENTARY INFORMATION: The BLM has responsibility to consider applications to lease Federal mineral

estate for oil and gas exploration and development. An interdisciplinary team will be used in the preparation of the PA/EAs. Preliminary issues, subject to change as a result of public input, are (1) potential impacts of oil and gas exploration and development on the surface resources and (2) consideration of restrictions on lease rights to protect surface resources.

Due to the scattered nature of the ten tracts proposed for leasing, a separate analysis will be prepared for each tract. Tract locations, along with acreages, are listed below.

Arkansas; Sebastian County, Fifth Meridian
T 7 N, R 31 W, Sec. 36;

T 7 N, R 30 W, Sec. 31 & 32; 970 acres.

Arkansas, Yell County, Fifth Meridian

T 5 N, R 25 W, Sec. 10; 511 acres.

Louisiana, Bienville Parish, LA Meridian

T 16 N, R 7 W, Sec. 15; 40 acres.

Louisiana, Livingston Parish, LA Meridian

T 5 S, R 4 E, Sec. 39; 636 acres.

Louisiana, Vermillion Parish, LA Meridian

T 12 S, R 1 E, Sec. 26 & 27; 295 acres.

Mississippi, Covington County, St. Stephens Meridian

T 6 N, R 14 W, Sec. 21; 88 acres.

Mississippi, Hancock County, St. Stephens Meridian

T 7 S, R 16 W, Sec 31;

T 8 S, R 16 W, Sec. 8 & 17; 1,404 acres.

Mississippi, Jones County, St. Stephens Meridian

T 7 N, R 13 W, Sec. 33; 29 acres.

Mississippi, Monroe County, Huntsville Meridian

T 15 S, R 17 W, Sec. 1; 120 acres.

Mississippi, Pearl River, St. Stephens Meridian

T 4 S, R 18 W, Sec. 37; 26 acres.

Due to the limited scope of this PA/EA process, public meetings are not scheduled.

Bruce E. Dawson,

District Manager, Jackson.

[FR Doc. 96-9970 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-GJ-M

[OR-958-1430-01; GP6-0072; OR-48432(WASH)]

Public Land Order No. 7193; Withdrawal of Public Lands and Reserved Minerals for Protection of Yakima Firing Center Expansion; Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 6,640.02 acres of public lands from surface entry and mining, and 3,090.80 acres of reserved mineral interests from mining for a period of 5 years. This will protect the expansion of the Yakima Firing Center for the Department of the Army, Corps of Engineers, pending the processing of an Engle Act withdrawal application. The lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: April 23, 1996.

FOR FURTHER INFORMATION CONTACT:

Betty McCarthy, BLM Oregon/Washington State Office, P.O. Box 2965, Portland, Oregon 97208-2965, 503-952-6155.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Subject to valid existing rights, the following described public lands are hereby withdrawn from settlement, sale, location, and entry under the general land laws, including the United States mining laws (30 U.S.C. Ch. 2 (1988)), but not the mineral leasing laws, to protect lands pending action on an Engle Act withdrawal application:

Willamette Meridian

Surface and Mineral Estates

- T. 17 N., R. 20 E.,
Sec. 22, S $\frac{1}{2}$;
Sec. 24, S $\frac{1}{2}$ SW $\frac{1}{4}$ and that portion of the E $\frac{1}{2}$ lying south of the Interstate Highway 90 right-of-way;
Sec. 26.
- T. 16 N., R. 21 E.,
Sec. 4, SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 12, SE $\frac{1}{4}$;
Sec. 18, lots 1, 2, 3, and 4, E $\frac{1}{2}$, and E $\frac{1}{2}$ W $\frac{1}{2}$.
- T. 17 N., R. 21 E.,
Sec. 30, lots 3 and 4;
Sec. 32, NE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 16 N., R. 22 E.,
Sec. 2, lots 1, 2, 3, and 4, S $\frac{1}{2}$ N $\frac{1}{2}$, and S $\frac{1}{2}$;
Sec. 4, lots 1, 2, 3, and 4, S $\frac{1}{2}$ N $\frac{1}{2}$, and S $\frac{1}{2}$;
Secs. 10 and 14;
Sec. 20, SE $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 22;
Sec. 26, N $\frac{1}{2}$;
Sec. 28, N $\frac{1}{2}$.
- T. 16 N., R. 23 E.,
Sec. 18, lots 3 and 4, E $\frac{1}{2}$ SW $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$, and that portion of the E $\frac{1}{2}$ SE $\frac{1}{4}$ lying westerly of the westerly right-of-way line of Huntzinger Road;
Sec. 20, that portion of the SW $\frac{1}{4}$ lying westerly of the easterly right-of-way line of the railroad;
Sec. 30, lots 1 and 2, NE $\frac{1}{4}$, and E $\frac{1}{2}$ NW $\frac{1}{4}$.

The areas described aggregate approximately 6,640.02 acres of public lands in Kittitas County.

2. Subject to valid existing rights, the reserved mineral interests in the following described lands are hereby

withdrawn from the United States mining laws (30 U.S.C. Ch. 2 (1988)), but not from the mineral leasing laws:

Willamette Meridian

Mineral Estate

- T. 16 N., R. 20 E.,
Sec. 12;
Sec. 18, lot 4 and SE $\frac{1}{4}$;
Sec. 20, S $\frac{1}{2}$.
- T. 16 N., R. 21 E.,
Sec. 4, lots 1, 2, 3, and 4, and S $\frac{1}{2}$ NE $\frac{1}{4}$;
Sec. 8.
- T. 17 N., R. 21 E.,
Sec. 32, S $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 34, W $\frac{1}{2}$.
- T. 16 N., R. 22 E.,
Sec. 12.

The areas described aggregate 3,090.80 acres of reserved minerals in Kittitas County.

3. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of the lands under lease, license, or permit or governing the disposal of their mineral or vegetative resources other than under the mining laws.

4. This withdrawal will expire 5 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1988), the Secretary determines the withdrawal shall be extended.

Dated: April 15, 1996.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 96-9898 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-33-P

National Park Service

Draft Environmental Impact Statement, Elwha River Ecosystem Restoration Implementation, Olympic National Park, WA

ACTION: Notice of Availability of Draft Environmental Impact Statement.

SUMMARY: This notice announces the availability of a draft environmental impact statement (DEIS) for the restoration of the Elwha River Ecosystem in Olympic National Park, Washington. This notice also announces public meetings for the purpose of receiving comments on the draft document.

DATES: There will be a 60-day public review period for comment on this document. Comments on the DEIS should be received no later than June 26, 1996. Public meetings will be held in Seattle, Washington, on Tuesday, May 21, 1996, from 5:30 to 9:00 p.m. at The Mountaineer's Building, Olympus

Room, 300 3rd Ave. West; and in Port Angeles, Washington, on Wednesday, May 22, 1996, from 1:30 to 4:00 p.m. and from 5:30 to 9:00 p.m. at the Vern Burton Community Center, 308 E. 4th Street.

ADDRESSES: Comments on the DEIS should be submitted to: Sarah Bransom, National Park Service—RP, P.O. Box 25287, Denver, CO 80225-0287.

Public reading copies of the DEIS will be available for review at the following locations:

Office of Public Affairs, National Park Service, Department of the Interior, 18th & C Streets, NW, Washington, DC 20240, Telephone: (202) 208-6843
Columbia/Cascades System Support Office, National Park Service, Rm. 650, 909 First Ave., Seattle, WA 98104-1060, Telephone: (206) 220-4154

Olympic National Park, National Park Service, 600 E. Park Ave., Port Angeles, WA 98362, Telephone: (360) 452-4501

North Olympic Library System, Port Angeles Branch, 207 S. Lincoln St., Port Angeles, WA, Telephone: (360) 452-9253

Government Documents, Seattle Public Library, 1000 4th Ave., Seattle, WA 98104-1193, Telephone (206) 386-4686

Government Publications, Suzzallo Library, University of Washington, Seattle, WA 98195, Telephone: (206) 543-1937

FOR FURTHER INFORMATION CONTACT:

Brian Winter, Elwha River Restoration Coordinator, Olympic National Park, 600 E. Park Ave., Port Angeles, WA 98362, Telephone: (360) 452-0302. A limited number of copies of the DEIS are available on request.

SUPPLEMENTARY INFORMATION: In 1994 and 1995, draft and final EISs were released which determined the Department of the Interior's policy on Elwha River Restoration. The Record of Decision on that EIS process, documenting the decision to pursue removal of the dams, is available from the Superintendent, Olympic National Park at the above address.

This document and analysis has resulted from the passage of Public Law 102-495, the Elwha River Ecosystem and Fisheries Restoration Act of 1992. The DEIS has been completed by the National Park Service in cooperation with the US Fish and Wildlife Service, Bureau of Reclamation, Bureau of Indian Affairs, and the Lower Elwha Klallam Tribe.

This draft environmental impact statement on implementing ecosystem restoration describes and analyzes a

proposed action and two alternatives. Under the proposed action, the Secretary of the Interior would remove both the Elwha and Glines Canyon dams, and allow natural river erosion to transport accumulated reservoir sediments to the ocean. The other alternatives are: remove both dams and dredge accumulated sediments into a slurry pipeline for transport to the ocean; and no action—continue to operate the dams without anadromous fish mitigation.

Impacts are analyzed on the following topics: fluvial processes and sediment transport, flooding, groundwater, surface water, native anadromous and resident fisheries, vegetation, wildlife, species of special concern, living marine resources, air quality and noise, cultural resources, socioeconomics, public health and safety, traffic, Indian trust resources, recreation, land use, and aesthetics.

All review comments received will become part of the public record and copies of comments, including names, addresses and telephone numbers provided by respondents, may be released for public inspection.

Dated: April 8, 1996

William C. Walters,

Deputy Field Director, Pacific West Area, National Park Service.

[FR Doc. 96-9979 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-70-M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before April 13, 1996. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, D.C. 20013-7127. Written comments should be submitted by May 8, 1996.

Carol D. Shull,

Keeper of the National Register.

ARIZONA

Maricopa County

Nohlechek, Rhoda, House, Jct. of 2nd St. and Date Ave., NW corner, Wenden, 96000529

ARKANSAS

Benton County

Stroud House (Benton County MPS), Jct. of SE F St. and E. Central Ave., SE corner, Bentonville, 96000527

Garland County

Hot Springs Railroad Warehouse Historic District, 401-439 Broadway, Hot Springs, 96000526

Lonoke County

Lonoke Downtown Historic District, Jct. of Front and Center Sts., Lonoke, 96000528

FLORIDA

Lee County

Galt Island Archeological District (Archeological Resources of the Caloosahatchee Region MPS), Address Restricted, St. James City vicinity, 96000531

Pardo, Mark Shellworks Site (Archeological Resources of the Caloosahatchee Region MPS), Address Restricted, Bokeelia vicinity, 96000533

Useppa Island Site (Archeological Resources of the Caloosahatchee Region MPS), Address Restricted, Bokeelia vicinity, 96000532

Leon County

Florida Agricultural and Mechanical College Historic District, Roughly, Martin Luther King Blvd. from S. Adams St. to Wahnish Way, Tallahassee, 96000530

GEORGIA

Oconee County

Bishop Historic District, Roughly along Price Mill, Old Bishop Rds., and US 441 within the Bishop city limits, Bishop, 96000534

MARYLAND

Wicomico County

Whitehaven Hotel, Whitehaven Rd., jct. of Whitehaven Rd. and River St., Whitehaven, 96000535

NEW JERSEY

Morris County

Palace Theatre, 7 Ledgewood Ave., Netcong, 96000536

Warren County

Bowerstown Historic District, Roughly bounded by Bowerstown, Plane Hill, Lanning and Mine Hill Rds., Washington Township, Belvidere vicinity, 96000537

TEXAS

Galveston County

Silk Stocking Residential Historic District, Roughly bounded by Ave. K, 23rd St., Ave. P, and 26th St., Galveston, 96000539

VIRGINIA

Albemarle County

East Belmont, W side of VA 22, jct. of VA 22 and Co. Rt. 616, Keswick vicinity, 96000540

WISCONSIN

Oconto County

Weber Lake Picnic Ground Shelter, Jct. of WI 32 and NFS 2308, Mountain, 96000541

Vilas County

Anvil Lake Campground Shelter, Jct. of Anvil Lake Rd. and WI 70, Eagle River, 96000542

In order to assist in the preservation of the following property, the comment period has been waived:

NORTH CAROLINA

Macon County

Glen Choga Lodge, 50 Lodge Rd., Aquone vicinity, 96000538

[FR Doc. 96-9929 Filed 4-22-96; 8:45 am]

BILLING CODE 4310-70-P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993; Cullen Engineering Research Foundation Cooperative Research Venture

Notice is hereby given that, on June 6, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Cullen Engineering Research Foundation filed 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 a research 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 Amoco Corporation, Naperville, IL; Elf Aquitaine, Inc., Washington, DC, a subsidiary of Societe Nationale Elf Aquitaine, Paris, France; Hydril Company, Houston, TX; Phillips Petroleum Company, Bartlesville, OK; Exploration and Production Technology Company, a division of Shell Exploration and Production Company, Houston, TX, a subsidiary of Royal Dutch/Shell Group of Companies, The Hague, Netherlands; University of Houston—CEAC, Houston, TX; and Cullen Engineering Research Foundation, Houston, TX. The purpose of the venture is to develop the technology to overcome the barriers to the design, manufacture, and utilization of a broad range of long continuous lengths of high performance, spoolable composite tubing. The activities of the project will be partially funded by an award from the Advanced Technology Program, National Institute of Standards and Technology, Department of Commerce.

Constance K. Robinson,

Director of Operations, Antitrust Division.

[FR Doc. 96-9884 Filed 4-22-96; 8:45 am]

BILLING CODE 4410-01-M

Notice Pursuant to the National Cooperative Research and Production Act of 1993; Joint Industry Program

Notice is hereby given that, on March 15, 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"), Southwest Research Institute (SwRI) has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership and restating the nature and objectives of the venture. 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. Pursuant to Section 6(b) of the Act, the new participant who has been added to the venture known as the Joint Industry Program is: Chevron Research and Technology Company, a division of Chevron U.S.A., Inc., Richmond, CA. SwRI wishes to restate the planned activities of JIP because the originally published notice was abbreviated and did not sufficiently state these activities. The planned research activities are to develop a cost effective nondestructive evaluation technique whose capabilities include the nonintrusive inspection of the entire cross section of pipe and to detect both OD and ID defects without the removal of insulating material at a high inspection speed with a short set up time and to develop a field deployable production model magnetostrictive sensor (MsS) for inspecting and detecting corrosion in insulated piping systems found in the oil, gas, chemical and petrochemical industries by evaluating the operating range of the MsS technique taking into consideration pipe diameter, grade, configuration, wall thickness, temperature and operating pressure of the line and by developing instrument specifications suitable for in-plant testing.

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 SwRI intends to file additional written notification disclosing all changes in membership.

On October 25, 1995, Southwest Research Institute, (Joint Industry Program, JIP) 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 February 23, 1996 (61 FR 7020). Constance K. Robinson, *Director of Operations, Antitrust Division.* [FR Doc. 96-9883 Filed 4-22-96; 8:45 am] BILLING CODE 4410-01-M

Foreign Claims Settlement Commission

Privacy Act of 1974; New System of Records Notice; Albanian Claims Program

AGENCY: Foreign Claims Settlement Commission; Justice.

ACTION: Notice of new system of records.

SUMMARY: The Foreign Claims Settlement Commission (FCSC) hereby publishes notice of the establishment of an additional records system to be effective as of May 24, 1996, and designated "FCSC-36, Albania, Claims Against." This records system will be added to the Commission's current Privacy Act Systems of Records.

DATES: The system of records designated "FCSC-36, Albania, Claims Against" shall be established and become effective on May 24, 1996, as published herein unless amended by notice published prior to that date. The existing systems of records continue in effect. Comments must be submitted on or before May 24, 1996.

ADDRESSES: Any person interested in commenting on this system may do so by submitting comments in writing to the Administrative Office of the Foreign Claims Settlement Commission, 600 E Street, NW, Washington, DC 20579.

FOR FURTHER INFORMATION CONTACT: David E. Bradley, Chief Counsel, Foreign Claims Settlement Commission, 600 E Street NW, Room 6002, Washington, DC 20579, telephone (202) 616-6975, fax (202) 616-6993.

FCSC-36

SYSTEM NAME:

Albania, Claims Against.

SYSTEM LOCATION:

Foreign Claims Settlement Commission, 600 E Street NW, Room 6002, Washington, DC 20579.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Natural and juridical persons who assert claims for losses of property resulting from expropriation or other taking by the Government of Albania.

CATEGORIES OF RECORDS IN THE SYSTEM:

Claim information, including name and address of claimant and

representative, if any; date and place of birth or naturalization; nature and valuation of claim; description, ownership, and value of property; other evidence establishing entitlement to compensation for claim.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title I, International Claims Settlement Act of 1949, as amended, and the Agreement Between the Government of the United States of America and the Government of Albania on the Settlement of Certain Outstanding Claims of March 10, 1995 (entered into force April 18, 1995).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF THE USES:

Records are used for the purpose of determining the validity and amount of claims; issuance of decisions concerning eligibility to receive compensation under the Act and Agreement; notifications to claimants of rights to appeal; and preparation of certifications of awards, if any, to the Treasury Department for payment. Names and other information furnished by claimants may be used for verifying citizenship status with the Immigration and Naturalization Service. The information contained in this system of records is considered by the Commission to be public information which may be disclosed as a routine use to interested persons who make inquiries about the claims program or individual claims therein, including but not limited to Members of Congress or Congressional staff, staff of the Office of Management and Budget, other persons interested in the work of the Commission, and members of the news media.

Law Enforcement: In the event that a system of records maintained by the FCSC to carry out its functions indicates a violation or potential violation of law, whether civil or criminal or regulatory in nature and whether arising by general statute or particular program statute or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal State, local or foreign, charged with enforcing or implementing the statute, rule, regulation or order issued pursuant thereto.

A record, or any facts derived therefrom, may be disclosed in a proceeding before a court or adjudicative body before which the FCSC is authorized to appear or to the

Department of Justice for use in such proceeding when:

- i. The FCSC, or any subdivision thereof, or
- ii. Any employee of the FCSC in his or her official capacity, or
- iii. Any employee of the FCSC in his or her official capacity where the Department of Justice has agreed to represent the employee, or
- iv. The United States, where the FCSC determines that the litigation is likely to affect it or any of its subdivisions, is a party to litigation or has an interest in litigation and such records are determined by the FCSC to be arguably relevant and necessary to the litigation and such disclosure is determined by the FCSC to be a use compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records maintained in file folders.

RETRIEVABILITY:

Filed numerically by claim number. Alphabetical index used for identification of claim.

SAFEGUARDS:

At FCSC: Building employs security guards.

Records are maintained in a locked room accessible to authorized FCSC personnel and other persons when accompanied by such personnel.

RETENTION AND DISPOSAL:

Records are maintained in accordance with 5 U.S.C. 301. Disposal of records will be in accordance with 44 U.S.C. 3301-3314 when such records are determined no longer useful.

SYSTEM MANAGER(S) AND ADDRESS:

Administrative Office, Foreign Claims Settlement Commission, 600 E Street, NW, Room 6002, Washington, DC 20579; telephone 202-616-6975, fax 202-616-6993.

NOTIFICATION PROCEDURE:

Same as above.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Claimant on whom the record is maintained.

David E. Bradley,
Chief Counsel.

[FR Doc. 96-9881 Filed 4-22-96; 8:45 am]

BILLING CODE 4410-01-P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATES: 9:30 a.m., Tuesday, April 30, 1996.

PLACE: The Board Room, 5th Floor, 490 L'Enfant Plaza, S.W., Washington, D.C. 20594.

STATUS: The first item is open to the public. The second item is closed to the public under Exemption 10 of the Government in Sunshine Act.

MATTERS TO BE CONSIDERED:

5745D—"Most Wanted" Safety Recommendations Program: Status Report and Suggested Modifications.

6661—Opinion and Order: Petersen v. Administrator, Docket SE-14007; disposition of Administrator's appeal.

NEWS MEDIA CONTACT: Telephone: (202) 382-0660.

FOR MORE INFORMATION CONTACT: Bea Hardesty, (202) 382-6525.

Dated: March 19, 1996.

Bea Hardesty,

Federal Register Liaison Officer.

[FR Doc. 96-10081 Filed 4-19-96; 2:53 pm]

BILLING CODE 7533-01-P

NUCLEAR REGULATORY COMMISSION

Nuclear Safety Research Review Committee; Subcommittees Meetings

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meetings.

The PRA Subcommittee will hold a meeting on May 13-14, 1996, the I&C and Human Factors Subcommittee on May 14-15, 1996, and the Accident Analysis Subcommittee on May 16-17, 1996. The meetings will take place, starting at 8:00 am, in room T-2B1, Two White Flint North (TWFN) Building, 11545 Rockville Pike, Rockville, MD and will be open to public attendance.

I. The PRA Subcommittee will review the following topics:

- (a) The accident sequence precursor program,
- (b) research supporting risk informed regulation, and
- (c) reactor related methods development.

II. The I&C and Human Factors Subcommittee will review the status of the issues and methods currently being addressed in the RES program on Human Factors and Instrumentation and Control Systems including:

- (a) Staffing levels,
- (b) root-cause analysis,

- (c) hybrid control rooms,
- (d) organizational factors,
- (e) human-system interfaces,
- (f) NAS study and workshop,
- (g) total systems,
- (h) numerical reliability of software tools, and
- (i) programming languages and CASE

tools, and

(j) digital hardware qualification.

III. The Accident Analysis Subcommittee's will review the following topics:

- (a) Assessment of RELAP adequacy for AP-600 analysis,
 - (b) plans for other advanced reactor thermal hydraulic work,
 - (c) status of high burnup fuel work
 - (d) status of severe accident research program, and
 - (e) future plans beyond ALWR work.
- Detailed agendas will be made available at the meetings.

Oral statements may be presented by members of the public with the concurrence of the presiding Subcommittee Chairman; written statements will be accepted and made available to the Subcommittee. Questions may be asked only by members of the NSRRC Committee and the staff. Persons desiring to make oral statements should notify the Nuclear Regulatory Commission staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portions of the meetings, the Subcommittees may exchange preliminary views regarding matters to be considered during the balance of the meeting. The Subcommittees will then hear presentations by and hold discussions with representatives of the NRC staff regarding the topics to be discussed.

Further information regarding topics to be covered, the rescheduling and/or cancellation of meeting sessions, and the Chairmen's ruling on requests for the opportunity to present oral statements and the time allotted for discussion can be obtained by a telephone call to Dr. Jose Luis M. Cortez (telephone 301/415-6596) between 9:00 a.m. and 4:30 p.m. (EST). Persons planning to attend these meetings are urged to contact the above named individual one or two business days before the scheduled meeting to be advised of any changes in schedule, etc., that may have occurred.

Dated: April 16, 1996.

Jose Luis M. Cortez,

Senior Research Program Coordinator, Office of Nuclear Regulatory Research.

[FR Doc. 96-9924 Filed 4-22-96; 8:45 am]

BILLING CODE 7590-01-P

Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Availability

The U.S. Nuclear Regulatory Commission (NRC) has published NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors." Part 1 of NUREG-1537 contains format and content guidance for non-power reactor applicants and licensees and Part 2 contains a standard review plan and acceptance criteria for NRC non-power reactor reviewers.

The format and content guide suggests a uniform format for presenting information in non-power reactor applications, helps ensure completeness of information provided, assists the Commission staff and others in locating information, and aids in increasing the efficiency of the review process. The format and content guide represents a format for non-power reactor applications that is acceptable to the NRC staff. Conformance with the format and content, however, is not required.

The standard review plan ensures the quality and uniformity of the staff reviews, makes information about regulatory matters concerning NPRs widely available, and improves the understanding of the staff review process by interested members of the non-power reactor community and the public.

The document covers all aspects of non-power reactor licensing. The document can be used for the construction permit and the initial operating license, license renewal, license amendment, decommissioning and license termination, and highly enriched to low-enriched uranium core conversions. There is also an appendix to the format and content guide that lists selected regulations that are applicable to non-power reactors.

NUREG-1537 is available for inspection and copying for a fee at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW, Washington, DC 20555. Copies of this document can also be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9828 or the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002.

Dated at Rockville, Maryland, this 16th day of April, 1996.

For the Nuclear Regulatory Commission.
Seymour H. Weiss, Director
Non-Power Reactors and Decommissioning Project Directorate, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 96-9923 Filed 4-22-96; 8:45 am]

BILLING CODE 7590-01-P

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of April 22, 29, May 6, and 13, 1996.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of April 22

There are no meetings scheduled for the week of April 22.

Week of April 29—Tentative

Friday, May 3

11:30 a.m.

Affirmation Session (Public Meeting) (if needed)

2:00 p.m.

Meeting with ACMUI and Dr. Robert Adler on Recommendations of NAS Report on Review of Medical Use Program (Public Meeting)

(Contact: Larry Camper, 301-415-7231)

Week of May 6—Tentative

Friday, May 10

10:00 a.m.

Briefing on Severe Accident Master Integration Plan (Public Meeting)

(Contact: Themis Speis, 301-415-6802)

11:30 a.m.

Affirmation Session (Public Meeting) (if needed)

Week of May 13—Tentative

Monday, May 13

2:00 p.m.

Briefing by Commonwealth Edison (Public Meeting)

Wednesday, May 15

2:00 p.m.

Briefing on Performance Assessment Program in HLW, LLW, and SDMP (Public Meeting)

(Contact: Norman Eisenberg, 301-415-7285)

3:30 p.m.

Affirmation Session (Public Meeting) (if needed)

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415-1292.

CONTACT PERSON FOR MORE INFORMATION: Bill Hill, (301) 415-1661.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301-415-1963).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or gkt@nrc.gov.

Dated: April 18, 1996.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 96-10117 Filed 4-19-96; 2:53 pm]

BILLING CODE 7590-01-M

OFFICE OF MANAGEMENT AND BUDGET

Budget Rescissions and Deferrals

April 12, 1996.

Dear Mr. President: In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report 10 proposed rescissions of budgetary resources, totaling \$400.4 million. These rescission proposals affect the Department of Defense.

Sincerely,

William J. Clinton

The Honorable Albert Gore, Jr., President of the Senate, Washington, DC 20510.

April 12, 1996.

Dear Mr. Speaker: In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report 10 proposed rescissions of budgetary resources, totaling \$400.4 million. These rescission proposals affect the Department of Defense.

Sincerely,

William J. Clinton

The Honorable Newt Gingrich, Speaker of the House of Representatives, Washington, DC 20515.

BILLING CODE 3110-01-P

CONTENTS OF SPECIAL MESSAGE**(in thousands of dollars)**

Rescission No	ITEM	Budgetary Resources
Department of Defense:		
Procurement:		
R96-11	Aircraft procurement, Army.....	140,000
R96-12	Procurement of ammunition, Army.....	47,200
R96-13	Other procurement, Army.....	5,800
R96-15	Procurement of ammunition, Navy and Marine Corps.....	10,000
R96-14	Shipbuilding and conversion, Navy.....	9,200
R96-16	National guard and reserve equipment.....	13,600
Research, Development, Test, and Evaluation:		
R96-17	Research, development, test, and evaluation, Army	9,600
R96-18	Research, development, test, and evaluation, Navy	39,800
R96-19	Research, development, test, and evaluation, Air Force	58,000
R96-20	Research, development, test, and evaluation, Defense-wide.....	67,200
Total, rescissions.....		400,400

R96-11

DEPARTMENT OF DEFENSE

PROCUREMENT

Aircraft Procurement, Army

Of the funds made available under this heading in Public Law 104-61, \$140,000,000 are rescinded.

Rescission Proposal No. R96-11**PROPOSED RESCISSION OF BUDGET AUTHORITY****Report Pursuant to Section 1012 of P.L. 93-344**

AGENCY: Department of Defense	New budget authority..... \$ <u>1,547,605,000</u> (P.L. 104-61)
BUREAU: Procurement	Other budgetary resources.. \$ <u>17,000,000</u>
Appropriations title and symbol: Aircraft procurement, Army 216/82031	Total budgetary resources... \$ <u>1,564,605,000</u>
OMB Identification code: 21-2031-0-1-051	Amount proposed for rescission..... \$ <u>140,000,000</u>
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1998</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for construction, procurement, production, modification, and modernization of aircraft, equipment (including ordnance), ground handling equipment, and spare parts. This proposal would rescind appropriations for procurement of Kiowa Warrior aircraft. Additional Kiowa Warrior aircraft are not required to meet early deployment requirements.

ESTIMATED PROGRAM EFFECT: The Department of the Army's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
1,326,892	1,300,292	-26,600	-43,120	-47,460	-15,260	-4,900	-2,240

R96-12

DEPARTMENT OF DEFENSE

PROCUREMENT

Procurement of Ammunition, Army

Of the funds made available under this heading in Public Law 104-61, \$47,200,000 are rescinded.

Rescission Proposal No. R96-12

PROPOSED RESCISSION OF BUDGET AUTHORITY

Report Pursuant to Section 1012 of P.L. 93-344

AGENCY: Department of Defense	New budget authority..... \$ <u>1,103,085,000</u>
BUREAU: Procurement	(P.L. 104-61) Other budgetary resources.. \$ <u>46,600,000</u>
Appropriations title and symbol: Procurement of ammunition, Army 216/82034	Total budgetary resources... \$ <u>1,149,685,000</u>
OMB identification code: 21-2034-0-1-051	Amount proposed for rescission..... \$ <u>47,200,000</u>
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1998</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for procurement, production, and modification of ammunition and accessories for specialized equipment and training devices. This proposal would rescind appropriations for the ARMS Initiative and Provision of Industrial Facilities. Additional resources are not required at this time to achieve the objectives of these programs.

ESTIMATED PROGRAM EFFECT: The Department of the Army's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
1,062,817	1,046,297	-16,520	-9,440	-11,328	—	-5,192	-2,832

R96-13

DEPARTMENT OF DEFENSE
PROCUREMENT

Other Procurement, Army

Of the funds made available under this heading in Public Law 104-61, \$5,800,000 are rescinded.

Rescission Proposal No. R96-13**PROPOSED RESCISSION OF BUDGET AUTHORITY****Report Pursuant to Section 1012 of P.L. 93-344**

AGENCY: Department of Defense	New budget authority..... \$ 2,730,694,000
BUREAU: Procurement	(P.L. 104-61) Other budgetary resources.. \$ 102,300,000
Appropriations title and symbol: Other procurement, Army 216/82035	Total budgetary resources... \$ 2,832,994,000
	Amount proposed for rescission..... \$ 5,800,000
OMB identification code: 21-2035-0-1-051	Legal authority (in addition to sec. 1012):
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1998</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for construction, procurement, production, and modification of vehicles, including tactical, support, and non-tracked combat vehicles; communications and electronics equipment; and other support equipment. This proposal would rescind appropriations for Automatic Data Processing Equipment (ADPE). ADPE projected requirements will be met without these funds.

ESTIMATED PROGRAM EFFECT: The Department of the Army's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
2,501,685	2,500,682	-1,003	-2,233	-1,102	-812	-406	-162

R96-15

DEPARTMENT OF DEFENSE

PROCUREMENT

Procurement of Ammunition, Navy and Marine Corps

Of the funds made available under this heading in Public Law 104-61, \$10,000,000 are rescinded.

Rescission Proposal No. R96-15

PROPOSED RESCISSION OF BUDGET AUTHORITY

Report Pursuant to Section 1012 of P.L. 91-344

AGENCY: Department of Defense	New budget authority..... \$ <u>430,053,000</u>
BUREAU: Procurement	(P.L. 104-61) Other budgetary resources.. \$ <u>10,000,000</u>
Appropriations title and symbol: Procurement of ammunition, Navy and Marine Corps 176/81508	Total budgetary resources... \$ <u>440,053,000</u>
OMB Identification code: 17-1508-0-1-051	Amount proposed for rescission..... \$ <u>10,000,000</u>
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1996</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for construction, procurement, production, and modification of ammunition for the Navy and Marine Corps. This proposal would rescind appropriations for procurement of 81 mm high-explosive (HE) ammunition. The current inventory of this ammunition meets projected requirements.

ESTIMATED PROGRAM EFFECT: The DoD's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
294,739	289,969	-4,770	-2,400	-1,300	-900	-430	-100

R96-14

DEPARTMENT OF DEFENSE

PROCUREMENT

Shipbuilding and Conversion, Navy

Of the funds made available under this heading in Public Law 104-61, \$9,200,000 are rescinded.

Rescission Proposal No. R96-14**PROPOSED RESCISSION OF BUDGET AUTHORITY****Report Pursuant to Section 1012 of P.L. 95-344**

AGENCY: Department of Defense	New budget authority..... \$ 6,601,958,000 (P.L. 104-61)
BUREAU: Procurement	Other budgetary resources.. \$ _____
Appropriations title and symbol: Shipbuilding and conversion, Navy 176/01611	Total budgetary resources... \$ 6,601,958,000
OMB identification code: 17-1611-0-1-051	Amount proposed for rescission..... \$ 9,200,000
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 2000</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for construction, acquisition, or conversion of Navy vessels, and procurement of critical, long leadtime components and designs for vessels to be constructed or converted in the future. This proposal will rescind appropriations for procurement of Fast Patrol Craft. The current inventory of patrol craft meets projected requirements.

ESTIMATED PROGRAM EFFECT: The Department of the Navy's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
7,226,078	7,225,609	-469	-1,684	-2,006	-1,711	-1,325	-1,030

R96-16

DEPARTMENT OF DEFENSE

PROCUREMENT

National Guard and Reserve Equipment

Of the funds made available under this heading in Public Law 104-61, \$13,600,000 are rescinded.

Rescission Proposal No. R96-16

PROPOSED RESCISSION OF BUDGET AUTHORITY

Report Pursuant to Section 1012 of P.L. 93-344

AGENCY: Department of Defense	New budget authority..... \$ <u>777,800,000</u> (P.L. 104-61)
BUREAU: Procurement	Other budgetary resources.. \$ _____
Appropriations title and symbol: National guard and reserve equipment 976/80350	Total budgetary resources... \$ <u>777,800,000</u>
	Amount proposed for rescission..... \$ <u>13,600,000</u>
OMB identification code: 97-0350-0-1-051	Legal authority (in addition to sec. 1012):
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1998</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides procurement of aircraft, missiles, tracked combat vehicles, ammunition, other weapons, and other procurement for the reserve components of the Armed Forces. This proposal would rescind appropriations for procurement of miscellaneous equipment for the Marine Corps Reserve and C-26 aircraft. Funding for procurement of equipment for the Marine Corps Reserve is provided within the appropriation, Procurement, Marine Corps. The current inventory of executive transport aircraft exceeds projected requirements.

ESTIMATED PROGRAM EFFECT: The DoD's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
945,737	944,717	-1,020	-3,781	-4,121	-2,584	-1,102	-544

R96-17

DEPARTMENT OF DEFENSE

RESEARCH, DEVELOPMENT, TEST, AND EVALUATION

Research, Development, Test, and Evaluation, Army

Of the funds made available under this heading in Public Law 104-61, \$9,600,000 are rescinded.

Rescission Proposal No. R96-17**PROPOSED RESCISSION OF BUDGET AUTHORITY**

Report Pursuant to Section 1012 of P.L. 93-344

AGENCY: Department of Defense	New budget authority..... \$ <u>4,781,272,000</u> (P.L. 104-61)
BUREAU: Research, Development, Test, and Evaluation	Other budgetary resources.. \$ <u>930,735,751</u>
Appropriations title and symbol: Research, development, test, and evaluation, Army 216/72040	Total budgetary resources... \$ <u>5,712,007,751</u>
OMB identification code: 21-2040-0-1-999	Amount proposed for rescission..... \$ <u>9,600,000</u>
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1997</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for basic and applied scientific research and development, test, and evaluation, including maintenance, rehabilitation, and lease and operation of facilities and equipment. Funds proposed for rescission are for Space Applied Technology, Wave Net Technology, Natural Gas Boiler Demonstration, and Battery Maintainer System. Either no funding for these projects is planned after FY 1996, or work to achieve similar ends is funded elsewhere.

ESTIMATED PROGRAM EFFECT: The Department of the Army's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
5,082,522	5,077,050	-5,472	-3,264	-509	-173	-77	-48

R96-18

DEPARTMENT OF DEFENSE

RESEARCH, DEVELOPMENT, TEST, AND EVALUATION

Research, Development, Test, and Evaluation, Navy

Of the funds made available under this heading in Public Law 104-61, \$39,800,000 are rescinded.

Rescission Proposal No. R96-18

PROPOSED RESCISSION OF BUDGET AUTHORITY

Report Pursuant to Section 1012 of P.L. 93-344

AGENCY: Department of Defense	New budget authority..... \$ 8,586,700,000 (P.L. 104-61)
BUREAU: Research, Development, Test, and Evaluation	Other budgetary resources.. \$ 25,650,294
Appropriations title and symbol: Research, development, test, and evaluation, Navy 176/71319	Total budgetary resources... \$ 8,612,350,294
OMB identification code: 17-1319-0-1-051	Amount proposed for rescission..... \$ 39,800,000
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1997</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for basic and applied scientific research, development, test, and evaluation, including maintenance, rehabilitation, and lease and operation of facilities and equipment. Funds proposed for rescission are for Air Systems and Weapons Advanced Technology (Advanced Antiradiation Guided Missile), Submarine Tactical Warfare Systems (Submarine Special Operations Support Development), and Medical Development (General Medical Development and Blood Storage Research). No funding for these projects is planned after FY 1996, or work to achieve similar ends is funded elsewhere.

ESTIMATED PROGRAM EFFECT: The Department of the Navy's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
8,397,081	8,374,833	-22,248	-12,537	-3,264	-796	-438	-159

R96-19

DEPARTMENT OF DEFENSE

RESEARCH, DEVELOPMENT, TEST, AND EVALUATION

Research, Development, Test, and Evaluation, Air Force

Of the funds made available under this heading in Public Law 104-61, \$58,000,000 are rescinded.

Rescission Proposal No. R96-19

PROPOSED RESCISSION OF BUDGET AUTHORITY
Report Pursuant to Section 1012 of P.L. 95-344

AGENCY: Department of Defense	New budget authority.....	\$ 12,845,476,000
BUREAU: Research, Development, Test and Evaluation	(P.L. 104-61) Other budgetary resources..	\$ 2,100,000,000
Appropriations title and symbol: Research, development, test and evaluation, Air Force 576/73600	Total budgetary resources...	\$ 14,945,476,000
OMB Identification code: 57-3600-0-1-051	Amount proposed for rescission.....	\$ 58,000,000
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____	
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1997</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____	

JUSTIFICATION: This appropriation provides for basic and applied scientific research, development, test, and evaluation, including maintenance, rehabilitation, and lease and operation of facilities and equipment. Funds proposed for rescission are for Metal Fatigue Monitoring Technology and Infrared Signature Control. Also proposed for rescission is funding for Space and Missile Tracking Systems Low. Acceleration of this project is not needed.

ESTIMATED PROGRAM EFFECT: The Department of the Air Force's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
11,953,848	11,930,648	-23,200	-26,564	-4,988	-2,030	-870	-116

R96-20

DEPARTMENT OF DEFENSE

RESEARCH, DEVELOPMENT, TEST, AND EVALUATION

Research, Development, Test, and Evaluation, Defense-Wide

Of the funds made available under this heading in Public Law 104-61, \$67,200,000 are rescinded.

Rescission Proposal No. R96-20

PROPOSED RESCISSION OF BUDGET AUTHORITY

Report Pursuant to Section 1012 of P.L. 93-344

AGENCY: Department of Defense	New budget authority..... \$ <u>9,244,775,000</u> (P.L. 104-61)
BUREAU: Research, Development, Test, and Evaluation	Other budgetary resources.. \$ <u>216,265,000</u>
Appropriations title and symbol: Research, development, test, and evaluation Defense-wide <u>976/70400</u>	Total budgetary resources... \$ <u>9,461,040,000</u>
OMB identification code: 97-0400-0-1-051	Amount proposed for rescission..... \$ <u>67,200,000</u>
Grant program: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Legal authority (in addition to sec. 1012): <input type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
Type of account or fund: <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1997</u> (expiration date) <input type="checkbox"/> No-Year	Type of budget authority: <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

JUSTIFICATION: This appropriation provides for basic and applied scientific research, development, test, and evaluation, including maintenance, rehabilitation, and lease and operation of facilities and equipment. Funds proposed for rescission are for Anti-Satellite (ASAT), Natural Language Text, Software Manager's Network, Rapid Acquisition of Manufactured Parts, Integrated Weapons System Data Base, Small Satellites, and Point Source X-ray Lithography. No funding for these projects is planned after FY 1996, or work to achieve similar ends is funded elsewhere.

ESTIMATED PROGRAM EFFECT: The DoD's ability to accomplish its mission successfully would not be affected by this rescission proposal.

OUTLAY EFFECT: (in thousands of dollars):

FY 1996 Outlay Estimate		Outlay Changes					
Without Rescission	With Rescission	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001
9,055,535	9,026,303	-29,232	-26,880	-8,064	-1,008	-1,008	-269

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 21900; International Series Release No. 970; 812-9868]

Emerging Markets Growth Fund, Inc., et al.; Notice of Application

April 17, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for an Order under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Emerging Markets Growth Fund, Inc. (the "Fund"), New Asia East Investment Fund Ltd. (the "New Asia Fund"), Capital International Emerging Markets Fund ("CIEMF"), Capital International, Inc. (the "Manager") and The Capital Group Companies, Inc. (the "Capital Group").

RELEVANT ACT SECTIONS: Order of exemption requested pursuant to section 6(c) of the Act from section 12(d)(1) of the Act, pursuant to sections 6(c) and 17(b) of the Act from section 17(a) of the Act, and pursuant to rule 17d-1 under the Act permitting certain joint transactions in accordance with section 17(d) of the Act and rule 17d-1 thereunder.

SUMMARY OF APPLICATION: The requested order would permit the Fund to invest up to 1% of its assets in the New Asia Fund, an affiliated closed-end Singapore investment company that invests in securities of companies in East and Southeast Asia.

FILING DATES: The application was filed on November 30, 1995 and amended on February 14, 1996 and on March 25, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing.

Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 13, 1996 and should be accompanied by proof of service on applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, c/o Capital International, Inc., 11100 Santa Monica Boulevard,

Los Angeles, California 90025, Attn.: Roberta A. Conroy, Esq.

FOR FURTHER INFORMATION CONTACT: Sarah A. Buescher, Staff Attorney, at (202) 942-0573, or Alison E. Baur, Branch Chief, at (202) 942-0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund, a Maryland corporation, registered under the Act as a closed-end diversified management investment company on June 2, 1986. The Fund's investment objective is to seek long-term capital growth through investment in equity securities of issuers in developing countries.¹ The Fund invests primarily in securities that are listed on a securities exchange or are actively traded in an over-the-counter market in developing countries. Under a fundamental investment policy, the Fund may not acquire any security if the acquisition would result in the Fund owning more than 10% of the outstanding voting securities of any one issuer.

2. Of the Fund's fifteen directors, eleven are not "interested persons" of the Fund ("Independent Directors"). Seven of the Independent Directors represent institutional shareholders of the Fund and three Independent Directors represent former shareholders of the Fund. All but one of the Independent Directors are full-time investment professionals who act in that capacity for their respective employers.

3. The Fund's suitability standards require each institutional investor in the Fund that is a "company," as defined in the Act, to have total assets in excess of \$5 million. An investor who is a natural person must be an "accredited investor" as defined in Regulation D under the Securities Act of 1933 ("Securities Act"). The minimum initial investment in the Fund is \$100,000, and \$25,000 for subsequent investments.

4. The Fund proposes to invest up to 1% of its assets in the New Asia Fund. The New Asia Fund is a closed-end investment company incorporated in Singapore. The New Asia Fund's

¹ The Commission also granted exemptive relief to permit the Fund to invest in the New Europe East Investment Fund, an affiliated closed-end Luxembourg investment company that invests in equity securities in Eastern Europe and the former Soviet republics. See Investment Company Act Release Nos. 20236 (Apr. 20, 1994) (notice) and 20305 (May 17, 1994) (order).

investment objective is to seek long-term capital appreciation through investment in companies doing the majority of their business in the countries of East and Southeast Asia that are member countries of the Asian Development Bank.

5. The New Asia Fund is privately offering two classes of securities in several tranches: (i) Voting preferred shares ("A Shares") and (ii) non-voting preferred shares ("B Shares") (collectively, the "Shares"). The par value per Share and subscription price per Share are \$0.01 and \$10.00, respectively. All subscriptions must be for A Shares, unless legal, tax or contractual restrictions limit a subscriber's ownership of voting securities. In that case, an investor must subscribe for the maximum number of A Shares it is able to hold and thereafter subscribe for B Shares.

6. The New Asia Fund offers and sells Shares only to a limited number of investors. The Shares are not listed on any stock exchange and they may not be offered or sold in the United States or to any United States person, unless the person is an "accredited investor" as defined in Regulation D under Securities Act. The Shares are not redeemable, and the New Asia Fund presently does not intend to repurchase the Shares.

7. Applicants represent that the New Asia Fund is currently not subject to registration under section 7(d) of the Act. Section 7(d) prohibits an investment company organized outside the United States from using the mails or any means or instrumentality of interstate commerce to offer, sell, or deliver after sale, in connection with a public offering, any security of which the company is the issuer.

8. The Fund proposes to invest \$43 million, approximately 1% of its assets, to acquire the New Asia Fund's securities. To comply with its fundamental investment policy, the Fund would invest in a combination of A Shares and B Shares so that it would hold between 3% and 10% of the total voting power, but approximately 30.71% of the economic power, of the New Asia Fund ("Proposed Investment").

9. CIEMF, an investment company organized and operated outside the United States, has invested \$5 million to acquire approximately 3.57% of the New Asia Fund's securities and approximately 3% of its voting stock. CIEMF anticipates acquiring both A and B Shares.

10. The Capital Group, the indirect parent company of the Manager, has invested approximately \$3 million to

acquire the New Asia Fund's A Shares, which will represent approximately 2.14% of the New Asia Fund's securities and 2.76% of its voting securities.

11. The Manager, an investment adviser registered under the Investment Advisers Act of 1940 ("Advisers Act"), advises the Fund, the New Asia Fund and CIEMF. Under an investment advisory and service agreement currently in force between the Fund and the Manager, the Fund pays the Manager a fee. To avoid the possibility that the Manager would receive duplicate fees from the Fund and the New Asia Fund, the Manager will waive its management fee, including administrative fees, with respect to the Fund's net assets represented by the Proposed Investment. Specifically, the Fund's aggregate net assets will be adjusted downward by the amount invested in the New Asia Fund prior to determining the Manager's fee. While the Fund does not have an expense cap arrangement with the Manager, the Fund is subject to mandatory expense cap limitations imposed by state regulatory authorities. Any applicable expense cap limitation or fee waiver will not limit the Manager's fee waiver with respect to the Fund's investment in the New Asia Fund.

12. As investment adviser to the New Asia Fund, the Manager will receive an advisory fee at the rate of 2% per annum of net asset value, as determined on the last business day of each quarter. However, until the Manager invests 90% of the proceeds raised by all tranches of the offering, the advisory fee for the uninvested portion shall be .90% per annum. The New Asia Fund will not pay an advisory fee on the value of securities held in any investment vehicle that pays management and advisory fees to an affiliate of the Capital Group.

13. The New Asia Fund will also pay the Manager an incentive fee equal to 20% of any amount available for distribution to the New Asia Fund shareholders, to be calculated and accrued immediately prior to any distribution. However, no incentive fee will be charged unless and until the New Asia Fund shareholders have recovered through distributions the entire amount of their original subscriptions for Shares, plus a return at the rate of 9% per annum (compounded) on the original subscription. Applicants represent that the incentive fee arrangement complies with the safe harbor of rule 205-3 under the Advisers Act.

14. Section 18(i) of the Act provides that each share of stock issued by a registered management investment

company shall be voting stock and shall have equal voting rights, except as provided in section 18(a) of the Act. Although the New Asia Fund is not subject to section 18(i), applicants represent that the New Asia Fund's capital structure does not present any of the potential harms that section 18(i) was intended to address. The New Asia Fund tailored the voting rights of the Shares to satisfy the needs of certain prospective investors, all of whom are sophisticated, institutional investors. Applicants represent that such investors will understand a capital structure that was created to suit their needs.

Applicants' Legal Analysis

Section 12(d)(1)

1. Section 12(d)(1)(A)(i) provides that no registered investment company may acquire securities of another investment company if such securities represent more than 3% of the acquired company's outstanding voting stock. The New Asia Fund may be considered an investment company for purposes of section 12(d)(1), and therefore, the Proposed Investment may be subject to section 12(d)(1).

2. Section 6(c) provides that the SEC may exempt persons or transactions if, and to the extent that, such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an order under section 6(c) exempting them from section 12(d)(1)(A)(i) to permit the Fund to purchase more than 3% but less than 10% of the outstanding voting securities of the New Asia Fund.

3. Section 12(d)(1) was intended to mitigate or eliminate actual or potential abuses that might arise when one investment company acquires shares or another investment company. These abuses include the acquiring fund imposing undue influence over the management of the acquired fund through the threat of large scale redemptions, the acquisition by the acquiring company of voting control of the acquiring company, the layer of sales charges, expenses, and fees, and the creation of a complex structure that may prevent shareholders from ascertaining the true value of their investments.

4. Applicants believe that the Proposed Investments creates none of the perceived abuses addressed by section 12(d)(1). The Fund would not exercise any influence over the management of the New Asia Fund by the threat of redemptions. Because the

New Asia Fund is a closed-end fund, its Shares are not redeemable and it does not need to have cash on hand to cover redemptions by shareholders. In addition, because the Fund is also a closed-end fund, its liquidity needs are not significant.

5. To minimize the risk that the Fund would exercise voting control over the New Asia Fund to the detriment of the New Asia Fund or its shareholders, the Fund will have its A Shares voted by an independent director designated to act in such capacity.

6. The Proposed Investment would contain no improper layering of sales charges or advisory fees. Shareholders of the Fund and the New Asia Fund do not pay any sales charge, redemption fee or distribution fee. In addition, the Manager will exclude the assets with respect to the Proposed Investment in calculating the Fund's management fees.

7. Applicants believe that the Proposed Investment will not result in a complex structure that could not be understood by the Fund or its shareholders. The New Asia Fund's offering of A and B Shares is designed to accommodate the needs of its sophisticated, institutional shareholders. In addition, the New Asia Fund has created procedures to accurately determine the net assets value of its Shares, which will allow the value of the Fund's investment in the New Asia Fund to be easily and accurately determinable.

Section 17(a)

8. Section 17(a) makes it unlawful for an affiliated person of a registered investment company to sell securities to, or purchase securities from, the company. Section 2(a)(3)(C) of the Act defines an "affiliated person" to include "any person directly or indirectly controlling, controlled by, or under common control with, such other person." In addition, under section 2(a)(3)(E), an investment adviser to an investment company is an "affiliated person" of such company. The Fund, the New Asia Fund, and CIEMF may be deemed to be under common control because the Manager is the investment adviser to each of them. Therefore, the New Asia Fund may be affiliated with the Fund, and section 17(a) may prohibit the New Asia Fund from selling its Shares to the Fund.

9. Section 17(b) provides that the SEC shall exempt a proposed transaction from section 17(a) if evidence establishes that: (a) the terms of the proposed transaction are reasonable and fair and do not involve overreaching; (b) the proposed transaction is consistent with the policies of the registered

investment company involved; and (c) the proposed transaction is consistent with the general provisions of the Act. Applicants request an exemption under sections 6(c) and 17(b) to permit the New Asia Fund to sell its Shares to the Fund.²

10. Applicants believe that the Proposed Investment satisfies the standards of sections 6(c) and 17(b). The Fund will purchase Shares of the New Asia Fund at the same purchase price and on the same basis as all other purchasers of Shares. In addition, the Proposed Investment is consistent with the Fund's investment objectives and policies as set forth in the Fund's registration statement. Applicants also believe that the Proposed Investment is consistent with the general purposes of the Act.

Section 17(d) and Rule 17d-1

11. Section 17(d) prohibits an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, from effecting any transaction in which such investment company is a joint, or joint and several, participant with such person in contravention of SEC rules and regulations. Rule 17d-1 provides that an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, shall not participate in, or effect any transaction in connection with, any joint enterprise or other joint arrangement in which the registered investment company is a participant unless the SEC has issued an order approving the arrangement. The Proposed Investment may constitute a joint enterprise or other joint arrangement within the meaning of rule 17d-1.

12. Applicants believe that the Proposed Investment satisfies the rule 17d-1 standards. Applicants represent that the Fund's board approved the investment by the Fund after carefully considering all relevant factors. All purchasers of the New Asia Fund Shares will receive equal treatment, and no one participant will be favored over any other in any respect.

Applicants' Conditions

Applicants agree that the order granting the requested relief shall be subject to the following conditions:

1. The Manager will waive its management fee (which includes

administrative fees) with respect to the Fund's net assets represented by the Fund's Proposed Investment in the New Asia Fund. To effectuate this waiver, Fund assets represented by the Shares purchased by the Fund under the Proposed Investment will be excluded from the net assets of the Fund in the calculation of the Manager's fee. As such waiver relates to the Manager's fee schedule, any Fund assets invested in the New Asia Fund will be excluded from the Fund's assets before any fee calculation is made; thus, the Fund's aggregate net assets will be adjusted by the amount invested in the New Asia Fund prior to determining the fee based on the Manager's fee schedule (the amount waived pursuant to this procedure shall be defined as the "Reduction Amount" for purposes of condition 4 below).

2. Any fees payable by the Fund to the Manager so excluded in connection with the Proposed Investment, as described herein, will be excluded for all time, and will not be subject to recoupment by the Manager or by any other investment adviser at any other time.

3. The Fund's Proposed Investment in the Shares will be limited to 1% of the Fund's total assets, taken at the time of the Fund's subscription.

4. If the Manager waives any portion of its fees or bears any portion of its expenses in respect of the Fund (an "Expense Waiver"), the adjusted fees for the Fund (gross fees minus Expense Waiver) will be calculated without reference to the Reduction Amount. Adjusted fees then will be reduced by the Reduction Amount. If the Reduction Amount exceeds adjusted fees, the Manager will reimburse the Fund in an amount equal to such excess.

5. The Shares owned by the Fund will be voted by an independent director designated to act in such capacity.

6. Capital Group, CIEMF, and any other Capital Group affiliates that may purchase Shares of the New Asia Fund in the future will vote their Shares in proportion to the vote of all other shareholders of the New Asia Fund.

7. Shares of the New Asia Fund will not be subject to a sales load, redemption fee, or a distribution fee.

8. Investment in Shares will be in accordance with the Fund's investment restrictions and will be consistent with its policies as recited in its registration statement and prospectus.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-9940 Filed 4-22-96; 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. IC-21899; 812-9948]

Glickenhau & Co., et al.; Notice of Application

April 16, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Glickenhau & Co. ("Glickenhau") and Lebenthal & Co., Inc. ("Lebenthal") (collectively, the "Sponsors"); Empire State Municipal Exempt Trust ("Empire Trust") and Glickenhau Value Portfolios ("Equity Trust").

RELEVANT ACT SECTIONS: Order requested under sections 11(a) and 11(c).

SUMMARY OF APPLICATION: Applicants request an order to permit certain offers of exchange between unit investment trusts.

FILING DATES: The application was filed on January 4, 1996 and amended on March 21, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 13, 1996, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary: SEC, 450 5th Street NW, Washington, DC 20549. Applicants: Glickenhau, 6 East 43rd Street, New York, New York 10017; Lebenthal, 120 Broadway, New York, New York 10271.

FOR FURTHER INFORMATION CONTACT: David W. Grim Staff Attorney (202) 942-0571, or David M. Goldberg, Branch Chief, at (202) 942-0564 (Division of Investment Management, Office of Investment Company Regulation).

²Section 17(b) applies to specific proposed transactions and not to an ongoing series of future transactions. See *Keystone Custodian Funds*, 21 S.E.C. 295, 298-299 (1945). Section 6(c) can be used to grant relief from section 17(a) for an ongoing series of future transactions.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. Glickenhau and Lebenthal are the sponsors for successive series of the Empire Trust, and Glickenhau is the sponsor for successive series of the Equity Trust, each series being a separate unit investment trust registered under the Securities Act of 1933 and the Act. Applicants request that any relief granted pursuant to the application also apply to future series of the Empire Trust and the Equity Trust and subsequently issued unit investment trusts sponsored by either or both of the Sponsors or a sponsor controlled by or under common control with the Sponsors and registered (or to be registered) under the Securities Act of 1933 and the Act (collectively with the Empire Trust and the Equity Trust, the "Trusts").

2. The sales charge for initial investment in the Empire Trust is 4.9% of the public offering price, and the sales charge for initial investment in the Equity Trust is 3.9% of the public offering price. Both sales charges are subject to discounts for certain volume transactions. The Sponsors intend to maintain a secondary market for the units of each series of the Empire Trust and the Equity Trust, although they are not obligated to do so. The maximum sales charge upon units sold in the secondary market is 5.9% for the Empire Trust and 3.9% for the Equity Trust.

3. Applicants propose to offer to purchasers of units of any of the Trusts ("Unitholders") the ability to exchange any or all of their units for units in one or more available series of the Trusts (the "Exchange Trusts") at a reduced sales charge (the "Exchange Privilege"). Applicants also propose to offer to Unitholders the ability to roll over any or all of their units in a series which is terminating for units of one or more new series of the Trusts (the "Rollover Trusts") at a reduced sales charge (the "Rollover Privilege").

4. A Unitholder must notify the Sponsors of his or her desire to exercise his or her Exchange Privilege. Exercise of the Exchange Privilege is subject to the following conditions: (a) the Sponsors must be maintaining a secondary market in units of the Trust held by the Unitholder and units of the available Exchange Trust, (b) at the time of the Unitholder's election to participate in the Exchange Privilege, there must be units of the Exchange

Trust available for sale, either under the initial primary distribution or in the Sponsors' secondary market, and (c) exchanges will be effected in whole units only. Any excess proceeds from the units surrendered for exchange will be remitted to the Unitholder; the Unitholder will not be permitted to advance any new funds in order to purchase units of any of the Exchange Trusts.

5. Except for Unitholders who wish to exercise the Exchange Privilege within the first five months of their purchase of units of the Trust, an investor who purchases units under the Exchange Privilege will pay a lower aggregate sales charge than that which would be paid for the units by a new investor. For Unitholders who wish to exercise the Exchange Privilege within the first five months of their purchase of units of an Exchange Trust will be greater of (a) the reduced sales charge or (b) an amount which, when coupled with the sales charge paid by the Unitholder upon his original purchase of units of the Trust, would equal the sales charge applicable to the direct purchase of units of an Exchange Trust, determined as of the date of the exchange.

6. A Unitholder must notify the Sponsors of his or her desire to exercise his or her Rollover Privilege. Exercise of the Rollover Privilege is subject to the following conditions: (a) the Sponsors must be maintaining a secondary market in units of the available Rollover Trust, and (b) at the time of the Unitholders' election to participate in the Rollover Privilege there must be units of the Rollover Trust available for sale, either under the initial primary distribution or in the Sponsors' secondary market. Any excess proceeds from the units surrendered for exchange will be remitted to the Unitholder.

Applicants' Legal Analysis

1. Section 11(a) requires SEC approval of an offer to exchange securities by a registered open-end investment company to the holder of a security of such company or of any other open-end investment company if the exchange occurs on any basis other than the relative net asset values of the securities to be exchanged. Section 11(c) makes section 11(a) applicable to any type of exchange offer of securities of registered unit investment trusts for the securities of any other investment company, irrespective of the basis of exchange.

2. Applicants represent that Unitholders will not be induced or encouraged to participate in the Exchange or rollover Privilege through an active advertising or sales campaign. The Sponsors state that they recognize

their responsibility to their customers not to generate excessive commissions through churning and represent that the sales charge collected will not be a significant economic incentive to salesmen to promote inappropriately the Exchange or Rollover Privilege. Applicants further believe that the Exchange and Rollover Privileges are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

If the requested order is granted, applicants agree to the following conditions:

1. The prospectus for each series and any sales literature or advertisement that mentions the existence of the Exchange Privilege or the Rollover Privilege will disclose that the Exchange and the Rollover Privilege are subject to termination and that their terms are subject to change.

2. Whenever the Exchange Privilege or the Rollover Privilege is to be terminated or its terms are to be amended materially, any holder of a security subject to that privilege will be given prominent notice of the impending termination or amendment at least 60 days prior to the date of termination or the effective date of the amendment, provided that:

a. No such notice need be given if the only material effect of an amendment is to reduce or eliminate the sales charge payable at the time of an exchange, to add one or more new series eligible for the Exchange Privilege or the Rollover Privilege, or to delete a series which has terminated; and

b. No notice need be given if, under extraordinary circumstances, either

i. There is a suspension of the redemption of units of an Exchange Trust or a Rollover Trust under section 22(e) of the Act and the rules and regulations thereunder, or

ii. An Exchange Trust or a Rollover Trust temporarily delays or ceases the sale of its units because it is unable to invest amounts effectively in accordance with applicable investment objectives, policies and restrictions.

3. An investor who purchases units under the Exchange or Rollover Privilege will pay a lower aggregate sales charge than that which would be paid for the units by a new investor.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-9865 Filed 4-22-96; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-37122; File No. SR-Amex-96-12]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the American Stock Exchange, Inc., Relating to Listing and Trading of Warrants Based on the Selected Tech Stock Index

April 17, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on April 9, 1996, the American Stock Exchange, Inc. ("Amex" 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 Amex. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex, pursuant to Rule 19b-4 of the Act, proposes to approve for listing and trading, under Section 106 of the Amex *Company Guide*, index warrants based on the Selected Tech Stock Index ("Index"), a price-weighted, narrow-based index developed by an issuer and comprised of 24 technology stocks which are traded on the Amex, the New York Stock Exchange, Inc. ("NYSE"), or through the facilities of the National Association of Securities Dealers Automated Quotation system and are reported national market system securities ("Nasdaq/NMS").

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 Amex 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 Amex 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

1. Purpose

Under Section 106 (Currency and Index Warrants) of the Amex *Company Guide*, the Exchange may approve for listing index warrants based on foreign and domestic market indices. While the Exchange currently lists and trades warrants on a number of foreign market indices and broad-based domestic market indices, it now proposes to list and trade a warrant based on a narrow-based domestic market index. The listing and trading of warrants on the Selected Tech Stock Index will comply in all respects with Exchange Rules 1100 through 1110 for the trading of stock index and currency warrants.

Warrant issues on the Index will conform to the listing guidelines under Section 106, which provide, among other things, that: (1) The issuer shall have tangible net worth in excess of \$250,000,000 and otherwise substantially exceed size and earnings requirements in Section 101(A) of the *Company Guide* or meet the alternate guideline in paragraph (a); (2) the term of the warrants shall be for a period ranging from one to three years from the date of issuance; and (3) the minimum public distribution of such issues shall be 1,000,000 warrants, together with a minimum of 400 public holders, and have an aggregate market value of \$4,000,000.

Index warrants will be direct obligations of their issuer subject to cash-settlement during their term, and either exercisable throughout their life (*i.e.*, American style) or exercisable only on their expiration date (*i.e.*, European style). Upon exercise, or at the warrant expiration date (if not exercisable prior to such date), the holder of a warrant structured as a "put" would receive payment in U.S. dollars to the extent that the Index has declined below a pre-stated cash settlement value. Conversely, holders of a warrant structured as a "call" would, upon exercise or at expiration, receive payment in U.S. dollars to the extent that the Index has increased above the pre-stated cash settlement value. If "out-of-the-money" at the time of expiration, the warrants would expire worthless. In addition, the Amex, prior to the commencement of trading, will distribute a circular to its membership

calling attention to specific risks associated with warrants on the Index.

The Amex is proposing to list index warrants based on the Selected Tech Stock Index, a price-weighted index developed by an issuer and representing a narrow-based portfolio of large, actively-traded technology stocks.³ The total market capitalization of the Index was \$329,094,000,000 on April 3, 1996. The median capitalization of the components in the Index on that date was \$3.8 billion, and the average market capitalization of these companies was \$13.71 billion. The individual market capitalization of the companies ranged from \$594 million to \$68.1 billion. Average monthly trading volume in the Index stocks ranged from approximately 4.4 million shares to approximately 229.6 million shares during the six-month period from October 1995 through March 1996. The Exchange will monitor the components in the basket on a monthly basis and will advise the Commission whenever less than 75% of those components are eligible for standardized options trading. Currently, 100% of the components are eligible for standardized options trading. The Selected Tech Stock Index shall be used as the basis for only one index warrant to be listed and traded on the Exchange. If the Exchange wishes to list and trade other products based on the Selected Tech Stock Index, including other index warrants, the Exchange shall advise the Commission to determine whether an additional filing pursuant to Rule 19b-4 of the Act is necessary or appropriate.

The Index is price-weighted; its value corresponds to the sum of the prices of one share of each of the component stocks, reduced by a divisor. The Index divisor will be determined to yield the benchmark value of 100.00 on the date the warrant is priced for initial offering to the public. Similar to other stock index values published by the Exchange, the value of the Index will be calculated continuously and disseminated every 15 seconds over the Consolidated Tape Association's Network B.

The Index will be monitored daily for certain types of corporate actions such as the payment of a dividend other than an ordinary cash dividend, stock distribution, stock split, reverse stock split, rights offering, distribution, reorganization, recapitalization, or similar event which may require a divisor adjustment to maintain

³The Commission notes that a list of the component securities and their respective weights in the Index were attached to the proposed rule filing as Exhibit A, and are available for examination at the Amex or at the Commission as specified in Item IV.

¹ 15 U.S.C. 78s(b)(1) (1988).

² 17 CFR 240.19b-4 (1994).

continuity of the index's value. In the event of a merger, consolidation, dissolution, or liquidation of an issuer, or in certain other events such as the distribution of property by an issuer to shareholders, components in the index may be deleted or replaced. Shares of a component stock may be replaced (or supplemented) with other securities under certain other circumstances, such as the conversion of a component stock into another class of security or the spin-off of a subsidiary. If the stock remains in the index, the divisor may be adjusted to maintain the continuity of the Index's value. In the event that a security in the index is removed due to a corporate consolidation and the holders of such security receive cash, the cash value of such security will be included in the Index and will accrue interest at LIBOR to term.

2. Statutory Basis

The Amex believes that the proposed rule change is consistent with Section 6(b) of the Act in general, and with Section 6(b)(5) in particular,⁴ in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Amex does not believe that 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

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the Amex consents, the Commission will:

A. By order approve the proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

⁴ 15 U.S.C. 78f(b)(5) (1988).

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, NW., Washington, DC 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 provisions 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, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR-Amex-96-12 and should be submitted by May 14, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁵

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96-9894 Filed 4-22-96; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-37121; International Series Release No. 969; File No. SR-CHX-96-12]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the Chicago Stock Exchange, Inc. Relating to Listing Standards for Investment Company Units

April 17, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1) ("Act"), notice is hereby given that on March 27, 1996, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. On April 12, 1996, the Exchange filed Amendment No. 1 to its proposal.¹ The Commission is

⁵ 17 CFR 200.30-3(a)(12) (1994).

¹ Amendment No. 1 serves to supersede entirely the Exchange's initial rule filing. Therefore, this notice incorporates Amendment No. 1 in its entirety. Letter from Charles R. Haywood, Foley & Lardner, to Francois Mazur, Attorney, Division of

publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Article XXVIII of its Rules governing the listing requirements of securities on the CHX, as well as Article XXX of the CHX's Rules governing specialists.

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 self-regulatory organization 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 self-regulatory organization 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 Exchange is proposing listing standards for units of trading ("Units") that represent an interest in a registered investment company ("Investment Company") that could be organized as a unit investment trust ("UIT"), an open-end management investment company, or a similar entity. The investment company would hold securities comprising, or otherwise based on or representing an investment in, an index or portfolio of securities. The investment company could either hold the securities directly or could hold another security representing the index or portfolio of securities (such as shares of a UIT that holds shares of an open-end investment company).

Under the proposed rules, the Investment Company would be required either to: (i) hold securities comprising or otherwise based on or representing and interest in an index or portfolio of securities, or (ii) hold securities in another registered investment company.² The Investment Company would then issue Units in a specified aggregate number in return for a deposit of either: (i) shares of securities

Market Regulation, Commission, dated April 11, 1996 ("Amendment No. 1").

² Telephone Conversation between David T. Rusoff, Foley & Lardner, and Francois Mazur, Office of Market Supervision, Division of Market Regulation, on April 12, 1996.

comprising or otherwise based on the relevant index or portfolio, or (ii) shares of a registered investment company. In addition or instead of the "in-kind" deposit, the Investment Company might require a cash deposit. Thus, Units could be structured as series of an open-end management investment company investing in a portfolio of securities ("Fund-only structure"). Alternatively, Units could be structured as UITs that have as their assets shares of an open-end investment company holding a portfolio of securities ("Fund/UIT structure"). Unit holders would receive periodic cash payments corresponding to the regular cash dividends or distributions declared with respect to the securities held by the Investment Company (after subtracting applicable expenses and charges).

Units would be distributed in "Creation Transactions." To effect a Creation Transaction in a Fund-only structure, an entity would buy shares from the investment company ("Fund") in "Creation Unit" size aggregations in exchange for a deposit of a basket of securities reflecting the securities underlying the Fund and/or cash deposit. To effect a Creation Transaction in a Fund/UIT structure, an entity would buy a Fund share with a similar deposit and exchange it for a Creation Unit.³ The owner of a Creation Unit could then subdivide the Creation Unit into a specific number of identical fractional non-redeemable sub-units, the Units, that would constitute securities traded. Units could be recombined into Creation Unit aggregations, and redeemed for the securities underlying the Fund and/or an amount of cash, either directly, or indirectly, depending on the structure chosen. The securities would not be redeemable other than in Creation Unit aggregations.⁴

Dealing in Units on the Exchange will be conducted pursuant to the Exchange's general agency-auction trading rules. The Exchange's general dealing and settlement rules would apply, including its rules on clearance and settlement of securities transactions and its equity margin rules. Other generally applicable Exchange equity rules and procedures also would apply. Unless the prospectus for a specific security states otherwise, the Units trading on the Exchange will have one vote per share; however, as with other securities issued by registered investment companies, there will not be a "pass-through" of the voting rights on the actual index securities held by a fund or directly or indirectly by a trust.

With respect to specialist dealings, Article XXX, Rule 23(a) of the Exchange's Rules precludes certain business relationships between an issuer of an "exclusive issue" and the specialist in that exclusive issue.⁵ Rule 23(a) could be interpreted when listing certain types of Units to prevent a specialist from engaging in Creation Transactions with the issuer. The Exchange believes, however, that such market activities could enhance liquidity in the Units and facilitate the specialist's market-making responsibilities. In addition, since the specialist will be able to engage in Creation Transactions and redemptions only according to the same terms and conditions as every other investor (and only at net asset value), the Exchange believes that there is no potential for abuse.

Therefore, the Exchange proposes amending Article XXX, Rule 23(a) to permit specialists to engage in these types of transactions if such transactions would facilitate the maintenance of a fair and orderly market in the Security. Any Creation Transactions in which the specialist engages, however, will have to be effected through the Distributor (as defined herein), and not directly with the issuer. This requirement will make clear that the specialist is purchasing Units in Creation Unit-size aggregations only to facilitate normal specialist trading activity.

With respect to investor disclosure, the Exchange notes that, pursuant to the requirements of the Securities Act of 1933 ("1933 Act"), all investors in Units will receive a prospectus regarding the Units. Because the Units will be in continuous distribution, the prospectus delivery requirements of the 1933 Act will apply to all investors in Units. It is possible, however, that an exemption from the prospectus delivery requirement may be obtained at some point in the future with respect to Units listed or traded on the Exchange. In the event of such an exemption, the Exchange will discuss with Commission staff the appropriate level of disclosure that should be required with respect to the Units being listed or traded, as appropriate, and will file any necessary rule change to provide for such disclosure.

Upon the initial listing of any class of Units or trading of such Units pursuant

to unlisted trading privileges, the Exchange will issue a circular to its membership explaining the unique characteristics and risks of this type of security. The circular will, among other things, inform member organizations of their responsibility to deliver a prospectus to investors.

With respect to trading halts, the trading of Units would be halted, along with the trading of all other listed stocks, in the event the "circuit breaker" thresholds of Article IX, Rule 10A of the Exchange's Rules are reached.

The Exchange proposes that Units trade either in certificated form or solely through the use of a global certificate. Permitting the use of global certificates would be consistent with expediting the processing of transactions in Units and would minimize the costs of engaging in transactions in these securities.

One existing form of Units are CountryBasket securities ("Securities"),⁶ which are created pursuant to a Fund-only structure. The New York Stock Exchange ("NYSE") has received permission to list and trade CountryBaskets.⁷ CHX is not asking permission to list CountryBaskets at this time, but rather will trade CountryBaskets pursuant to unlisted trading privileges ("UTP") once the generic listing standards set forth herein are approved.

Pursuant to Rule 12f-5 under the Act,⁸ prior to trading a particular class or type of security pursuant to UTP, CHX must have listing standards comparable to those of the primary exchange on which the security is listed. The NYSE has adopted listing standards for investment company units, and CHX's proposed rule change is designed to create similar standards for investment company unit listing and/or trading on CHX. As stated above, CHX propose to trade CountryBaskets pursuant to UTP upon approval of this rule filing.

The remainder of this section of the filing merely provides background information on CountryBaskets. The information, taken from File No. SR-NYSE-95-23, describes the structure and mechanics of CountryBaskets.

CountryBasket securities are issued as series of an open-end management investment company that will invest in a portfolio of securities ("Index Securities") included in a corresponding index. Each series of the

⁵ Interpretation and Policy .01 of Article XXX, Rule 23 defines "exclusive issue" as the stock of any company traded on the Exchange no otherwise traded on the NYSE, American Stock Exchange, or NASDAQ/NMS, and, where there exists another market for such issue, the Exchange has executed 15% or more of the volume in the issue during the three previous months.

⁶ CHX understands that "CountryBaskets" and "The CountryBaskets Index Fund" are service marks of Deutsche Morgan Grenfell/C.J. Lawrence, Inc. ("DMG"), the investment advisor to the fund.

⁷ Securities Exchange Act Release No. 36923 (March 5, 1996), 61 FR 10410.

⁸ 17 CFR 240.12f-5 (1995).

³ *Id.*

⁴ *Id.*

investment company is designed to provide investment results that substantially correspond to the price and yield performance of a corresponding FT/S&P-Actuaries World Index ("Index" or "FT/S&P").⁹ The initial nine series of Funds will be based on the following Indices: Australia, France, Germany, Hong Kong, Italy, Japan, South Africa, United Kingdom, and the United States.

Distribution of the Securities

The Securities are distributed in transactions with the Fund through Creation Transactions. To effect a Creation Transaction, a person would buy Fund shares from the Fund at their net asset value ("NAV") next computed. The sales will be in Creation Unit-size aggregations in exchange for a deposit ("Deposit") of Index Securities (a "Fund Basket") and a specified amount of cash sufficient to equal the NAV of such shares.

Securities in Creation Unit-size aggregations may be redeemed, at NAV, generally for an in-kind distribution of Index Securities comprising the Fund shares, plus a cash payment. A Creation Unit-size of Fund shares will represent securities with approximately \$2 to \$9.5 million in market value. The Creation Unit would be disaggregated into the individual Securities that would trade on the Exchange.¹⁰ For the nine initial

⁹ According to Amendment No. 1 to SR-NYSE-95-23, the Indices are a continuation of the FT-Actuaries World Indices, which were jointly founded by The Financial Times Limited ("FT"), Goldman, Sachs & Co. ("Goldman"), and NatWest Securities Limited ("NatWest," and each a "Founding Member"). In May 1995, Standard & Poor's ("S&P"), a division of The McGraw-Hill Companies, Inc., joined FT and Goldman as co-publishers of the predecessor to the Indices. As part of the new arrangement, NatWest withdrew from the management of those indices, but continues to be recognized as a Founding Member. The Indices are now jointly owned by S&P, FT and Goldman. Following a transition period, FT and S&P will jointly calculate the Indices. In November 1995, FT transferred its ownership rights in the Indices to FT-SE International, a new company jointly owned by the FT and the London Stock Exchange. By the end of 1996, it is expected that FT-SE International will assume responsibility for calculating the European and Asia-Pacific Indices and S&P will calculate the U.S. Index.

¹⁰ If a Fund/UIT structure instead had been used, a "Redeemable Unit" would represent the functional equivalent of the Creation Unit. The owner of a Redeemable Unit could separate it into a specific number of identical fractional non-redeemable sub-units that would constitute the Securities traded on the Exchange. In the case of the Germany CountryBasket series, for example, there would be 100,000 Securities per Redeemable Unit. These Securities could be recombined into Redeemable Units and then redeemed, at NAV, for the appropriate number of Fund shares. In turn, the Fund shares could be redeemed for the Index Securities and cash. The Securities would not be redeemable other than in the Creation Unit aggregations.

CountryBasket securities, there would be the following number of Securities per Creation Unit:
 Australia—100,000
 France—100,000
 Germany—100,000
 Hong Kong—100,000
 Italy—100,000
 Japan—250,000
 South Africa—100,000
 United Kingdom—100,000
 United States—100,000

There may be an initial distribution period of Fund shares lasting from one to a few weeks. During this period, the principal underwriter or distributor ("Distributor") directly or through soliciting dealers would accept subscriptions to purchase Fund shares.

Exchange Trading of Units

The proposed listing criteria provide flexible standards for the listing of Units. Before commencing trading, the Exchange will require that there be at least 300,000 tradeable Units outstanding, representing, for the nine series encompassed by this filing, at least three Creation Units (except for the Japan CountryBasket). The Exchange will consider the suspension of trading and the delisting of a series of Units if:

- After the first year of trading, there are fewer than 50 record or beneficial holders of the Units for 30 or more consecutive trading days;
- The value of the underlying index or portfolio of securities is no longer calculated or available; or
- There occurs another event that makes further dealings in the Units on the Exchange inadvisable.

The FT/S&P-Actuaries World Indices

Deutsche Bank Securities Corporation, formerly investment adviser to the Funds, provided the NYSE with certain information describing the FT/S&P-Actuaries World Indices, contained within NYSE filing SR-NYSE-95-23, as amended. The following combines information from the initial filing and Amendment Nos. 1 and 2 to that filing.

Establishing an Index

The FT/S&P are jointly compiled by the Financial Times Limited, Goldman, Sachs & Co., and Standard & Poor's, a division of The McGraw-Hill Companies, Inc., in conjunction with the Institute of Actuaries (together, the "consortium").¹¹ The aim of the

¹¹ In Amendment No. 1 to SR-NYSE-95-23, the NYSE stated that certain modifications had occurred to the indices. The Chicago Stock Exchange's filing has incorporated the additional information, and operates under the assumption that the original information detailed in SR-NYSE-95-23 continues to be accurate to the extent not modified by the NYSE's amendment.

Consortium is to create and maintain a series of high quality equity indices for use by the global investment community. Specifically, the Consortium seeks to establish and maintain the FT/S&P so that the respect to their corresponding markets, they are comprehensive, consistent, flexible, accurate, investible, and representative.

The World Index Policy Committee ("WIPC") makes all policy decisions concerning the FT/S&P, including objectives, selection criteria, liquidity requirements, calculation methodologies, and the timing and disclosure of additions and deletions. The WIPC makes those decisions in a manner that is consistent with the stated aims and objectives of the Consortium. In general, the WIPC aims for a minimum of 70 percent coverage of the aggregate value of all domestic exchange-listed stocks in every country, region and sector in which it maintains an index.

The WIPC consists of one representative of each Consortium member, one member nominated by each of the parties as representing an actual or prospective main user group of the World Indices, a Chairman and additional member who are members of the Institute of Actuaries of the Faculty of Actuaries.

A country must satisfy the following criteria for the WIPC to include it in the FT/S&P-Actuaries World Indices: (1) Direct equity investment by non-nationals must be permitted, (2) accurate and timely data must be available; (3) no significant exchange controls should exist that would prevent the timely repatriation of capital or dividends; (4) significant international investor interest in the local equity market must have been demonstrated; and (5) adequate liquidity must exist.

Securities in the FT/S&P are subject to the following "investibility screens": (1) Securities comprising the bottom five percent of any market's capitalization are excluded; (2) securities must be eligible to be owned by foreign investors; (3) 25 percent or more of the full capitalization of eligible securities must be publicly available for investment and not in the hands of a single party or parties "acting in concert"; and (4) securities that fail to trade for more than 15 business days within each of two consecutive quarters are excluded.

The WIPC seeks to select constituent stocks that capture 85 percent of the equity that remains in any market (known as the "investible universe") after applying the investibility screens. Securities are selected with regard to economic sector and market

capitalization to make a given FT/S&P highly representative of the overall economic sector make-up and market capitalization distribution of the investible universe of a market.

Maintaining an Index

The WIPC may add securities to the FT/S&P for any of the following reasons:

(1) The addition would make the economic sector make-up and market capitalization distribution of the FT/S&P component more representative of its investible universe; (2) a non-constituent security has gained in importance and replaces an existing constituent security under the rules of review established by the WIPC; (3) the FT/S&P component represents less than its targeted percentage of the capitalization of its investible universe (usually in cases where the investible universe has grown faster than the corresponding FT/S&P); (4) a new, eligible security becomes available whose total capitalization is one percent or more of the current capitalization of the relevant FT/S&P; (5) an existing constituent "spins off" a part of its business and issues new equity to the existing shareholders; or (6) changes in investibility factors lead to a stock becoming eligible for inclusion and that stock now qualifies on other grounds.

The WIPC may adjust the FT/S&P for any of the following reasons: (1) The component comprises too high a percentage of its representative universe; (2) a review by the WIPC shows that a constituent security has declined in importance and should be replaced by a non-constituent security; (3) the deletion of a security that has declined in importance would make the FT/S&P more representative of the economic make-up of its investible universe; (4) circumstances regarding investibility and free float change, causing the constituent security to fail the FT/S&P screening criteria; (5) and existing constituent security is acquired by another entity; or (6) the stock has been suspended from trading for a period of more than ten working days. Generally, but not in all cases, changes resulting from review by the WIPC occur at the end of a calendar quarter. Changes resulting from merger or "spin-off" activity will be effectuated as soon as practicable.

Dissemination of Changes to the Constituent Stocks in the Indices

Changes to an Index made during a calendar quarter are noted at the foot of the tables containing the Indices that are published daily in the ET. Consistent with the FT publication policy, these changes also are shown prior to the

actual day of implementation (unless for reasons beyond the control of FT this is not possible). Decisions regarding the addition of new eligible constituent stocks that are unrelated to existing stocks in an Index, or weighting changes to existing constituent stocks, are announced in the FT at least four working days before they are implemented. Monday editions of the FT also show all constituent changes made during the previous week, together with base values for each Index. Changes to be made in an Index at the end of a calendar quarter are published as soon as is practicable following the quarterly meeting of the World Indices Policy Committee, but before the quarter-end.

Calculation and Dissemination of an Index

The FT/S&P are calculated through widely accepted mathematical formulae, with the effect that the Indices are weighted arithmetic averages of the price relatives of the constituents—as produced solely by changes in the marketplace—adjusted for intervening capital changes. The FT/S&P are base-weighted aggregates of the initial market capitalization, the price of each issue being weighted by the number of shares outstanding, modified to reflect only those shares outstanding that are eligible to be owned by foreign investors.

For each constituent security, the implied annual dividend is divided by 260 (an accepted approximation for the number of business days in a calendar year). This dividend is then reinvested daily according to standard actuarial calculations. Distributions affect adjustments to the base capital or the price per share in accordance with prescribed FT/S&P standards. The indices' values and related performance figures for various periods of time are calculated daily and are disseminated to the public.

The FT/S&P are valued in terms of local currency, U.S. dollars, and U.K. pounds sterling, thereby allowing the effect of currency value on the Index value to be measured. Changes to the indices are announced as soon as possible, and on Mondays the Financial Times publishes a list of changes to each index implemented during the previous week, if any. The FT/S&P are calculated once a day on weekdays when one or more of the constituent markets are open; the indices are syndicated and published in the financial sections of several newspapers worldwide. FT/S&P data also may be purchased electronically.

Recognizing the importance of having current information on the value of the Indices, DMG has arranged for Telesphere Corporation (formerly Telekurs (North America) Inc.) ("Telesphere") to calculate "indicative values" for the nine Indices on which CountryBaskets are based on a more frequent basis. CHX understands that the NYSE will provide for the dissemination of these indicative values through the facilities of the Consolidated Tape Association ("CTA").

In calculating "indicative values," Telesphere will use the most currently available stock price information for the constituent stocks in an Index (based on home currency prices) and prevailing currency exchange rates to translate the Index value into U.S. dollars. Telesphere will also use the same pricing algorithm and methodology as the Index calculators in calculating the indicative values. These values will be disseminated every 30 seconds by the NYSE during regular trading hours of 9:30 A.M. to 4:00 P.M. Eastern time. Due to the differences in trading hours in the markets for the stocks underlying the Indices, the calculation of the indicative values will be implemented as follows:

- *Pacific Rim.* Australia, Hong Kong, and Japan. There is no overlap between the NYSE trading hours and the home-country trading hours. Thus, the indicative values will always reflect the closing prices of the underlying securities on the most recently completed trading day, but will be updated every 30 seconds to reflect changes in exchange rates.

- *Europe.* France, Germany, Italy, and the United Kingdom. There is some overlap between NYSE trading hours and home-country trading hours. Thus, the 30-second updates for these Indices will reflect changes in both current stock price information and currency exchange rates while the relevant market is open; it will reflect only changes in exchange rates once the home-market closes.

- *United States.* Each 30-second update will reflect the current price of U.S. component stocks.

- *South Africa.* During Eastern Standard Time there is no overlap between NYSE and South African trading hours. During Eastern Daylight Savings Time there is a half-hour overlap. Thus, during Standard Time, the disseminated Index values will reflect the closing South African prices. During Daylight Savings Time, there will be a real-time feed of stock prices from the Johannesburg Stock Exchange and there will be a real-time calculation of the indicative value of the Index at 30-second intervals during the half-hour overlap.

While these indicative values will not be the official values of the Indices (which will continue to be calculated and disseminated once each day), the

Exchange believes that these values will provide investors with accurate, timely information on the values of the Indices. Of course, it cannot be guaranteed that the indicative value will at all times be a completely accurate reflection of the value of the underlying index. This also will provide all investors with equal access to information concerning the values of the Indices. While some market participants may be able to perform these calculations for their own trading purposes during the business day, many participants lack sufficient resources to do so. Providing standardized information through CTA facilities will help ensure that all investors have equal access to this market information.¹²

Although the Chicago Stock Exchange operates under Central Time, its trading hours are timed to coincide with those of the NYSE. Therefore, the time zone difference will not affect the ability to trade CountryBaskets on the CHX with full price information.

Telesphere is providing the indicative values subject to substantially the following terms regarding its liability:

The values are representative, unofficial, and indicative estimates of the FT/S&P-Actuaries World Indices ("FT/S&P") calculated by Telesphere Corporation ("Telesphere"). Although they are provided with permission under a licensing agreement with Deutsche Morgan Grenfell/C.J. Lawrence Inc. ("Subscriber"), they are not, and should not be considered as, official FT/S&P index values. They are provided as an information service to benefit the investment community. Neither Telesphere nor Subscriber, The Financial Times Ltd., Standard & Poor's, Goldman, Sachs & Co., or their partners, affiliates employees and Agents, shall have any liability contingent or otherwise, to third parties for the completeness, or interruption in the delivery of the indicative indices. In no event will any such party be liable for any special, indirect, incidental, or consequential damages.

The Exchange believes that its proposal is consistent with Section 6(b)(5) of the Act in that the proposal fosters cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, removes impediments to and perfects the mechanism of a free and open

¹² In the unlikely event that Telesphere determines that it no longer will calculate the indicative values of the Indices, according to the NYSE DMG will seek to find another entity to provide such values on substantially the same basis as Telesphere. If this were to occur, the NYSE has represented that it will consult with the staff of the Division of Market Regulation to ensure that the staff finds any proposed new arrangements acceptable, including the possibility of ending trading in the securities.

market and a national market system and protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the 1934 Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (a) By order approve such proposed rule change, or
- (b) Institute proceedings to determine whether the proposed rule change should be disapproved.

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, NW., Washington, DC 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 provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-

regulatory organization. All submissions should refer to File No. SR-CHX-96-12 and should be submitted by May 14, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.¹³

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-9893 Filed 4-22-96; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional "peg" rate (13 CFR 122.8-4(d)) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 5¾ percent for the April-June quarter of FY 96.

Pursuant to 13 CFR 108.503-8(b)(4), the maximum legal interest rate for a commercial loan which funds any portion of the cost of a project (see 13 CFR 108.503-4) shall be the greater of 6% over the New York prime rate or the limitation established by the constitution or laws of a given State. The initial rate for a fixed rate loan shall be the legal rate for the term of the loan.

John R. Cox,

Associate Administrator for Financial Assistance.

[FR Doc. 96-9876 Filed 4-22-96; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements Filed During the Week Ending April 12, 1996

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: OST-96-1251

Date filed: April 11, 1996

Parties: Members of the International Air Transport Association

Subject:

COMP Telex Mail Vote 798

Fares from Sudan

Intended effective date: May 1, 1996

Docket Number: OST-96-1252

Date filed: April 11, 1996

¹³ 17 CFR 200.30-3(a)(12) (1994).

Parties: Members of the International Air Transport Association

Subject:

TC Telex Mail Vote 796
 Hong Kong-Japan fares
 r-1-053i r-2-043i r-3-070t
 TC2 Telex Mail Vote 797
 Iran-Europe fares
 r-4-003j

Intended effective date: May 1, 1996

Paulette V. Twine,

Chief, Documentary Services Division.

[FR Doc. 96-9904 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-62-P

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ending April 12, 1996

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et seq.). The due date for Answers, Conforming Applications, or Motions to modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST-96-1248

Date filed: April 9, 1996

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: May 7, 1996

Description: Application of United Air Lines, Inc., pursuant to 49 U.S.C. Section 41101 and Subpart Q of the Regulations, requests an amendment of its certificate of public convenience and necessity for Route 130 for authority to offer scheduled foreign air transportation of property and mail between all points in the U.S., on the one hand, and a point or points in Japan and points beyond Japan, on the other hand. United also requests authority to integrate its new services described above with other services consistent with outstanding bilateral agreements.

Paulette V. Twine,

Chief, Documentary Services Division.

[FR Doc. 96-9905 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-62-P

Federal Aviation Administration

Index of Administrator's Decisions and Orders in Civil Penalty Actions; Publication

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of publication.

SUMMARY: This notice constitutes the required quarterly publication of an index of the Administrator's decisions and orders in civil penalty cases. The FAA is publishing an index by order number, an index by subject matter, and case digests that contain identifying information about the final decisions and orders issued by the Administrator. Publication of these indexes and digests is intended to increase the public's awareness of the Administrator's decisions and orders. Also, the publication of these indexes and digests should assist litigants and practitioners in their research and review of decisions and orders that may have precedential value in a particular civil penalty action. Publication of the index by order number, as supplemented by the index by subject matter, ensures that the agency is in compliance with statutory indexing requirements.

FOR FURTHER INFORMATION CONTACT:

James S. Dillman, Assistant Chief Counsel for Litigation (AGC-400), Federal Aviation Administration, 701 Pennsylvania Avenue NW, Suite 925, Washington, DC 20004; telephone (202) 376-6441.

SUPPLEMENTARY INFORMATION: The Administrative Procedure Act requires Federal agencies to maintain and make available for public inspection and copying current indexes containing identifying information regarding materials required to be made available or published. 5 U.S.C. 552(a)(2). In a notice issued on July 11, 1990, and published in the Federal Register (55 FR 29148; July 17, 1990), the FAA announced the public availability of several indexes and summaries that provide identifying information about the decisions and orders issued by the Administrator under the FAA's civil penalty assessment authority and the rules of practice governing hearings and appeals of civil penalty actions. 14 CFR Part 13, Subpart G.

The FAA maintains an index of the Administrator's decisions and orders in civil penalty actions organized by order number and containing identifying information about each decision or order. The FAA also maintains a subject-matter index, and digests organized by order number.

In a notice issued on October 26, 1990, the FAA published these indexes and digests for all decisions and orders issued by the Administrator through September 30, 1990. 55 FR 45984; October 31, 1990. The FAA announced in that notice that it would publish supplements to these indexes and digests on a quarterly basis (*i.e.*, in January, April, July, and October of each year). The FAA announced further in that notice that only the subject-matter index would be published cumulatively, and that both the order number index and the digests would be non-cumulative.

Since that first index was issued on October 26, 1990 (55 FR 45984; October 31, 1990), the FAA has issued supplementary notices containing the quarterly indexes of the Administrator's civil penalty decisions as follows:

Dates of quarter	Federal Register publication
10/1/90-12/31/90	56 FR 44886; 2/6/91.
1/1/91-3/31/91	56 FR 20250; 5/2/91.
4/1/91-6/30/91	56 FR 31984; 7/12/91.
7/1/91-9/30/91	56 FR 51735; 10/15/91.
10/1/91-12/31/91	57 FR 2299; 1/21/92.
1/1/92-3/31/92	57 FR 12359; 4/9/92.
4/1/92-6/30/92	57 FR 32825; 7/23/92.
7/1/92-9/30/92	57 FR 48255; 10/22/92.
10/1/92-12/31/92	58 FR 5044; 1/19/93.
1/1/93-3/31/93	58 FR 21199; 4/19/93.
4/1/93-6/30/93	58 FR 42120; 8/6/93.
7/1/93-9/30/93	58 FR 58218; 10/29/93.
10/1/93-12/31/93	59 FR 5466; 2/4/94.
1/1/94-3/31/94	59 FR 22196; 4/29/94.
4/1/94-6/30/94	59 FR 39618; 8/3/94.
7/1/94-12/31/94*	60 FR 4454; 1/23/95*.
1/1/95-3/31/95	60 FR 19318; 4/17/95.
4/1/95-6/30/95	60 FR 36854; 7/18/95.
7/1/95-9/30/95	60 FR 53228; 10/12/95.

Dates of quarter	Federal Register publication
10/1/95–12/31/95	61 FR 1972; 1/24/96.

*Due to administrative oversight, the index for the third quarter of 1994, including information pertaining to the decisions and orders issued by the Administrator between July 1 and September 30, 1994, was not published on time. The information regarding the third quarter's decisions and orders, as well as the fourth quarter's decisions and orders in 1994, were included in the index published on January 23, 1995.

In the notice published on January 19, 1993, the Administrator announced that for the convenience of the users of these indexes, the order number index published at the end of the year would reflect all of the civil penalty decisions for that year. 58 FR 5044; 1/19/93. The order number indexes for the first,

second, and third quarters would be non-cumulative.

The Administrator's final decisions and orders, indexes, and digests are available for public inspection and copying at all FAA legal offices. (The addresses of the FAA legal offices are listed at the end of this notice.)

Also, the Administrator's decisions and orders have been published by commercial publishers and are available on computer databases. (Information about three commercial publications and computer databases is provided at the end of this notice.)

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Civil Penalty Actions—Orders Issued by the Administrator Digests

(Current as of March 31, 1996)

The digests of the Administrator's final decisions and orders are arranged by order number, and briefly summarize key points of the decision. The following compilation of digests includes all final decisions and orders issued by the Administrator from January 1, 1996, to March 31, 1996. The FAA will publish noncumulative supplements to this compilation on a quarterly basis (e.g., April, July, October, and January of each year).

These digests do not constitute legal authority, and should not be cited or relied upon as such. The digests are not intended to serve as a substitute for proper legal research. Parties, attorneys, and other interested persons should always consult the full text of the Administrator's decision before citing them in any context.

In the Matter of: [Airport Operator]

Order No. 96-1 (1/4/96)

Vehicle Gates Must Control Pedestrian Access. This case arose when FAA security inspectors found gaps, under or near two vehicle gates at the airport, that were large enough to permit unauthorized individuals to slip through into the air operations area. Despite repeated and warnings from the inspectors, the airport operator failed to correct the problem. The airport operator argued that it did not violate 14 CFR 107.13(a)(1), the regulation requiring it to control access to the air operations area, because the gates were vehicles gates. Contrary to the airport operator's arguments, the vehicle gates must control pedestrian access.

Regulation Not Unconstitutional. Section 107.13(a)(1) is not unconstitutionally vague or overbroad.

Penalty. The law judge's imposition of a \$1,000 civil penalty is affirmed.

In the Matter of: Skydiving Center of Washington, D.C.

Order No. 96-2 (1/5/96)

Appeal Dismissed. Complainant has failed to perfect its appeal by filing an appeal brief, as required by the Rules of Practice. Therefore, its appeal is dismissed.

In the Matter of: America West Airlines

Order No. 96-3 (2/13/96)

Failure to use methods acceptable to the Administrator. America West violated 14 CFR 43.13(a) when it repaired three Boeing 737s with speed tape. It employed methods that were not in the Boeing Structural Repair Manual and had not been accepted or approved by the Administrator for this type and extent of damage to these aircraft. America West failed to prove that it had used practices that were in keeping with those employed in the industry for this type of damage to these aircraft. Air carriers must use repair methods that have been approved or accepted by the Administrator even if the actual minor repair on a particular aircraft does not have to be inspected by a FAA representative before putting the aircraft back into service.

Airworthiness. There is a two-prong test for airworthiness: (1) the aircraft must conform to its type design or supplemental type design and to any applicable airworthiness directives, and (2) it must be in a condition for safe operation. In this case, the parties stipulated that the aircraft with the minor damage and temporary speed tape repairs did not present a safety problem. However, the aircraft with the minor damage (engine fan cowl puncture of a Boeing 737-300, and flap trailing edge delamination of a Boeing 737-200 and a Boeing 737-300) and the speed tape were not in conformity with their type designs. Although the type designs were not introduced into evidence, there was still sufficient circumstantial evidence to prove that the aircraft did not conform to their type designs. Consequently, America West

violated 14 CFR 121.153 when it operated these aircraft in an unairworthy condition.

Sanction. The civil penalties totalling \$44,750, for these operational and maintenance violations are affirmed.

In the Matter of: South Aero

Order No. 96-4 (2/13/96)

Competency Check Flights.

Competency check flights administered by a company check pilot in a company plane occurred on duty time rather than rest time and therefore needed to be recorded on the company's flight and duty time records, even though the air carrier did not pay the pilots specifically for the time the pilots spent taking their competency checks.

In the Matter of: Alphin Aircraft, Inc.

Order No. 96-5 (2/13/96)

Petition for Modification Granted. FAA Order No. 95-22 is modified in part to allow Alphin Aircraft to file an appeal brief within 30 days of service of FAA Order No. 96-5.

In the Matter of: Evgeniy V. Ignatov

Order No. 96-6 (2/13/96)

Assault and Interference with

Crewmember. Willful intent to injure need not be present to show assault under 14 CFR 91.11, which prohibits assaulting, intimidating, threatening, or interfering with a crewmember in the performance of the crewmember's duties. Under Section 91.11, assault includes the concept of battery. In the instant case, Respondent committed two separate violations of Section 91.11. The first violation, which consisted of interfering with a crewmember, occurred when Respondent refused to sit down in compliance with the seat belt light and the flight attendant's request, and when he blocked the flight attendant's passage as she was attempting to serve the passengers. The second violation, which consisted of assault, occurred when Respondent pushed past the flight attendant when there was not enough room to get by

safely, grabbed the flight attendant's shoulders, and stepped on the flight attendant's foot, causing her sharp pain and a bruise.

Section. The civil penalty the law judge imposed, of \$750 for one violation and \$1,000 for the other, is not too severe. Although Respondent points out that in another case involving the same regulation, the civil penalty assessed was only \$1,000, that case involved only one violation of Section 91.11, while the instant case involves two separate violations.

In the Matter of: Delta Air Lines, Inc.

Order No. 96-7 (2/15/96)

Appeals Dismissed. The parties have withdrawn their respective notices of appeal in this matter. Therefore, the cross-appeals are dismissed.

In the Matter of: Empire Airlines, Inc.

Order No. 96-8 (2/29/96)

Appeals Dismissed. The parties have withdrawn their respective notices of appeal in this matter. Therefore, the cross-appeals are dismissed.

In the Matter of: [Airport Operator]

Order No. 96-9 (3/5/96)

Reconsideration Denied. Nothing in the airport operator's petition for reconsideration warrants modification or reversal of Order No. 96-1. Notably absent from the petition is any case law or other legal authority to support the airport operator's contention that Order No. 96-1 was in error. Moreover, the principal arguments contained in the petition are not new. They have already been considered and rejected by the Administrator. Section 13.234(d) of the Rules of Practice, 14 CFR 13.234(d), permits the Administrator to dismiss summarily petitions to reconsider that are repetitious.

In the Matter of: U.S. Air, Inc.

Order No. 96-10 (3/11/96)

Appeal dismissed. Complainant withdrew its appeal from the law judge's initial decision. Complainant's appeal is dismissed.

In the Matter of: US Air, Inc.

Order No. 96-11 (3/19/96)

Appeal dismissed. Respondent withdrew its appeal from the law judge's initial decision. Respondent's appeal is dismissed.

In the Matter of: U.S. Air, Inc.

Order No. 96-12 (3/19/96)

Appeal dismissed. Respondent withdrew its appeal from the law judge's initial decision. Respondent's appeal is dismissed.

Commercial Reporting Services of the Administrator's Civil Penalty Decisions and Orders

In June 1991, as a public service, the FAA began releasing to commercial publishers the Administrator's decisions and orders in civil penalty cases. The goal was to make these decisions and orders more accessible to the public. The Administrator's decisions and orders in civil penalty cases are now available in the following commercial publications:

AvLex, published by Aviation Daily, 1156 15th Street, NW, Washington, DC 20005, (202) 822-4669;

Civil Penalty Cases Digest Service, published by Hawkins Publishing Company, Inc., P.O. Box 480, Mayo, MD 21106, (410) 798-1677;

Federal Aviation Decisions, Clark Boardman Callaghan, 50 Broad Street East, Rochester, NY 14694, (716) 546-1490.

The decisions and orders may be obtained on disk from Aviation Records, Inc., P.O. Box 172, Battle Ground, WA 98604, (206) 896-0376. Aeroflight Publications, P.O. Box 854, 433 Main Street, Gruver, TX 79040, (806) 733-2483, is placing the decisions on CD-ROM. Finally, the Administrator's decisions and orders in civil penalty cases are available on Compuserve and FedWorld.

The FAA has stated previously that publication of the subject-matter index and the digests may be discontinued once a commercial reporting service publishes similar information in a timely and accurate manner. No decision has been made yet on this matter, and for the time being, the FAA will continue to prepare and publish the subject-matter index and digests.

FAA Offices

The Administrator's decisions and orders, indexes, and digests are available for public inspection and copying at the following location in FAA headquarters:

FAA Hearing Docket, Federal Aviation Administration; 800 Independence Avenue, SW., Room 924A, Washington, DC 20591; (202) 267-3641.

These materials are also available at all FAA regional and center legal offices at the following locations:

Office of the Assistant Chief Counsel for the Aeronautical Center (AMC-7), Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73125; (405) 954-3296.

Office of the Assistant Chief Counsel for the Alaskan Region (AAL-7), Alaskan Region Headquarters, 222 West 7th Avenue, Anchorage, AK 99513; (907) 271-5269.

Office of the Assistant Chief Counsel for the Central Region (ACE-7), Central Region Headquarters, 601 East 12th Street, Federal Building, Kansas City, MO 64106; (816) 426-5446.

Office of the Assistant Chief Counsel for the Eastern Region (AEA-7), Eastern Region Headquarters, JFK International Airport, Federal Building, Jamaica, NY 11430; (718) 553-3285.

Office of the Assistant Chief Counsel for the Great Lakes Region (AGL-7), 2300 East Devon Avenue, Suite 419, Des Plaines, IL 60018; (708) 294-7108.

Office of the Assistant Chief Counsel for the New England Region (ANE-7), New England Region Headquarters, 12 New England Executive Park, Room 401, Burlington, MA 01803-5299; (617) 238-7050.

Office of the Assistant Chief Counsel for the Northwest Mountain Region (ANM-7), Northwest Mountain Region Headquarters, 1601 Lind Avenue, SW, Renton, WA 98055-4056; (206) 227-2007.

Office of the Assistant Chief Counsel for the Southern Region (ASO-7), Southern Region Headquarters, 1701 Columbia Avenue, College Park, GA 30337; (404) 305-5200.

Office of the Assistant Chief Counsel for the Southwest Region (ASW-7), Southwest Region Headquarters, 2601 Meacham Blvd., Fort Worth, TX 76137-4298; (817) 222-5087.

Office of the Assistant Chief Counsel for the Technical Center (ACT-7), Federal Aviation Administration Technical Center, Atlantic City International Airport, Atlantic City, NJ 08405; (609) 485-7087.

Office of the Assistant Chief Counsel for the Western-Pacific Region (AWP-7), Western-Pacific Region Headquarters, 15000 Aviation Boulevard, Lawndale, CA 90261; (310) 725-7100.

Issued in Washington, DC on April 11, 1996.

James S. Dillman,

Assistant Chief Counsel for Litigation.

[FR Doc. 96-9962 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-M

[Summary Notice No. PE-96-21]

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.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before May 13, 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@mail.hq.faa.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: Mr. D. Michael Smith, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-7470.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulation (14 CFR Part 11).

Donald P. Byrne,
Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 28502.

Petitioner: Cape Smythe Air Service, Inc.

Sections of the FAR Affected: 14 CFR 121.1 and 135.1.

Description of Relief Sought: To permit Cape Smythe Air Service, Inc., to continue to operate its Beechcraft 99 aircraft with up to 15 passenger seats, in part 135 scheduled passenger service.

Docket No.: 28504.

Petitioner: Renown Aviation, Inc.

Sections of the FAR Affected: 14 CFR 121.356(a).

Description of Relief Sought: To permit Renown Aviation, Inc., to operate one Convair 330 non-turbine-powered aircraft (Registration No. N3HH, Serial No. 173), and two Convair 440 non-turbine-powered aircraft (Registration Nos. N202RA and N204RA; Serial Nos. 497 and 504, respectively) without traffic alert and

collision avoidance system (TCAS) II equipment installed.

Docket No.: 28513.

Petitioner: Evergreen Helicopters of Alaska, Inc.

Sections of the FAR Affected: 14 CFR 135.153 and 135.180.

Description of Relief Sought: To permit Evergreen Helicopters of Alaska, Inc., to operate five CASA C-212-200-CC aircraft in Angola, Africa, in support of the United Nations Angolan Verification and Enforcement Mission, without these aircraft being equipped with an FAA-approved ground proximity warning system or a traffic alert and collision avoidance system.

Docket No.: 28543.

Petitioner: Bombardier, Inc.

Sections of the FAR Affected: 14 CFR 25.562.

Description of Relief Sought: To allow U.S. certification of the Canadair new model Global Express airplane without being required to meet the dynamic seat test requirements of the FAR.

Dispositions of Petitions

Docket No.: 25493.

Petitioner: Corporate Air.

Sections of the FAR Affected: 14 CFR 21.197(c)(2).

Description of Relief Sought/Disposition: To allow the issuance of a special flight permit with continuing authorization to the petitioner for aircraft that are operated and maintained in accordance with §§ 135.411(a)(1) and 135.419, "Approved aircraft inspection program."

Denial, March 18, 1996, Exemption No. 6416.

[FR Doc. 96-9963 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-13-M

National Highway Traffic Safety Administration

[Docket No. 94-93; Notice 2]

Decision That Nonconforming 1995 Chevrolet 400 SS Pickup Trucks Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of decision by NHTSA that nonconforming 1995 Chevrolet 400 SS pickup trucks manufactured for the Mexican market are eligible for importation.

SUMMARY: This notice announces the decision by NHTSA that 1995 Chevrolet 400 SS pickup trucks manufactured for the Mexican market and not originally manufactured to comply with all

applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to a vehicle originally manufactured for sale in the United States and certified by its manufacturer as complying with the safety standards (the 1995 Chevrolet C1500), and they are capable of being readily altered to conform to the standards.

DATES: The decision is effective on or before April 23, 1996.

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A) (formerly section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act)), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115 (formerly section 114 of the Act), and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the Federal Register of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the Federal Register.

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas (Registered Importer No. R-90-005) petitioned NHTSA to decide whether 1995 Chevrolet 400 SS pickup trucks manufactured for the Mexican market are eligible for importation into the United States. NHTSA published notice of the petition on February 22, 1996 (61 FR 6889) to afford an opportunity for public comment. The reader is referred to that notice for a thorough description

of the petition. No comments were received in response to the notice. Based on its review of the information submitted by the petitioner, NHTSA has decided to grant the petition.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final decision must indicate on the form HS-7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. VSP-150 is the vehicle eligibility number assigned to vehicles admissible under this notice of final decision.

Final Decision

Accordingly, on the basis of the foregoing, NHTSA hereby decides that a 1995 Chevrolet 400 SS pickup truck manufactured for the Mexican market is substantially similar to a 1995 Chevrolet C1500 originally manufactured for sale in the United States and certified under 49 U.S.C. 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 17, 1996.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.
[FR Doc. 96-9901 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-59-M

[Docket No. 96-13; Notice 2]

Decision That Nonconforming 1972 Ford Mustang Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, (NHTSA), DOT.

ACTION: Notice of decision by NHTSA that nonconforming 1972 Ford Mustang passenger cars manufactured for the Mexican market are eligible for importation.

SUMMARY: This notice announces the decision by NHTSA that 1972 Ford Mustang passenger cars manufactured for the Mexican market that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to a vehicle originally manufactured for importation into and sale in the United States and certified by its manufacturer as complying with the safety standards (the U.S.-certified version of the 1972 Ford Mustang), and they are capable of

being readily altered to conform to the standards.

DATES: This decision is effective on or before April 23, 1996.

FOR FURTHER INFORMATION CONTACT:

George Entwistle, Office of Vehicle Safety Compliance, NHTS (202-366-5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A) (formerly section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act)), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115 (formerly section 114 of the Act), and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the Federal Register of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the Federal Register.

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas (Registered Importer R-90-005) petitioned NHTSA to decide whether 1972 Ford Mustang passenger cars manufactured for the Mexican market are eligible for importation into the United States. NHTSA published notice of the petition on February 21, 1996 (61 FR 6685) to afford an opportunity for public comment. The reader is referred to that notice for a thorough description of the petition. No comments were received in response to the notice. Based on its review of the information submitted by the petitioner, NHTSA has decided to grant the petition.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final decision must indicate on the form HS-7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. VSP-151 is the vehicle eligibility number assigned to vehicles admissible under this decision.

Final Decision

Accordingly, on the basis of the foregoing, NHTSA hereby decides that a 1972 Ford Mustang manufactured for the Mexican market that was not originally manufactured to comply with all applicable Federal motor vehicle safety standards is substantially similar to a 1972 Ford Mustang originally manufactured for sale in the United States and certified under 49 U.S.C. 30115, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: April 17, 1996.

Marilynne Jacobs

Director, Office of Vehicle Safety Compliance.
[FR Doc. 96-9903 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-59-M

Research and Special Programs Administration

Submission for OMB Review; Comment Request

ACTION: Notice of request to extend an existing OMB approved information collection (2137-0584).

SUMMARY: As required by the Paperwork Reduction Act of 1995, a notice was published in the Federal Register on February 1, 1996 stating the Research and Special Programs Administration's (RSPA) intention to request OMB approval to extend this information collection. The notice allowed 60 days for public comments; none were received. The information collection has been submitted to OMB for review and approval, and the purpose of this notice is to allow 30 days from the date of this notice 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: (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: Renewal of Existing Collection.

Title of Information Collection:

Certification and Agreement Forms for the Gas and Hazardous Liquid Pipeline Safety Program.

OMB Approval Number: 2137-0584.

Frequency: Annually.

Use: This collection is used by RSPA to ensure that state agencies attesting they have regulatory jurisdiction over pipeline safety have adopted and are complying with minimum Federal safety standards. This information is used to calculate grants to states.

Estimated Number of Respondents: 61.

Respondents: State Agencies.

Total Annual Hours Requested: 3,649.

Copies of this information collection can be reviewed at the Dockets Unit (Docket PS-146; Notice 2), Room 8421, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh St. SW., Washington, D.C.

ADDRESSES: Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice directly to the Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503, ATTN: Desk Officer for Department of Transportation, RSPA.

FOR FURTHER INFORMATION CONTACT: Marvin Fell, Office of Pipeline Safety, Research and Special Programs Administration, Department of Transportation, 400 Seventh Street SW., Washington, DC 20590 (202) 366-1640.

Dated: April 17, 1996.

Michael T. Horkan,
Clearance Officer, United States Department of Transportation.

[FR Doc. 96-9957 Filed 4-22-96; 8:45 am]

BILLING CODE 4910-60-P

Surface Transportation Board¹

[STB Finance Docket No. 32902]

Central Railroad Company of Indiana—Trackage Rights Exemption—CSX Transportation, Inc.

Central Railroad Company of Indiana (CIND) has filed a verified notice under

¹ The ICC Termination Act of 1995, Pub. L. 104-88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996,

49 CFR 1180.2(d)(7) to acquire trackage rights from the CSX Transportation, Inc. (CSXT) from connection with CIND on CSXT's connection track T-1415 (D)(1) at Ownership Point (O.P.) 1+53 at North Bend, OH, near CSXT's milepost B.C.15 and CSXT's connection with CIND on CSXT's connection track T-2 at O.P. 1144+96.2 at Lawrenceburg, IN near CSXT's milepost 22, a distance of approximately 7 miles.

The purpose of the transaction is to reroute overhead traffic for CIND's Lawrenceburg, IN customers via CSXT, in order that CIND may abandon its own 2.3 miles of right-of-way from railroad milepost 22.4 near Lawrenceburg Junction (about 0.4 miles north of the intersection of Route 50 and Route 1 in Greendale) to railroad milepost 24.7 near Dearborn Junction (at the CIND/CSXT connection south of the former Pierson-Hollowell site in Lawrenceburg), in Dearborn County, IN. See *Central Railroad Company of Indiana—Abandonment Exemption—in Dearborn County, IN*, STB Docket No. AB-459 (Sub-No. 1X) (ICC served Mar. 11, 1996). By Board decision served April 5, 1996, the effective date of the abandonment exemption was postponed until April 30, 1996.

The trackage rights transaction is expected to be consummated immediately after conveyance of the abandoned right of way for construction of a public highway.

As a condition to this exemption, any employees affected by the trackage 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*, 354 I.C.C. 732 (1978) and 360 I.C.C. 653 (1980).

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. 32902, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue NW., Washington, DC 20423 and served on: Jo A. DeRoche, Weiner, Brodsky, Sidman & Kider, P.C., 1350 New York Avenue NW., Suite 800, Washington, DC 20005-4797.

abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 11323.

Decided: April 16, 1996.

By the Board, David M. Konschnik,
Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96-9967 Filed 4-22-96; 8:45 am]

BILLING CODE 4915-00-P

Surface Transportation Board¹

[STB Finance Docket No. 32885 (Sub-No. 1)]

Central of Tennessee Railway & Navigation Company Incorporated d/b/a The Longhorn Railway Company—Change of Operator Exemption—The City of Austin, TX

AGENCY: Surface Transportation Board.

ACTION: Notice of exemption.

SUMMARY: The Board, under 49 U.S.C. 10502, exempts from the prior approval requirements of 49 U.S.C. 10902 the operation by Central of Tennessee Railway & Navigation Company Incorporated doing business as The Longhorn Railway Company (CTRN) of a rail line owned by the City of Austin, TX (the City)² and currently operated by Austin Railroad Company d/b/a Austin & Northwestern Railroad (AUNW). The line extends between AUNW milepost 00.00, west of Giddings, and AUNW milepost 154.07, at Llano, including the Marble Falls Branch (6.43 miles), the Scobee Spur (3.3 miles), and the Burnet Spur (0.93 mile), for approximately 162 miles, in Bastrop, Burnet, Lee, Llano, Travis and Williamson Counties, TX.

DATES: This exemption is effective on May 3, 1996. Petitions to stay must be

¹ The ICC Termination Act of 1995, Pub. L. No. 104-88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10902.

² Before 1986, the Southern Pacific Transportation Company (SP) owned and operated the line from Giddings to Austin (the Giddings Branch) and the connecting line from Austin to Llano, TX (the Llano Branch). SP also owned and operated a line extending off of the Llano Branch at Fairland, TX, to Marble Falls, TX (the Marble Falls Branch). In 1986, the City purchased the Giddings, Llano and Marble Falls Branches from SP. See *Austin Railroad Co.—Operation Exemption—City of Austin, TX*, Finance Docket No. 30861(B) (ICC served Nov. 4, 1986) (51 FR 40084). Subsequently, the City was exempted from the requirements of 49 U.S.C. Subtitle IV, with respect to the acquisition which, among other things, relieved the City of any common carrier obligation that it would incur upon consummation of the transaction. See *City of Austin, TX—Exemption—From 49 U.S.C. Subtitle IV*, Finance Docket No. 30861(A) (Sub-No. 1) (ICC served Apr. 23, 1987).

filed by April 29, 1996, and petitions to reopen must be filed by May 16, 1996.

ADDRESSES: Send pleadings, referring to STB Finance Docket No. 32885 (Sub-No. 1) to: (1) Surface Transportation Board, Office of the Secretary, Case Control Branch, 1201 Constitution Avenue, N.W., Washington, DC 20423; and (2) Donald T. Cheatham, 150 Fourth Avenue, North, Suite 1210, Nashville, TN 37219.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 927-5610. [TDD for the hearing impaired: (202) 927-5721.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: DC Data & News, Inc., Room 2229, 1201 Constitution Avenue, N.W., Washington, DC 20423. Telephone: (202) 289-4357/4359. [Assistance for the hearing impaired is available through TDD services, (202) 927-5721.]

Decided: April 16, 1996.

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

Vernon A. Williams,
Secretary.

[FR Doc. 96-9964 Filed 4-22-96; 8:45 am]

BILLING CODE 4915-00-P

Surface Transportation Board¹

[STB Docket No. AB-6 (Sub-No. 377X)]

Burlington Northern Railroad Company—Abandonment Exemption—in Thayer County, NE

Burlington Northern Railroad Company (BN) filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonments* to abandon 12.15 miles of its line of railroad between milepost 24.00 near Bruning and milepost 32.20 near Hebron, including the station of Hebron at milepost 26.2, in Thayer County, NE.²

¹ The ICC Termination Act of 1995, Pub. L. No. 104-88, 109 Stat. 803, which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to the Board's jurisdiction pursuant to 49 U.S.C. 10903.

² BN has proposed a consummation date for the abandonment that is four months from the date of filing of its verified notice. This proposed consummation date is based on BN's reading of 49 U.S.C. 10904. The first sentence of 10904(c) provides, "Within 4 months after an application is filed under section 10903, any person may offer to subsidize or purchase the railroad line that is the subject of such application."

The Board recently addressed this provision in proposing revised abandonment regulations to implement 49 U.S.C. 10903-04, as established by the ICC Termination Act. In *Abandonment and*

BN has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic to be rerouted from the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to use of this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on May 23, 1996, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,³ formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),⁴ and trail use/rail banking requests under 49 CFR 1152.29⁵ must

Discontinuance of Rail Lines and Rail Transportation Under 49 U.S.C. 10903, STB Ex Parte No. 537 (STB served Mar. 15, 1996) slip op. at 10 [61 FR 11174, 11176 (Mar. 19, 1996)], the Board said, "We see the 4-month statutory deadline as an outer limit, which does not require us to delay resolution of proceedings where the entire time is not needed."

Based on the Board's statement, the exemption in this proceeding will be scheduled to become effective on May 23, 1996, or 50 days after BN's filing of its verified notice of exemption. This is consistent with the existing rules at 49 CFR 1152.50. Offers of financial assistance will be due according to deadlines established in this notice. Potential offerors will *not* have until 4 months after the notice was filed by BN with the Board to make an offer of financial assistance.

While the exemption is scheduled to take effect on May 23, 1996, BN may of course delay consummation until a later date.

³ The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

⁴ See *Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

⁵ The Board will accept late-filed trail use requests so long as the abandonment has not been

be filed by May 3, 1996. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by May 13, 1996, with: Office of the Secretary, Case Control Branch, Surface Transportation Board, 1201 Constitution Avenue, N.W., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's representative: Sarah J. Whitley, General Attorney, Burlington Northern Railroad Company, 3800 Continental Plaza, 777 Main Street, Fort Worth, TX 76102-5384.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

BN has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by April 26, 1996. Interested persons may obtain a copy of the EA by writing to SEA (Room 3219, Surface Transportation Board, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEA, at (202) 927-6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: April 12, 1996.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 96-9964 Filed 4-22-96; 8:45 am]

BILLING CODE 4915-00-P

Surface Transportation Board¹

[STB Docket No. AB-469]

Jacksonville Port Authority; Adverse Discontinuance; In Duval County, FL

AGENCY: Surface Transportation Board.
ACTION: Exemption from statutory provisions concerning giving of notice of an application and filing of a system diagram map.

SUMMARY: Under 49 U.S.C. 10502, the Board is exempting the Jacksonville Port

consummated and the abandoning railroad is willing to negotiate an agreement.

¹ The ICC Termination Act of 1995, Pub. L. 104-88, 109 Stat. 803 (the Act), which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission and transferred certain functions to the Surface Transportation Board (Board). This notice relates to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10903.

Authority from the requirements that it post and publish notice of its application and certify that it has done so, and that it file with the Board a system diagram map identifying and describing the subject line. The Board is granting an exemption because the application is being filed by a party other than the carrier whose operations are the object of the discontinuance.

DATES: The exemption will take effect on April 23, 1996. Petitions to reopen must be filed by May 3, 1996.

ADDRESSES: Send pleadings referring to STB Docket No. AB-469 to: (1) Office of the Secretary, Case Control Branch, Surface Transportation Board, 1201 Constitution Avenue, N.W., Washington, DC 20423; and (2) petitioner's representatives: Ernst D. Mueller, 220 East Bay Street, Jacksonville, FL 32202; and Kelvin J. Dowd, 1224 Seventeenth Street, N.W., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 927-5660. [TDD for the hearing impaired: (202) 927-5721.]

SUPPLEMENTARY INFORMATION: The Jacksonville Port Authority (JPA) has filed an application seeking a determination by the Board that the public convenience and necessity require or permit the discontinuance of service by Jaxport Terminal Railway Company (JTRC) over approximately 10 miles of terminal switching tracks that JPA owns and that connect its Talleyrand Marine Dock and Terminal Facilities in Jacksonville, FL, with the tracks of line-haul carriers. The fact that the application has been filed by a party other than the carrier whose operations are the subject of the discontinuance has led JPA to seek a waiver of the requirement that it post and publish notice of its application. Also, JPA is unable to require JTRC to file a system diagram map (SDM). Accordingly, JPA seeks exemption from the provisions of 49 U.S.C. 10903(a)(3) (B), (C), and (E), which require, respectively posting of a copy of a notice of the application in terminals and stations, publishing a copy of the notice in newspapers for specified periods, and certifying that it has satisfied these requirements. JPA also seeks exemption from the provisions of 49 U.S.C. 10903(c), which require carriers to submit to the Board an SDM identifying each line for which the carrier plans to file a discontinuance application.

The Board is granting the exemption, finding that compliance with the statute is not required to carry out the rail transportation policy of 49 U.S.C. 10101, the matter is of limited scope,

and strict adherence to the statutory requirements is not needed to protect shippers from the abuse of market power. The Board is also granting JPA a waiver of certain regulatory requirements relating to (1) the submission of service, financial and environmental information and (2) the notice and SDM matters discussed above.

Additional information is contained in the Board's decision, in which the Board also declined to institute an investigation into the proposed discontinuance. To purchase a copy of the full decision, write to, call, or pick up in person from: DC News & Data, Inc., 1201 Constitution Avenue, N.W., Room 2229, Washington, DC 20423. Telephone: (202) 289-4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927-5721.]

Decided: April 16, 1996.

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

Vernon A. Williams,
Secretary.

[FR Doc. 96-9965 Filed 4-22-96; 8:45 am]
BILLING CODE 4915-00-P

Board Conference; Sunshine Act Meeting

TIME & DATES: 10:00 a.m., April 30, 1996.

PLACE: Hearing Room A, Surface Transportation Board, 1201 Constitution Avenue, N.W., Washington, D.C. 20423.

STATUS: The Board will meet to discuss among themselves the following agenda items. Although the conference is open for the public observation, no public participation is permitted.

MATTERS TO BE DISCUSSED:

STB Ex Parte No. 528, *Disclosure, Publication, and Notice of Change of Rates and Other Service Terms for Rail Common Carriage.*

Ex Parte No. 392 (Sub-No. 2), *Class Exemption for the Construction of Connection Track Under 49 U.S.C. 10901* and Ex Parte No. 392 (Sub-No. 3), *Class Exemption for Rail Construction Under 49 U.S.C. 10901.*

Finance Docket No. 32830, *Alameda Corridor Construction Application.*

STB Finance Docket No. 32858, *Illinois Central Corporation and Illinois Central Railroad Company—Control—CCP Holdings, Inc., Chicago, Central & Pacific Railroad Company and Cedar River Railroad Company.*

No. MC-F-20783, *Capitol Bus Company—Pooling—Greyhound Lines, Inc.*

CONTACT PERSON FOR MORE INFORMATION: Dennis Watson, Office of Congressional

and Press Service, Telephone: (202) 927-5350, TDD: (202) 927-5721.

Vernon A. Williams,
Secretary.

[FR Doc. 96-10064 Filed 4-19-96; 2:53 pm]
BILLING CODE 4915-00-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

April 15, 1996.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, N.W., Washington, DC 20220.

Bureau of the Public Debt (BPD)

OMB Number: 1535-0001.

Form Number: SB-60 and SB-60a.

Type of Review: Extension.

Title: Payroll Savings Report.

Description: These forms are used to determine the total number of participants purchasing U.S. Savings Bonds through the Payroll Savings Plan.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 25,910.

Estimated Burden Hours Per Response: 41 minutes.

Frequency of Response: Semi-annually.

Estimated Total Reporting Burden: 17,871 hours.

OMB Number: 1535-0059.

Form Number: PD F 1832.

Type of Review: Extension.

Title: Special Form of Assignment for U.S. Registered Definitive Securities.

Description: PD F 1832 is used to certify assignments of U.S. Registered Definitive Securities.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 10,000.

Estimated Burden Hours Per Response: 15 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 2,500 hours.

OMB Number: 1535-0070.

Form Number: PD F 5192.

Type of Review: Extension.

Title: Stop Payment/Replacement Check Request.

Description: PD F 5192 is used by the payee to report loss, stolen, destroyed or nonreceipt of fiscal agency check and to request a replacement check.

Respondents: Individuals or households, Business or other for-profit, not-for-profit institutions, State, Local or Tribal Government.

Estimated Number of Respondents: 500.

Estimated Burden Hours Per Response: 15 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 125 hours.

OMB Number: 1535-0113.

Form Number: PD F 1849.

Type of Review: Extension.

Title: Disclaimer and Consent With Respect to United States Savings Bonds/Notes.

Description: PD F 1849 is used to obtain a disclaimer and consent as the result of an error in registration or otherwise the payment, refund of the purchase price, or reissue as requested by one person would appear to affect the right, title or interest of some other person.

Respondents: Individuals or households.

Estimated Number of Respondents: 7,000.

Estimated Burden Hours Per Response: 6 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 700 hours.

OMB Number: 1535-0114.

Form Number: PD F 2001.

Type of Review: Extension.

Title: Release.

Description: PD F 2001 is used by the owner, coowner, or other person entitled to ratify payment of savings bonds/notes and release the United States of America from any liability.

Respondents: Individuals or households.

Estimated Number of Respondents: 200.

Estimated Burden Hours Per Response: 6 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 20 hours.

Clearance Officer: Vicki S. Ott (304) 480-6553, Bureau of the Public Debt, 200 Third Street, Parkersburg, West VA 26106-1328.

OMB Reviewer: Milo Sunderhauf (202) 395-7340, Office of Management

and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 96-9890 Filed 4-22-96; 8:45 am]

BILLING CODE 4810-40-P

Submission for OMB Review; Comment Request

April 10, 1996.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220. SPECIAL REQUEST: In order to implement the process described below by the June 1996 start-up date, the Department of Treasury is requesting Office of Management and Budget (OMB) review and approve this information collection by April 23, 1996. To obtain a copy of this survey, please contact the IRS Clearance Officer at the address listed below.

Internal Revenue Service (IRS)

OMB Number: 1545-1432.

Project Number: M:SP:V 96-011-G.

Type of Review: Revision.

Title: EP/EO Determination Centralization Customer Satisfaction Survey.

Description: In order to ascertain whether the centralized determination process is of value, IRS will administer this survey twice for each key district office.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 16,980.

Estimated Burden Hours Per Respondent: 3 minutes.

Frequency of Response: Other.

Estimated Total Reporting Burden: 849 hours.

Clearance Officer: Garrick Shear (202) 622-3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395-7340, Office of Management and Budget, Room 10226, New

Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 96-9891 Filed 4-22-96; 8:45 am]

BILLING CODE 4830-01-P

Submission to OMB for Review; Comment Request

April 16, 1996.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Internal Revenue Service (IRS)

OMB Number: 1545-0863.

Regulation ID Number: LR-218-78 Final.

Type of Review: Extension.

Title: Product Liability Losses and Accumulations for Product Liability Losses.

Description: Generally, a taxpayer who sustains a product liability loss must carry the loss back 10 years. However, a taxpayer may elect to have such loss treated as a regular net operating loss under section 172. If desired, such election is made by attaching a statement to the tax return. This statement will enable the IRS to monitor compliance with the statutory requirements.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 5,000.

Estimated Burden Hours Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 2,500 hours.

OMB Number: 1545-1100.

Regulation ID Number: EE-84-89 NPRM.

Type of Review: Extension.

Title: Changes with Respect to Prizes and Awards and Employee Achievement Awards.

Description: This regulation requires recipients of prizes and awards to maintain records to determine whether a qualifying designation has been made. The affected public are prize and award

recipients who seek to exclude the cost of a qualifying prize or award.

Respondents: Individuals or households.

Estimated Number of Respondents: 1.

Estimated Burden Hours Per

Respondent: 1.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 1 hour.

OMB Number: 1545-1126.

Regulation ID Number: INTL-121-90 NPRM, INTL-292-90 Final, INTL-361-89 Final, INTL-103-89 Temporary

Type of Review: Extension.

Title: Treaty-Based Return Positions.

Description: Section 301.6114 sets forth the reporting requirements under § 6114. Persons or entities subject to this reporting requirement must make the required disclosure on a statement attached to their return, in the manner set forth, or be subject to a penalty. Section 301.7701(b)-7(a)(4)(iv)(C) sets forth the reporting requirement for dual resident S corporation shareholders who claim treaty benefits as nonresidents of the United States.

Respondents: Individuals or households, business or other for-profit.

Estimated Number of Respondents: 5,000.

Estimated Burden Hours Per

Respondent: 1 hour.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 5,000 hours.

OMB Number: 1545-1385.

Regulation ID Number: GL-238-88 Final.

Type of Review: Extension.

Title: Preparer Penalties—Manual Signature Requirement.

Description: The reporting requirements affect returns preparers of fiduciary returns. They will be required to submit a list of the names and identifying numbers of all fiduciary returns which are being filed with facsimile signature of the returns preparer.

Respondents: Business or other for-profit.

Estimated Number of Respondents/Recordkeepers: 20,000.

Estimated Burden Hours Per

Respondent/Recordkeeper: 1 hour, 17 minutes.

Frequency of Response: Annually.

Estimated Total Reporting/Recordkeeping Burden: 25,825 hours.

OMB Number: 1545-1435.

Regulation ID Number: EE-45-93 NPRM and Temporary

Type of Review: Extension.

Title: Electronic Filing of Form W-4.

Description: Information is required by the Internal Revenue Service to

verify compliance with section 31.3402(f)(2)-1(g)(1), which requires submission to the Service of certain withholding exemption certificates. The affected respondents are employers that choose to make electronic filing of Forms W-4 available to their employees.

Respondents: Business or other for-profit, not-for profit institutions, Federal Government, State, Local or Tribal Government.

Estimated Number of Respondents: 2,000.

Estimated Burden Hours Per

Respondent: 20 hours.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 40,000 hours.

Clearance Officer: Garrick Shear (202) 622-3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224.

OMB Reviewer: Milo Sunderhau (202) 395-7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 96-9892 Filed 4-22-96; 8:45 am]

BILLING CODE 4830-01-P

Customs Service

[T.D. 96-34]

Determination That Merchandise Imported From the People's Republic of China Is Produced Using Convict, Forced, or Indentured Labor by the Tianjin Malleable Iron Factory

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

ACTION: Determination that Subject Merchandise is Prohibited by 19 U.S.C. 1307 From Importation into the United States.

SUMMARY: This document advises that the Commissioner of Customs, with the approval of the Secretary of the Treasury, has determined that certain iron pipe fittings, which are being, or are likely to be imported into the United States from the People's Republic of China (PRC), are being manufactured with the use of convict, forced, or indentured labor by the Tianjin Malleable Iron Factory, Tianjin Municipality, People's Republic of China. This facility may also be known as the Tianjin Tongbao Fittings Company, the Tianjin NO. 2 Malleable Iron Plant, the Tianjin Secondary Mugging Factory, or the Tianjin NO. 2 Prison. The Commissioner of Customs, pursuant to 19 CFR 12.42(f), has

determined, on the basis of a Customs investigation, that such merchandise is being, or is likely to be, imported into the United States in violation of Section 307 of the Tariff Act of 1930 as amended (19 U.S.C. 1307), unless, pursuant to 19 CFR 12.42(g), 12.43, and 12.44, the importer establishes by satisfactory evidence that the merchandise was not mined, produced, or manufactured in any part with the use of a class of labor specified herein.

EFFECTIVE DATE: This determination shall take effect on or before April 29, 1996.

FOR FURTHER INFORMATION CONTACT: Buford E. Gates, Senior Special Agent, Office of Investigations, Fraud Investigations Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue, Washington, D.C. 20229, 202-927-2195.

SUPPLEMENTARY INFORMATION:

Background

Section 307, Tariff Act of 1930 as amended, (19 U.S.C. 1307) provides in pertinent part that:

All goods, wares, articles, and merchandise, mined, produced, or manufactured wholly, or in part, in any foreign country by convict labor or/and forced labor or/and indentured labor under penal sanctions, shall not be entitled to entry at any of the ports of the United States, and the importation thereof is hereby prohibited, and the Secretary of the Treasury is authorized and directed to prescribe such regulations as may be necessary for the enforcement of this provision.

Forced labor is defined as "All work or service which is exacted from any person under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily."

Pursuant to section 307, the Secretary of the Treasury promulgated implementing regulations found at 19 CFR 12.42, *et seq.* These regulations set forth the procedure for the Commissioner of Customs to make a finding that an article being produced, whether by mining, manufacture, or other means, in any foreign locality with the use of convict labor, forced labor, or indentured labor under penal sanctions so as to come under the purview of 19 U.S.C. 1307 is being, or is likely to be, imported into the United States. Paragraph (f) of section 12.42, Customs Regulations (19 CFR 12.42(f), provides that if the Commissioner of Customs finds that merchandise within the purview of 19 U.S.C. 1307 is being, or is likely to be, imported into the United States, {s}he will, with the approval of the Secretary of the Treasury, publish a finding to that effect in a weekly issue

of the *Customs Bulletin* and in the Federal Register.

Finding

Pursuant to section 12.42(f), Customs Regulations (19 CFR 12.42(f)), it is hereby determined that certain articles of the People's Republic of China which are produced, whether by mining, manufacture, or other means, with the use of convict, forced, or indentured labor, are being, or are likely to be, imported into the United States.

Accordingly, based upon this finding, Customs officers shall withhold release of any of these articles from the People's Republic of China. Such discovered articles may be only exported by the Customs Service.

Articles Covered by This Finding

Malleable Iron Pipe Fittings manufactured by the Tianjin Malleable Iron Factory, also known as the Tianjin Tongbao Fittings Company, also known as the Tianjin NO. 2 Malleable Iron Plant, also known as the Tianjin Secondary Mugging Factory, also known as the Tianjin NO.2 Prison.

Subject Harmonized Tariff Schedule Numbers

7307.1930, 7307.1990, 7307.911000, 7307.915010, 7307.915050, 7307.923010, 7307.929000, 7307.933000, 7307.939030, 7307.991000, 7307.995015, and 7307.995045.

Dated: March 6, 1996.

Michael H. Lane,

Acting Commissioner of Customs.

Dated: March 20, 1996.

John P. Simpson,

Deputy Assistant Secretary Regulatory, Tariff and Trade Enforcement.

[FR Doc. 96-9875 Filed 4-22-96; 8:45 am]

BILLING CODE 4820-02-P

Office of Thrift Supervision

[AC-26; OTS No. 03497]

First Federal Savings and Loan Association of Ironton, Ironton, OH; Approval of Conversion Application

Notice is hereby given that on April 15, 1996, the Director, Corporate Activities, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of First Federal Savings and Loan Association of Ironton, Ironton, Ohio, to convert to the stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Central Regional Office, Office of Thrift Supervision, 200 West Madison Street, Suite 1300, Chicago, Illinois 60606.

Dated: April 17, 1996.

By the Office of Thrift Supervision,
Nadine Y. Washington,
Corporate Secretary.

[FR Doc. 96-9917 Filed 4-22-96; 8:45 am]

BILLING CODE 6720-01-P

[AC-27; OTS No. 02100]

First Federal Savings and Loan Association of Bloomington, Bloomington, IL; Approval of Conversion Application

Notice is hereby given that on April 16, 1996, the Director, Corporate Activities, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of First Federal Savings and Loan Association of Bloomington, Bloomington, Illinois, to convert to the

stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Central Regional Office, Office of Thrift Supervision, 200 West Madison Street, Suite 1300, Chicago, Illinois 60606.

Dated: April 17, 1996.

By the Office of Thrift Supervision,
Nadine Y. Washington,
Corporate Secretary.

[FR Doc. 96-9918 Filed 4-22-96; 8:45 am]

BILLING CODE 6720-01-P

[AC-25; OTS No. 07058]

First Lancaster Federal Savings Bank, Lancaster, KY; Approval of Conversion Application

Notice is hereby given that on April 10, 1996, the Director, Corporate Activities, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of First Lancaster Federal Savings Bank, Lancaster, Kentucky, to convert to the stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, N.W., Washington, D.C. 20552, and the Central Regional Office, Office of Thrift Supervision, 200 West Madison Street, Suite 1300, Chicago, Illinois 60606.

Dated: April 17, 1996.

By the Office of Thrift Supervision,
Nadine Y. Washington,
Corporate Secretary.

[FR Doc. 96-9916 Filed 4-22-96; 8:45 am]

BILLING CODE 6720-01-P

Corrections

Federal Register

Vol. 61, No. 79

Tuesday, April 23, 1996

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA-135F]

RIN 1117-AA30

Correction

In rule document 96-7739, beginning on page 14022, in the issue of Friday, March 29, 1996, make the following correction:

On page 14024, in the first column, in the last sentence, "manufacture of drug

dosage from," should read "manufacture of drug dosage form."

BILLING CODE 1505-01-D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ronald Phillips, D.O.; Revocation of Registration

Correction

In notice document 96-8387 beginning on page 15304 in the issue of Friday, April 5, 1996, make the following corrections:

1. On page 15304, in the third column, in the first paragraph, the tenth line is corrected to read "Certificate of Registration, AP9171048".

2. On page 15305, in the first column, in the second complete paragraph, "Vicondin" should read "Vicodin" wherever it appears. And on the same page, in the third column, in the seventh line, "and" the second time it appears should read "any".

BILLING CODE 1505-01-D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 94-81]

Shahid Musud Siddiqui, M.D.; Revocation of Registration

Correction

In notice document 96-8043 beginning on page 14818 in the issue of Wednesday, April 3, 1996, make the following corrections:

1. On page 14818, in the second column, in the first paragraph, the last line should read "42 U.S.C. 1320a-7(a)". In the same column, third paragraph, in the second line "field" should read "filed". And on the same page, in the third column, in the second full paragraph, in the sixth line "deputy" should read "Deputy".

2. On page 14819, in the first column, in the ninth line "Kir" should read "Kirk".

BILLING CODE 1505-01-D

**United States
Federal Register**

Tuesday
April 23, 1996

Part II

**Environmental
Protection Agency**

**Proposed Guidelines for Carcinogen Risk
Assessment; Notice**

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5460-3]

Proposed Guidelines for Carcinogen Risk Assessment**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of Availability and Opportunity to Comment on Proposed Guidelines for Carcinogen Risk Assessment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today publishing a document entitled Proposed Guidelines for Carcinogen Risk Assessment (hereafter "Proposed Guidelines"). These Proposed Guidelines were developed as part of an interoffice guidelines development program by a Technical Panel of the Risk Assessment Forum within EPA's Office of Research and Development. These Proposed Guidelines are a revision of EPA's 1986 Guidelines for Carcinogen Risk Assessment (hereafter "1986 cancer guidelines") published on September 24, 1986 (51 FR 33992). When final, these guidelines will replace the 1986 guidelines.

In a future Federal Register notice, the Agency intends to publish for comment how it will implement the Proposed Guidelines once they are finalized. The plans will propose and seek comment on how the Guidelines will be used for Agency carcinogen risk assessment and, in particular, will address the impact of the Guidelines on the Agency's existing assessments, and any mechanisms for handling reassessments under finalized Guidelines.

DATES: The Proposed Guidelines are being made available for a 120-day public review and comment period. Comments must be in writing and must be postmarked by August 21, 1996. See **ADDRESSES** section for guidance on submitting comments.

ADDRESSES: The Proposed Guidelines will be made available in the following ways:

(1) The electronic version will be accessible on EPA's Office of Research and Development home page on the Internet at <http://www.epa.gov/ORD>

(2) 3½" high-density computer diskettes in Wordperfect 5.1 format will be available from ORD Publications, Technology Transfer and Support Division, National Risk Management Research Laboratory, Cincinnati, OH; telephone: 513-569-7562; fax: 513-569-7566. Please provide the EPA No. (EPA/600/P-92/003Ca) when ordering.

(3) This notice contains the full draft document. In addition, copies of the draft will be available for inspection at EPA headquarters and regional libraries, through the U.S. Government Depository Library program, and for purchase from the National Technical Information Service (NTIS), Springfield, VA; telephone: 703-487-4650, fax: 703-321-8547. Please provide the NTIS PB No. (PB96-157599) (\$35.00) when ordering.

SUBMITTING COMMENTS: Comments on the Proposed Guidelines may be mailed or delivered to the Technical Information Staff (8623), NCEA-WA/OSG, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Comments should be in writing and must be postmarked by the date indicated. Please submit one unbound original with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively with the comment, and submit an unbound original and three copies.

Please note that all technical comments received in response to this notice will be placed in a public record. For that reason, commenters should not submit personal information (such as medical data or home address), Confidential Business Information, or information protected by copyright. Due to limited resources, acknowledgments will not be sent.

FOR FURTHER INFORMATION CONTACT: Technical Information Staff, Operations and Support Group, National Center for Environmental Assessment—Washington Office, telephone: 202-260-7345. Email inquiries may be sent to cancer-guidelines@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In 1983, the National Academy of Sciences (NAS)/National Research Council (NRC) published its report entitled Risk Assessment in the Federal Government: Managing the Process (NRC, 1983). In that report, the NRC recommended that Federal regulatory agencies establish "inference guidelines" to ensure consistency and technical quality in risk assessments and to ensure that the risk assessment process was maintained as a scientific effort separate from risk management. The 1986 cancer guidelines were issued on September 24, 1986 (51 FR 33992). The Proposed Guidelines published today continue the guidelines development process. These guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency cancer risk assessments and to inform Agency decisionmakers and the public about these procedures.

Both the 1986 guidelines and the current proposal contain inference guidance in the form of default inferences to bridge gaps in knowledge and data. Research conducted in the past decade has elucidated much about the nature of carcinogenic processes and continues to provide new information. The intent of this proposal is to take account of knowledge available now and to provide flexibility for the future in assessing data and employing default inferences, recognizing that the guidelines cannot always anticipate future research findings. Because methods and knowledge are expected to change more rapidly than guidelines can practicably be revised, the Agency will update specific assessment procedures with peer-reviewed supplementary, technical documents as needed. Further revision of the guidelines themselves will take place when extensive changes are necessary.

Since 1986, the EPA has sponsored several workshops about revising the cancer guidelines (U.S. EPA, 1989b, 1989c, 1994a). The Society for Risk Analysis conducted a workshop on the subject in connection with its 1992 annual meeting (Anderson et al., 1993). Participants in the most recent workshop in 1994 reviewed an earlier version of the guidelines proposed here and made numerous recommendations about individual issues as well as broad recommendations about explanations and perspectives that should be added. Most recently, the Committee on the Environment and Natural Resources of the Office of Science and Technology Policy reviewed the guidelines at a meeting held on August 15, 1995. The EPA appreciates the efforts of all participants in the process and has tried to address their recommendations in this proposal.

In addition, the recommendations of the NRC (1994) in Science and Judgment in Risk Assessment have been addressed. Responses to these recommendations are given generally in Appendix B as well as being embodied in the Proposed Guidelines. Responses that explain the major default assumptions adopted under these guidelines and the policy for using and departing from these default assumptions appear in Section 1.3.

The Science Advisory Board also will review these Proposed Guidelines at a meeting to be announced in a future Federal Register notice. Following these reviews Agency staff will prepare summaries of the public and SAB comments. Appropriate comments will be incorporated, and the revised Guidelines will be submitted to the Risk Assessment Forum for review. The

Agency will consider comments from the public, the SAB, and the Risk Assessment Forum in its recommendations to the EPA Administrator.

Major Changes From the 1986 Guidelines

Characterizations

Increased emphasis on providing characterization discussions for the hazard, dose response, and exposure sections is part of the proposal. These discussions will summarize the assessments to explain the extent and weight of evidence, major points of interpretation and rationale, and strengths and weaknesses of the evidence and the analysis, and to discuss alternative conclusions and uncertainties that deserve serious consideration (U.S. EPA, 1995). They serve as starting materials for the risk characterization process which completes the risk assessment.

Weighing Evidence of Hazard

A major change is in the way hazard evidence is weighed in reaching conclusions about the human carcinogenic potential of agents. In the 1986 cancer guidelines, tumor findings in animals or humans were the dominant components of decisions. Other information about an agent's properties, its structure-activity relationships to other carcinogenic agents, and its activities in studies of carcinogenic processes was often limited and played only a modulating role as compared with tumor findings. In this proposal, decisions come from considering all of the evidence. This change recognizes the growing sophistication of research methods, particularly in their ability to reveal the modes of action of carcinogenic agents at cellular and subcellular levels as well as toxicokinetic and metabolic processes. The effect of the change on the assessment of individual agents will depend greatly on the availability of new kinds of data on them in keeping with the state of the art. If these new kinds of data are not forthcoming from public and private research on agents, assessments under these guidelines will not differ significantly from assessments under former guidelines.

Weighing of the evidence includes addressing the likelihood of human carcinogenic effects of the agent and the conditions under which such effects may be expressed, as these are revealed in the toxicological and other biologically important features of the agent. (Consideration of actual human exposure and risk implications are done

separately; they are not parts of the hazard characterization). In this respect, the guidelines incorporate recommendations of the NRC (1994). In that report, the NRC recommends expansion of the former concept of hazard identification, which rests on simply a finding of carcinogenic potential, to a concept of characterization that includes dimensions of the expression of this potential. For example, an agent might be observed to be carcinogenic via inhalation exposure and not via oral exposure, or its carcinogenic activity might be secondary to another toxic effect. In addition, the consideration of evidence includes the mode(s) of action of the agent apparent from the available data as a basis for approaching dose response assessment.

Classification Descriptors

To express the weight of evidence for carcinogenic hazard potential, the 1986 cancer guidelines provided summary rankings for human and animal cancer studies. These summary rankings were integrated to place the overall evidence in classification groups A through E, Group A being associated with the greatest probability of human carcinogenicity and Group E with evidence of noncarcinogenicity in humans. Data other than tumor findings played a modifying role after initial placement of an agent into a group.

These Proposed Guidelines take a different approach, consistent with the change in the basic approach to weighing evidence. No interim classification of tumor findings followed by modifications with other data takes place. Instead, the conclusion reflects the weighing of evidence in one step. Moreover, standard descriptors of conclusions are employed rather than letter designations, and these are incorporated into a brief narrative description of their informational basis. The narrative with descriptors replaces the previous letter designation. The descriptors are in three categories: "known/likely," "cannot be determined," or "not likely." For instance, using a descriptor in context, a narrative could say that an agent is likely to be carcinogenic by inhalation exposure and not likely to be carcinogenic by oral exposure. The narrative explains the kinds of evidence available and how they fit together in drawing conclusions, and points out significant issues/strengths/limitations of the data and conclusions. Subdescriptors are used to further refine the conclusion. The narrative also summarizes the mode of action

information underlying a recommended approach to dose response assessment.

In considering revision of the former classification method, the Agency has examined other possibilities that would retain the use of letter and number designation of weights of evidence. The use of standard descriptors within a narrative presentation is proposed for three primary reasons. First, the proposed method permits inclusion of explanations of data and of their strengths and limitations. This is more consistent with current policy emphasis on risk characterization. Second, it would take a large set of individual number or letter codes to cover differences in the nature of contributing information (animal, human, other), route of exposure, mode of action, and relative overall weight. When such a set becomes large—10 to 30 codes—it is too large to be a good communication device, because people cannot remember the definitions of the codes so they have to be explained in narrative. Third, it is impossible to predefine the course of cancer research and the kinds of data that may become available. A flexible system is needed to accommodate change in the underlying data and inferences, and a system of codes might become out of date, as has the one in the 1986 cancer guidelines.

Dose Response Assessment

The approach to dose response assessment calls for analysis that follows the conclusions reached in the hazard assessment as to potential mode(s) of action. The assessment begins by analyzing the empirical data in the range of observation. When animal studies are the basis of the analysis, the estimation of a human equivalent dose utilizes toxicokinetic data, if appropriate and adequate data are available. Otherwise, default procedures are applied. For oral dose, the default is to scale daily applied doses experienced for a lifetime in proportion to body weight raised to the 0.75 power. For inhalation dose, the default methodology estimates respiratory deposition of particles and gases and estimates internal doses of gases with different absorption characteristics. These two defaults are a change from the 1986 cancer guidelines which provided a single scaling factor of body weight raised to the 0.66 power. Another change from the 1986 guidelines is that response data on effects of the agent on carcinogenic processes are analyzed (nontumor data) in addition to data on tumor incidence. If appropriate, the analyses of data on tumor incidence and on precursor effects may be combined, using

precursor data to extend the dose response curve below the tumor data. Even if combining data is not appropriate, study of the dose response for effects believed to be part of the carcinogenic influence of the agent may assist in thinking about the relationship of exposure and response in the range of observation and at exposure levels below the range of observation.

Whenever data are sufficient, a biologically based or case-specific dose response model is developed to relate dose and response data in the range of empirical observation. Otherwise, as a standard, default procedure, a model is used to curve-fit the data. The lower 95% confidence limit on a dose associated with an estimated 10% increased tumor or relevant nontumor response (LED_{10}) is identified. This generally serves as the point of departure for extrapolating the relationship to environmental exposure levels of interest when the latter are outside the range of observed data. The environmental exposures of interest may be measured ones or levels of risk management interest in considering potential exposure control options. Other points of departure may be more appropriate for certain data sets; as described in the guidance, these may be used instead of the LED_{10} . Additionally, the LED_{10} is available for comparison with parallel analyses of other carcinogenic agents or of noncancer effects of agents and for gauging and explaining the magnitude of subsequent extrapolation to low-dose levels. The LED_{10} , rather than the ED_{10} (the estimate of a 10% increased response), is the proposed standard point of departure for two reasons. One is to permit easier comparison with the benchmark dose procedure for noncancer health assessment—also based on the lower limit on dose. Another is that the lower limit, as opposed to the central estimate, accounts for uncertainty in the experimental data. The issue of using a lower limit or central estimate was discussed at a workshop held on the benchmark procedure for noncancer assessment (Barnes et al., 1995) and at a workshop on a previous version of this proposal (U.S. EPA, 1994b). The latter workshop recommended a central estimate; the benchmark workshop recommended a lower limit.

The second step of dose response assessment is extrapolation to lower dose levels, if needed. This is based on a biologically based or case-specific model if supportable by substantial data. Otherwise, default approaches are applied that accord with the view of mode(s) of action of the agent. These include approaches that assume

linearity or nonlinearity of the dose response relationship or both. The default approach for linearity is to extend a straight line to zero dose, zero response. The default approach for nonlinearity is to use a margin of exposure analysis rather than estimating the probability of effects at low doses. A margin of exposure analysis explains the biological considerations for comparing the observed data with the environmental exposure levels of interest and helps in deciding on an acceptable level of exposure in accordance with applicable management factors.

The use of straight line extrapolation for a linear default is a change from the 1986 guidelines which used the "linearized multistage" (LMS) procedure. This change is made because the former modeling procedure gave an appearance of specific knowledge and sophistication unwarranted for a default. The proposed approach is also more like that employed by the Food and Drug Administration (U.S. FDA, 1987). The numerical results of the straight line and LMS procedures are not significantly different (Krewski et al., 1984). The use of a margin of exposure approach is included as a new default procedure to accommodate cases in which there is sufficient evidence of a nonlinear dose response, but not enough evidence to construct a mathematical model for the relationship. (The Agency will continue to seek a modeling method to apply in these cases. If a modeling approach is developed, it will be subject to peer review and public notice in the context of a supplementary document for these guidelines.)

The public is invited to provide comments to be considered in EPA decisions about the content of the final guidelines. After the public comment period, the EPA Science Advisory Board will be asked to review and provide advice on the guidelines and issues raised in comments. EPA asks those who respond to this notice to include their views on the following:

(1) The proposed guidance for characterization of hazard, including the weight of evidence descriptors and weight of evidence narrative which are major features of the proposal. There are three categories of descriptors: "known/likely," "cannot be determined," and "not likely" which are further refined by subdescriptors. It is felt that these three descriptors will satisfactorily delineate the types of evidence bearing on carcinogenicity as they are used with subdescriptors in the context of a narrative of data and rationale. However, an issue that has been

discussed by external peer reviewers and by EPA staff is whether the descriptor-subdescriptor called "cannot be determined—suggestive evidence" should become a separate, fourth category called "suggestive." The EPA may choose this course in the final guidelines and requests comment. In considering this issue, commenters may wish to refer not only to Sections 2.6.2. and 2.7.2. which cover the descriptors and narrative, but also to case study example #6 in Section 2.6.3. and example narrative #2 in Appendix A of the proposal. EPA asks commenters on this question to address the rationale (science as well as policy) for leaving the categories of descriptors as proposed or making the fourth category. How might the coverage of a "suggestive" category be defined in order to be most useful?

(2) The use of mode of action information in hazard characterization and to guide dose response assessment is a central part of the proposed approach to bringing new research on carcinogenic processes to bear in assessments of environmental agents (Sections 1.3.2., 2.3.2., 2.5., 3.1.). The appropriate use of this information now and in the future is important. EPA requests comment on the treatment of such information in the proposal, including reliance on peer review as a part of the judgmental process on its application.

(3) Uses of nontumor data in the dose response assessment and the methodological and science policy issues posed are new to these guidelines (Sections 1.3.2., 3.1.2.). EPA requests comment on both issues.

(4) Dose response assessment is proposed to be considered in two parts—range of observed data and range of extrapolation (Section 3.1.). The lower 95% confidence limit on a dose associated with a 10% response (tumor or nontumor response) is proposed as a default point of departure, marking the beginning of extrapolation. This is a parallel to the benchmark procedure for evaluating dose-response of noncancer health endpoints (Barnes et al., 1995). An alternative is to use the central estimate of a 10% response. Another alternative is to use a 1%, instead of a 10%, response when the observed data are tumor incidence data. Does the generally larger sample size of tumor effect studies support using a 1% response as compared with using 10% for smaller studies? Are there other approaches for the point of departure that might be considered?

(5) Discussions of default assumptions and other responses to the 1994 NRC report Science and Judgment in Risk

Assessment appear in Section 1.3.1. and Appendix B of the proposal, respectively. Comments are requested on responses to the NRC recommendations and how the guidelines as a whole address them.

Dated: April 10, 1996.

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Administrator.

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1. Introduction

1.1. Purpose and Scope of the Guidelines

These guidelines revise and replace United States Environmental Protection Agency (EPA) Guidelines for Carcinogen Risk Assessment published in 51 FR 33992, September 24, 1986. The guidelines provide EPA staff and decisionmakers with guidance and perspectives to develop and use risk assessments. They also provide basic information to the public about the Agency's risk assessment methods.

The guidelines encourage both regularity in procedures to support consistency in scientific components of Agency decisionmaking and innovation to remain up-to-date in scientific thinking. In balancing these goals, the Agency relies on input from the general

scientific community through established scientific peer review processes. The guidelines incorporate basic principles and science policies based on evaluation of the currently available information. As more is discovered about carcinogenesis, the need will arise to make appropriate changes in risk assessment guidance. The Agency will revise these guidelines when extensive changes are due. In the interim, the Agency will issue special reports, after appropriate peer review, to supplement and update guidance on single topics, (e.g., U.S. EPA, 1991b)

1.2. Organization and Application of the Guidelines

1.2.1. Organization

Publications of the Office of Science and Technology Policy (OSTP, 1985) and the National Research Council (NRC, 1983, 1994) provide information and general principles about risk assessment. Risk assessment uses available scientific information on the properties of an agent¹ and its effects in biological systems to provide an evaluation of the potential for harm as a consequence of environmental exposure to the agent. Risk assessment is one of the scientific analyses available for consideration, with other analyses, in decisionmaking on environmental protection. The 1983 and 1994 NRC documents organize risk assessment information into four areas: hazard identification, dose response assessment, exposure assessment, and risk characterization. This structure appears in these guidelines, which additionally emphasize characterization of evidence and conclusions in each part of the assessment. In particular, the guidelines adopt the approach of the NRC's 1994 report in adding a dimension of characterization to the hazard identification step. Added to the identification of hazard is an evaluation of the conditions under which its expression is anticipated. The risk assessment questions addressed in these guidelines are:

- For hazard—Can the agent present a carcinogenic hazard to humans, and if so, under what circumstances?
- For dose response—At what levels of exposure might effects occur?
- For exposure—What are the conditions of human exposure?
- For risk—What is the character of the risk? How well do data support conclusions about the nature and extent of the risk?

¹ The term "agent" refers generally to any chemical substance, mixture, or physical or biological entity being assessed, unless otherwise noted.

1.2.2. Application

The guidelines apply within the framework of policies provided by applicable EPA statutes and do not alter such policies. The guidelines cover assessment of available data. They do not imply that one kind of data or another is prerequisite for regulatory action concerning any agent. Risk management applies directives of regulatory legislation, which may require consideration of potential risk, or solely hazard or exposure potential, along with social, economic, technical, and other factors in decisionmaking. Risk assessments support decisions, but to maintain their integrity as decisionmaking tools, they are not influenced by consideration of the social or economic consequences of regulatory action.

Not every EPA assessment has the same scope or depth. Agency staff often conduct screening-level assessments for priority-setting or separate assessments of hazard or exposure for ranking purposes or to decide whether to invest resources in collecting data for a full assessment. Moreover, a given assessment of hazard and dose response may be used with more than one exposure assessment that may be conducted separately and at different times as the need arises in studying environmental problems in various media. The guidelines apply to these various situations in appropriate detail given the scope and depth of the particular assessment. For example, a screening assessment may be based almost entirely on structure-activity relationships and default assumptions. As more data become available, assessments can replace or modify default assumptions accordingly. These guidelines do not require that all of the kinds of data covered here be available for either assessment or decisionmaking. The level of detail of an assessment is a matter of Agency management policy regarding the applicable decisionmaking framework.

1.3. Use of Default Assumptions

The National Research Council, in its 1983 report on the science of risk assessment (NRC, 1983), recognized that default assumptions are necessarily made in risk assessments where gaps exist in general knowledge or in available data for a particular agent. These default assumptions are inferences based on general scientific knowledge of the phenomena in question and are also matters of policy concerning the appropriate way to bridge uncertainties that concern potential risk to human health (or, more

generally, to environmental systems) from the agent under assessment.

EPA's 1986 guidelines for cancer risk assessment (EPA, 1986) were developed in response to the 1983 NRC report. The guidelines contained a number of default assumptions. They also encouraged research and analysis that would lead to new risk assessment methods and data and anticipated that these would replace defaults. The 1986 guidelines did not explicitly discuss how to depart from defaults. In practice, the agency's assessments routinely have employed defaults and, until recently, only occasionally departed from them.

In its 1994 report on risk assessment, the NRC supported continued use of default assumptions (NRC, 1994). The NRC report thus validated a central premise of the approach to risk assessment that EPA had evolved in preceding years—the making of science policy inferences to bridge gaps in knowledge—while at the same time recommending that EPA develop more systematic and transparent guidelines to inform the public of the default inferences EPA uses in practice. It recommended that the EPA review and update the 1986 guidelines in light of evolving scientific information and experience in practice in applying those guidelines, and that the EPA explain the science and policy considerations underlying current views as to the appropriate defaults and provide general criteria to guide preparers and reviewers of risks assessments in deciding when to depart from a default. Pursuant to this recommendation, the following discussion presents descriptions of the major defaults and their rationales. In addition, it presents general policy guidance on using and departing from defaults in specific risk assessments.

1.3.1. Default Assumptions

The 1994 NRC report contains several recommendations regarding flexibility and the use of default options:

- EPA should continue to regard the use of default options as a reasonable way to deal with uncertainty about underlying mechanisms in selecting methods and models for use in risk assessment.
- EPA should explicitly identify each use of a default option in risk assessments.
- EPA should clearly state the scientific and policy basis for each default option.
- The Agency should consider attempting to give greater formality to its criteria for a departure from default options in order to give greater guidance to the public and to lessen the

possibility of ad hoc, undocumented departures from default options that would undercut the scientific credibility of the Agency's risk assessments. At the same time, the Agency should be aware of the undesirability of having its guidelines evolve into inflexible rules.

- EPA should continue to use the Science Advisory Board and other expert bodies. In particular, the Agency should continue to make the greatest possible use of peer review, workshops, and other devices to ensure broad peer and scientific participation to guarantee that its risk assessment decisions will be based on the best science available through a process that allows full public discussion and peer participation by the scientific community.

In the 1983 report (p. 28), NAS defined the use of "inference options" (default options) as a means to bridge inherent uncertainties in risk assessment. These options exist when the assessment encounters either "missing or ambiguous information on a particular substance" or "gaps in current scientific theory." Since there is no instance in which a set of data on an agent or exposure is complete, all risk assessments must use general knowledge and policy guidance to bridge data gaps. Animal toxicity data are used, for example, to substitute for human data because we do not test human beings. The report described the components of risk assessment in terms of questions encountered during analysis for which inferences must be made. The report noted (p. 36) that many components "* * * lack definitive scientific answers, that the degree of scientific consensus concerning the best answer varies (some are more controversial than others), and that the inference options available for each component differ in their degree of conservatism. The choices encountered in risk assessment rest, to various degrees, on a mixture of scientific fact and consensus, on informed scientific judgment, and on policy determinations (the appropriate degree of conservatism) * * *." The report did not note that the mix varies significantly from case to case. For instance, a question that arises in hazard identification is how to use experimental animal data when the routes of exposure differ between animals and humans. A spectrum of inferences could be made, ranging from the most conservative, or risk adverse one that effects in animals from one route may be seen in humans by another route, to an intermediate, conditional inference that such translation of effects will be assumed if the agent is absorbed by humans through the second route, to

a nonconservative view that no inference is possible and the agent's effects in animals must be tested by the second route. The choice of an inference, as the report observed, comes from more than scientific thinking alone. While the report focused mainly on the idea of conservatism of public health as a science policy rationale for making the choice, it did not evaluate other considerations. These include such things as the matters of time and resources and whether the analysis is for an important decision required to be made soon or is simply a screening or ranking effort. For a screening analysis, one might make several "worst case" inferences to determine if, even under those conditions, risk is low enough that a problem can be eliminated from further consideration. In the above discussion concerning inferences about route-to-route extrapolation, one might use the most conservative one for screening.

These revised guidelines retain the use of default assumptions as recommended in the 1994 report. Generally, these defaults remain public health conservative, but in some instances, they have been modified to reflect the evolution of scientific knowledge since 1986.

In addition, the guidelines reflect evaluation of experience in practice in applying defaults and departing from them in individual risk assessments conducted under the 1986 guidelines. The application and departure from defaults and the principles to be used in these judgments have been matters of debate among practitioners and reviewers of risk assessments. Some observers believe that in practice EPA risk assessors have been too resistant to considering departures; others question whether proposed departures have been adequately supported. Some cases in which departures have been considered have been generally accepted, while others have been controversial. The guidelines here are intended to be both explicit and more flexible than in the past concerning the basis for making departures from defaults, recognizing that expert judgment and peer review are essential elements of the process.

In response to the recommendations of the 1994 report, these guidelines call for identification of the default assumptions used within assessments and for highlighting significant issues about defaults within characterization summaries of component analyses in assessment documents. As to the use of peer review to aid in making judgments about applying or departing from defaults, we agree with the NRC recommendation. The Agency has long

made use of workshops, peer review of documents and guidelines, and consultations as well as formal peer review by the Science Advisory Board (SAB). In 1994, the Administrator of EPA published formal guidance for peer review of EPA scientific work products that increases the amount of peer review for risk assessments as well as other work, as a response to the NRC report and to SAB recommendations (U.S. EPA, 1994b).

The 1994 NRC report recommended that EPA should consider adopting principles or criteria that would give greater formality and transparency to decisions to depart from defaults. The report named several possible criteria for such principles (p. 7): "* * * [P]rotecting the public health, ensuring scientific validity, minimizing serious errors in estimating risks, maximizing incentives for research, creating an orderly and predictable process, and fostering openness and trustworthiness. There might be additional relevant criteria* * *." The report indicated, however, that the committee members had not reached consensus on a single criterion to address the key issue of how much certainty or proof a risk assessor must have in order to justify departing from a default. Appendix N of the report contains two presentations of alternative views held by some committee members on this issue. One view, known as "plausible conservatism," suggested that departures from defaults should not be made unless new information improves the understanding of a biological process to the point that relevant experts reach consensus that the conservative default assumption concerning that process is no longer plausible. The same criterion was recommended where the underlying scientific mechanism is well understood, but where a default is used to address missing data. In this case, the default should not be replaced with case-specific data unless it is the consensus of relevant experts that the proffered data make the default assumption no longer plausible. Another view, known as the "maximum use of scientific information" approach, acknowledged that the initial choice of defaults should be conservative but argued that conservatism should not be a factor in determining whether to depart from the default in favor of an alternate biological theory or alternate data. According to this view, it should not be necessary to reach expert consensus that the default assumption had been rendered implausible; it should be sufficient that risk assessors

find the alternate approach more plausible than the default.

The EPA is not adopting a list of formal decision criteria in the sense of a checklist based on either view. It would not be helpful to generate a checklist of uniform criteria for several reasons. First, risk assessments are highly variable in content and purpose. Screening assessments may be purposely "worst case" in their default assumptions to eliminate problems from further investigation. Subsequent risk assessments based on a fuller data set can discard worst-case default assumptions in favor of plausibly conservative assumptions and progressively replace or modify the latter with data. No uniform checklist will fit all cases. Second, a checklist would likely become more a source of rote discussion than of enlightenment about the process.

Instead, these guidelines use a combination of principles and process in the application of and departure from default assumptions. The guidelines provide a framework of default assumptions to allow risk assessment to proceed when current scientific theory or available case-specific data do not provide firm answers in a particular case, as the 1983 report outlined. Some of the default assumptions bridge large gaps in fundamental knowledge which will be filled by basic research on the causes of cancer and on other biological processes, rather than by agent-specific testing. Other default assumptions bridge smaller data gaps that can feasibly be filled for a single agent, such as whether a metabolic pathway in test animals is like (default) or unlike that in humans.

The decision to use a default, or not, is a choice considering available information on an underlying scientific process and agent-specific data, depending on which kind of default it is. Generally, if a gap in basic understanding exists, or if agent-specific data are missing, the default is used without pause. If data are present, their evaluation may reveal inadequacies that also lead to use of the default. If data support a plausible alternative to the default, but no more strongly than they support the default, both the default and its alternative are carried through the assessment and characterized for the risk manager. If data support an alternative to the default as the more reasonable judgment, the data are used. (This framework of choices is not wholly applicable to screening assessments. As mentioned above, screening assessments may appropriately use "worst case" inferences to determine if, even under

those conditions, risk is low enough that a problem can be eliminated from further consideration.)

Scientific peer review, peer consultative workshops and similar processes are the principal ways determining the strength of thinking and generally accepted views within the scientific community about the application of and departure from defaults and about judgments concerning the plausibility and persuasiveness of data in a particular case. The choices made are explicitly discussed in the assessment, and if a particular choice raises a significant issue, it is highlighted in the risk characterization.

The discussion of major defaults in these guidelines together with the explicit discussion of the choice of inferences within the assessment and the processes of peer review and peer consultation will serve the several goals stated in the 1994 report. One is to encourage research, since results of research efforts will be considered. Another is to allow timely decisionmaking, when time is a constraint, by supporting completion of the risk assessment using defaults as needed. Another is to be flexible, using new science as it develops. Finally, the use of public processes of peer consultation and peer review will ensure that discipline of thought is maintained to support trust in assessment results.

Experience has shown that the most difficult part of the framework of choices is the judgment of whether a data analysis is both biologically plausible and persuasive as applied to the case at hand. There is no set of rules for making this judgment in all cases. Two criteria that apply in these guidelines are that the underlying scientific principle has been generally accepted within the scientific community and that supportive experiments are available that test the application of the principle to the agent under review. For example, mutagenicity through reactivity with DNA has been generally accepted as a carcinogenic influence for many years. This acceptance, together with evidence of such mutagenicity in experiments on an agent, provides plausible and persuasive support for the inference that mutagenicity is a mode of action for the agent.

Judgments about plausibility and persuasiveness of analyses vary according to the scientific nature of the default. An analysis of data may replace a default or modify it. An illustration of the former is development of EPA science policy on the issue of the

relevance for humans of male rat kidney neoplasia involving alpha 2u globulin (U.S. EPA, 1991b). The 1991 EPA policy gives guidance on the kind of experimental findings that demonstrate whether the alpha 2u globulin mechanism is present and responsible for carcinogenicity in a particular case. Before this policy guidance was issued, the default assumption was that neoplasia in question was relevant to humans and indicated the potential for hazard to humans. A substantial body of data was developed by public and private research groups as a foundation for the view that the alpha 2u globulin-induced response was not relevant to humans. These studies first addressed the alpha 2u globulin mechanism in the rat and whether this mechanism has a counterpart in the human being, both were large research efforts. The resulting data presented difficulties; some reviewers were concerned that the mechanism in the rat appeared to be understood only in outline, not in detail, and felt that the data were insufficient to show the lack of a counterpart mechanism in humans. It was particularly difficult to support a negative such as the nonexistence of a mechanism in humans because so little is known about what the mechanisms are in humans. Despite these concerns, in its 1991 policy guidance, EPA concluded that the alpha 2u globulin-induced response in rats should be regarded as not relevant to humans (i.e., as not indicating human hazard).

One lesson in the development and peer review of this policy is that if the default concerns an inherently complex biological question, large amounts of work will be required to replace the default. A second is that addressing a negative is difficult. A third is that "proof" in the strict sense of having laid all reasonable doubt to rest is not required. Instead, an alternative may displace a default when it is generally accepted in peer review as the most reasonable judgment. The issue of relevance may not always be so difficult. It would be an experimentally easier task, for example, to determine whether carcinogenesis in an animal species is due to a metabolite of the agent in question that is not produced in humans.

When scientific processes are understood but case-specific data are missing, defaults can be constructed to be modified by experimental data, even if data do not suffice to replace them entirely. For example, the approaches adopted in these guidelines for scaling dose from experimental animals to humans are constructed to be either modified or replaced as data become

available on toxicokinetic parameters for the particular agent being assessed. Similarly, the selection of an approach or approaches for dose response assessment is based on a series of decisions that consider the nature and adequacy of available data in choosing among alternative modeling and default approaches.

The 1994 NRC report notes (p. 6) that "[a]s scientific knowledge increases, the science policy choices made by the Agency and Congress should have less impact on regulatory decisionmaking. Better data and increased understanding of biological mechanisms should enable risk assessments that are less dependent on conservative default assumptions and more accurate as predictions of human risk." Undoubtedly, this is the trend as scientific understanding increases. However, some gaps in knowledge and data will doubtless continue to be encountered in assessment of even data-rich cases, and it will remain necessary for risk assessments to continue using defaults within the framework set forth here.

1.3.2. Major Defaults

This discussion covers the major default assumptions commonly employed in a cancer risk assessment and adopted in these guidelines. They are predominantly inferences necessary to use data observed under empirical conditions to estimate events and outcomes under environmental conditions. Several inferential issues arise when effects seen in a subpopulation of humans or animals are used to qualitatively infer potential effects in the population of environmentally exposed humans. Several more inferential issues arise in extrapolating the exposure-effect relationship observed empirically to lower-exposure environmental conditions. The following issues cover the major default areas. Typically, an issue has some subissues; they are introduced here, but are discussed in greater detail in subsequent sections.

- Is the presence or absence of effects observed in a human population predictive of effects in another exposed human population?
- Is the presence or absence of effects observed in an animal population predictive of effects in exposed humans?
- How do metabolic pathways relate across species?
- How do toxicokinetic processes relate across species?
- What is the correlation of the observed dose response relationship to the relationship at lower doses?

1.3.2.1. *Is the Presence or Absence of Effects Observed in a Human Population Predictive of Effects in Another Exposed Human Population?*

When cancer effects in exposed humans are attributed to exposure to an exogenous agent, the default assumption is that such data are predictive of cancer in any other exposed human population. Studies either attributing cancer effects in humans to exogenous agents or reporting no effects are often studies of occupationally exposed humans. By sex, age, and general health, workers are not representative of the general population exposed environmentally to the same agents. In such studies there is no opportunity to observe whether infants and children, males, or females who are under represented in the study, or people whose health is not good, would respond differently. Therefore, it is understood that this assumption could still underestimate the response of certain sensitive human subpopulations, i.e. biologically vulnerable parts of the population may be left out of risk assessments (NRC, 1993a, 1994). Consequently, this is a default that does not err on the side of public health conservatism, as the 1994 NRC report also recognizes.

On the one hand, if effects are seen in a worker population, this may be in fact indicative of heightened effects in sensitive subpopulations. There is not enough knowledge yet to form a basis for any generally applicable, qualitative inference to compensate for this knowledge gap. In these guidelines, this problem is left to case-by-case analysis, to be attended to as future research and information on particular agents allow. When information on a sensitive subpopulation exists, it will be used. The topic of variability is addressed further in the discussion of quantitative default assumptions about dose response relationships below. On the other hand, when cancer effects are not found in an exposed human population, this information by itself is not generally sufficient to conclude that the agent poses no carcinogenic hazard to this or other populations of potentially exposed humans. This is because epidemiologic studies usually have low power to detect and attribute responses (section 2.2.1.). This may be particularly true when extrapolating null results from a healthy, worker population to other potentially sensitive exposed humans. Again, the problem is left to case-by-case analysis.

1.3.2.2. *Is the Presence or Absence of Effects Observed in an Animal Population Predictive of Effects in Exposed Humans?* The default

assumption is that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans. Thus, if no adequate human data are present, positive effects in animal cancer studies are a basis for assessing the carcinogenic hazard to humans. This assumption is a public health conservative policy, and it is both appropriate and necessary given that we do not test for carcinogenicity in humans. The assumption is supported by the fact that nearly all of the agents known to cause cancer in humans are carcinogenic in animals in tests with adequate protocols (IARC, 1994; Tomatis et al., 1989; Huff, 1994). Moreover, almost one-third of human carcinogens were identified subsequent to animal testing (Huff, 1993). Further support is provided by research on the molecular biology of cancer processes, which has shown that the mechanisms of control of cell growth and differentiation are remarkably homologous among species and highly conserved in evolution. Nevertheless, the same research tools that have enabled recognition of the nature and commonality of cancer processes at the molecular level also have the power to reveal differences and instances in which animal responses are not relevant to humans (Linjinsky, 1993; U.S. EPA, 1991b). Under these guidelines, available mode of action information is studied for its implications in both hazard and dose response assessment and its effect on default assumptions.

There may be instances in which the use of an animal model would identify a hazard in animals that is not truly a hazard in humans (e.g., the alpha-2u-globulin association with renal neoplasia in male rats (U.S. EPA, 1991b)). The extent to which animal studies may yield false positive indications for humans is a matter of scientific debate. To demonstrate that a response in animals is not relevant to any human situation, adequate data to assess the relevancy issue must be available.

Animal studies are conducted at high doses in order to provide statistical power, the highest dose being one that is minimally toxic (maximum tolerated dose). Consequently, the question often arises whether a carcinogenic effect at the highest dose may be a consequence of cell killing with compensatory cell replication or of general physiological disruption, rather than inherent carcinogenicity of the tested agent. There is little doubt that this may happen in some cases, but skepticism exists among some scientists that it is a pervasive problem (Ames and Gold, 1990; Melnick et al., 1993a; Melnick et

al., 1993b; Barrett, 1993). In light of this question, the default assumption is that effects seen at the highest dose tested are appropriate for assessment, but it is necessary that the experimental conditions be scrutinized. If adequate data demonstrate that the effects are solely the result of excessive toxicity rather than carcinogenicity of the tested agent per se, then the effects may be regarded as not appropriate to include in assessment of the potential for human carcinogenicity of the agent. This is a matter of expert judgment, considering all of the data available about the agent including effects in other toxicity studies, structure-activity relationships, and effects on growth control and differentiation.

When cancer effects are not found in well-conducted animal cancer studies in two or more appropriate species and other information does not support the carcinogenic potential of the agent, these data provide a basis for concluding that the agent is not likely to possess human carcinogenic potential, in the absence of human data to the contrary. This default assumption about lack of cancer effects is not public health conservative. For instance, the tested animal species may not be predictive of effects in humans; arsenic shows only minimal or no effect in animals, while it is clearly positive in humans. (Other information, such as absence of mutagenic activity or absence of carcinogenic activity among structural analogues, can increase the confidence that negative results in animal studies indicate a lack of human hazard.) Also, it is recognized that animal studies (and epidemiologic studies as well) have very low power to detect cancer effects. Detection of a 10% tumor incidence is generally the limit of power with currently conducted animal studies (with the exception of rare tumors that are virtually markers for a particular agent, e.g., angiosarcoma caused by vinyl chloride).

Target organs of carcinogenesis for agents that cause cancer in both animals and humans are most often concordant at one or more sites (Tomatis et al., 1989; Huff, 1994). However, concordance by site is not uniform. The default assumption is that target organ concordance is not a prerequisite for evaluating the implications of animal study results for humans. This is a public health conservative science policy. The mechanisms of control of cell growth and differentiation are concordant among species, but there are marked differences among species in the way control is managed in various tissues. For example, in humans, mutation of the tumor suppressor gene

p53 is one of the most frequently observed genetic changes in tumors. This tumor suppressor is also observed to be operating in some rodent tissues, but other growth control mechanisms predominate in rodents. Thus, an animal response may be due to changes in a control that are relevant to humans, but appear in animals in a different way. However, it is appropriate under these guidelines to consider the influences of route of exposure, metabolism, and, particularly, hormonal modes of action that may either support or not support target organ concordance between animals and humans. When data allow, these influences are considered in deciding whether the default remains appropriate in individual instances (NRC, 1994, p. 121). An exception to the basic default of not assuming site concordance exists in the context of toxicokinetic modeling. Site concordance is inherently assumed when these models are used to estimate delivered dose in humans based on animal data.

As in the approach of the National Toxicology Program and the International Agency for Research on Cancer, the default is to include benign tumors observed in animal studies in the assessment of animal tumor incidence if they have the capacity to progress to the malignancies with which they are associated. This treats the benign and malignant tumors as representative of related responses to the test agent, which is scientifically appropriate. This is a science policy decision that is somewhat more conservative of public health than not including benign tumors in the assessment. Nonetheless, in assessing findings from animal studies, a greater proportion of malignancy is weighed more heavily than a response with a greater proportion of benign tumors. Greater frequency of malignancy of a particular tumor type in comparison with other tumor responses observed in an animal study is also a factor to be considered in selecting the response to be used in dose response assessment.

Benign tumors that are not observed to progress to malignancy are assessed on a case-by-case basis. There is a range of possibilities for their overall significance. They may deserve attention because they are serious health problems even though they are not malignant; for instance, benign tumors may be a health risk because of their effect on the function of a target tissue such as the brain. They may be significant indicators of the need for further testing of an agent if they are observed in a short term test protocol, or such an observation may add to the

overall weight of evidence if the same agent causes malignancies in a long term study. Knowledge of the mode of action associated with a benign tumor response may aid in the interpretation of other tumor responses associated with the same agent. In other cases, observation of a benign tumor response alone may have no significant health hazard implications when other sources of evidence show no suggestion of carcinogenicity.

1.3.2.3. How Do Metabolic Pathways Relate Across Species? The default assumption is that there is a similarity of the basic pathways of metabolism and the occurrence of metabolites in tissues in regard to the species-to-species extrapolation of cancer hazard and risk. If comparative metabolism studies were to show no similarity between the tested species and humans and a metabolite(s) were the active form, there would be less support for an inference that the animal response(s) relates to humans. In other cases, parameters of metabolism may vary quantitatively between species; this becomes part of deciding on an appropriate human equivalent dose based on animal studies, optimally in the context of a toxicokinetic model.

1.3.2.4. How Do Toxicokinetic Processes Relate Across Species? A major issue is how to estimate human equivalent doses in extrapolating from animal studies. As a default for oral exposure, a human equivalent dose is estimated from data on another species by an adjustment of animal oral dose by a scaling factor of body weight to the 0.75 power. This adjustment factor is used because it represents scaling of metabolic rate across animals of different size. Because the factor adjusts for a parameter that can be improved on and brought into more sophisticated toxicokinetic modeling, when such data become available, the default assumption of 0.75 power can be refined or replaced.

For inhalation exposure, a human equivalent dose is estimated by default methodologies that provide estimates of lung deposition and of internal dose. The methodologies can be refined to more sophisticated forms with data on toxicokinetic and metabolic parameters of the specific agent. This default assumption, like the one with oral exposure, is selected in part because it lays a foundation for incorporating better data. The use of information to improve dose estimation from applied, to internal, to delivered dose is encouraged, including use of toxicokinetic modeling instead of any default, where data are available. Health conservatism is not an element in choosing the default.

For a route-to-route of exposure extrapolation, the default assumption is that an agent that causes internal tumors by one route of exposure will be carcinogenic by another route if it is absorbed by the second route to give an internal dose. This is a qualitative assumption and is considered to be public health conservative. The rationale is that for internal tumors an internal dose is significant no matter what the route of exposure. Additionally, the metabolism of the agent will be qualitatively the same for an internal dose. The issue of quantitative extrapolation of the dose-response relationship from one route to another is addressed case by case. Quantitative extrapolation is complicated by considerations such as first-pass metabolism, but is approachable with empirical data. Adequate data are necessary to demonstrate that an agent will act differently by one route versus another route of exposure.

1.3.2.5. What Is the Correlation of the Observed Dose Response Relationship to the Relationship at Lower Doses? The overriding preferred approach is to use a biologically based or case-specific model for both the observed range and extrapolation below that range when there are sufficient data. While biologically based models are still under development, it is likely that they will be used more frequently in the future. The default procedure for the observed range of data, when the preferred approach cannot be used, is to use a curve-fitting model.

In the absence of data supporting a biologically based or case-specific model for extrapolation outside of the observed range, the choice of approach is based on the view of mode of action of the agent arrived at in the hazard assessment. A linear default approach is used when the mode of action information is supportive of linearity or, alternatively, is insufficient to support a nonlinear mode of action. The linear approach is used when a view of the mode of action indicates a linear response, for example, when a conclusion is made that an agent directly causes alterations in DNA, a kind of interaction that not only theoretically requires one reaction, but also is likely to be additive to ongoing, spontaneous gene mutation. Other kinds of activity may have linear implications, e.g., linear rate-limiting steps, that support a linear procedure also. The linear approach is to draw a straight line between a point of departure from observed data, generally, as a default, the LED₁₀, and the origin (zero dose, zero response). Other points of

departure may be more appropriate for certain data sets; these may be used instead of the LED₁₀. This approach is generally considered to be public health conservative. The LED₁₀ is the lower 95% limit on a dose that is estimated to cause a 10% response. This level is chosen to account (conservatively) for experimental variability. Additionally, it is chosen because it rewards experiments with better designs in regard to number of doses and dose spacing, since these generally will have narrower confidence limits. It is also an appropriate representative of the lower end of the observed range because the limit of detection of studies of tumor effect is about 10%.

The linear default is thought to generally produce an upper bound on potential risk at low doses, e.g., a 1/100,000 to 1/1,000,000 risk; the straight line approach gives numerical results about the same as a linearized multistage procedure (Krewski et al., 1984). This upper bound is thought to cover the range of human variability although, in some cases, it may not completely do so (Bois et al., 1995). The EPA considers the linear default to be inherently conservative of public health, without addition of another factor for human variability. In any case, the size of such a factor would be hard to determine since a good empirical basis on which to construct an estimate does not currently exist. The question of what may be the actual variability in human sensitivity is one that the 1994 NRC report discussed as did the 1993 NRC report on pesticides in children and infants. The NRC has recommended research on the question, and the EPA and other agencies have begun such research.

When adequate data on mode of action show that linearity is not the most reasonable working judgment and provide sufficient evidence to support a nonlinear mode of action, the default changes to a different approach—a margin of exposure analysis—which assumes that nonlinearity is more reasonable. The departure point is again

generally the LED₁₀. A margin of exposure analysis compares the LED₁₀ with the dose associated with the environmental exposure(s) of interest by computing the ratio between the two.

The purpose of a margin of exposure analysis is to provide the risk manager with all available information on how much reduction in risk may be associated with reduction in exposure from the point of departure. This is to support the risk manager's decision as to what constitutes an acceptable margin of exposure, given requirements of the statute under which the decision is being made. There are several factors to be considered. (For perspective, keep in mind that a sufficient basis to support this nonlinear procedure often will include data on responses that are precursors to tumor effects. This means that the point of departure may well be from these biological response data rather than tumor incidence data, e.g., hormone levels, mitogenic effects.) One factor to consider is the slope of the dose response curve at the point of departure. A steeper slope implies an apparent greater reduction in risk as exposure decreases. This may support a smaller margin of exposure. Conversely, a shallow slope may support use of a greater margin of exposure. A second factor is the nature of the response used in the assessment—A precursor effect or frank toxicity or tumor response. The latter two may support a greater margin of exposure. A third factor is the nature and extent of human variability in sensitivity to the phenomenon. A fourth factor is the agent's persistence in the body. Greater variability or persistence argue for greater margins of exposure. A fifth factor is human sensitivity to the phenomenon as compared with experimental animals. The size of the margin of exposure that is acceptable would increase or decrease as this factor increases or decreases. If human variability cannot be estimated based on data, it should be considered to be at least 10-fold. Similarly, if comparison of species sensitivities cannot be estimated from available data, humans can be

considered to be 10-fold more sensitive. If it is found that humans are less sensitive than animals a factor that is a fraction no smaller than 1/10 may be assumed. The 10-fold factors are moderately conservative, traditional ones used for decades in the assessment of toxicological effects. It should not be assumed that the numerical factors are the sole components for determination of an acceptable margin of exposure. Each case calls for individual judgment. It should be noted that for cancer assessment the margin of exposure analysis begins from a point of departure that is adjusted for toxicokinetic differences between species to give a human equivalent dose. Since the traditional factor for interspecies difference is thought to contain a measure for toxicokinetics as well as sensitivity to effect, the result of beginning with a human equivalent dose is to add some conservatism. The ultimate judgment whether a particular margin of exposure is acceptable is a risk management decision under applicable law, rather than being inherent in the risk assessment. Nonetheless, the risk assessor is responsible for providing scientific rationale to support the the decision.

When the mode of action information indicates that the dose response may be adequately described by both a linear and a nonlinear approach, then the default is to present both the linear and margin of exposure analyses. An assessment may use both linear and nonlinear approaches either for responses that are thought to result from different modes of action or for presenting considerations for a response that appears to be very different at high and low doses due to influence of separate modes of action. Also, separate approaches may be used for different induced responses (i.e. tumor types) from the same agent. These would also be carried forward and presented in the assessment. Figure 1-1 presents the decision points in deciding on a dose response approach or approaches.

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Data to Support:					
Biologically Based or Case-Specific Model	yes	no	no	no	no
Linearity		yes	no	yes	no
Nonlinearity		no	yes	yes	no
Extrapolation Used:	model	default--linear	default--nonlinear	default--linear and nonlinear	default--linear

Figure 1-1. Decisions on dose response assessment approaches for the range of extrapolation.

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A default assumption is made that cumulative dose received over a lifetime, expressed as a lifetime average daily dose, is an appropriate measure of dose. This assumes that a high dose of such an agent received over a shorter period of time is equivalent to a low dose spread over a lifetime. This is thought to be a relatively public health conservative assumption and has empirical support (Monro, 1992). An example of effects of short-term, high exposure that results in subsequent cancer development is treatment of cancer patients with certain chemotherapeutic agents. An example of cancer from long-term exposure to an agent of relatively low potency is smoking. Whether the cumulative dose measure is exactly the correct measure in both such instances is not certain and should be assessed case by case and altered when data are available to support another approach. Other measures of dose that consider dose rate and duration are appropriate, e.g., when

an agent acts by causing cell toxicity or hormone disruption. In these cases both agent concentration and duration are likely to be important, because such effects are generally observed to be reversible at cessation of short-term exposure.

1.4. Characterizations

The risk characterization process first summarizes findings on hazard, dose response, and exposure characterizations, then develops an integrative analysis of the whole risk case. It ends in a nontechnical Risk Characterization Summary. The Risk Characterization Summary is a presentation for risk managers who may or may not be familiar with the scientific details of cancer assessment. It also provides information for other interested readers. The initial steps in the risk characterization process are to make building blocks in the form of characterizations of the assessments of hazard, dose response, and exposure. The individual assessments and characterizations are then integrated to

arrive at risk estimates for exposure scenarios of interest. There are two reasons for individually characterizing the hazard, dose response, and exposure assessments. One is that they are often done by different people than those who do the integrative analyses. The second is that there is very often a lapse of time between the conduct of hazard and dose response analyses and the conduct of exposure assessment and integrative analysis. Thus, it is necessary to capture characterizations of assessments as the assessments are done to avoid the need to go back and reconstruct them. Figure 1-2 shows the relationships of analyses. The figure does not necessarily correspond to the number of documents involved; there may be one or several. "Integrative analysis" is a generic term. At EPA, the documents of various programs that contain integrative analyses have other names such as the "Staff Paper" that discusses air quality criteria issues. In the following sections, the elements of this figure are discussed.

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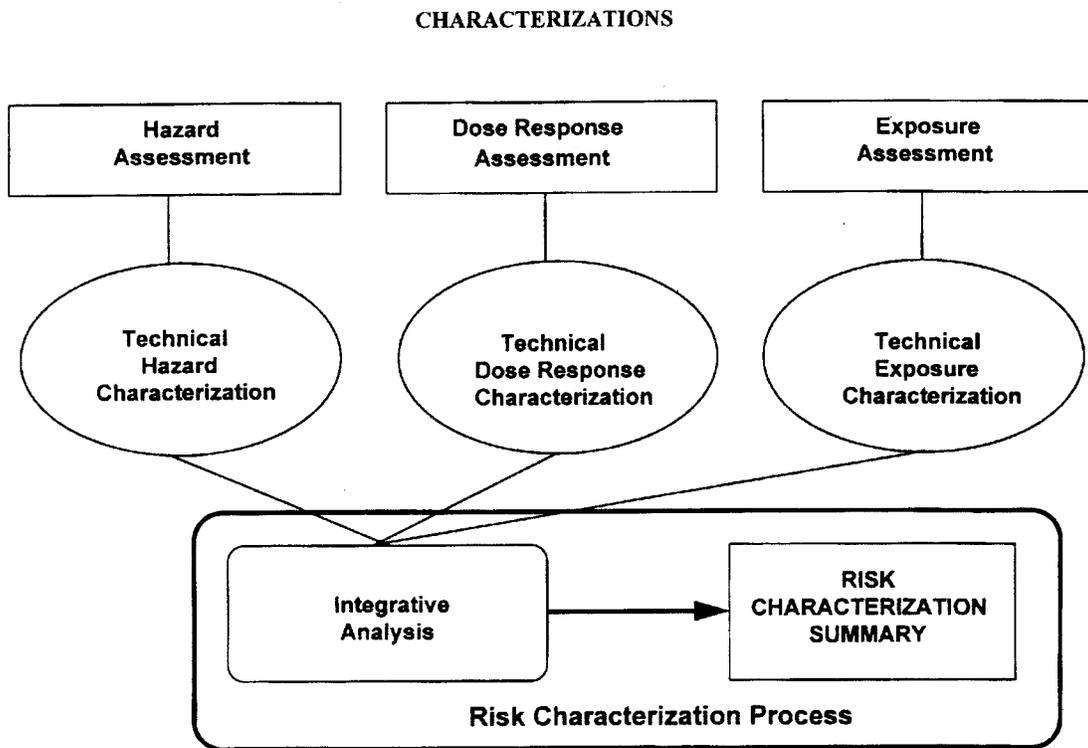


Figure 1-2. Risk Characterization

2. Hazard Assessment

2.1. Overview of Hazard Assessment and Characterization

2.1.1. Analyses of Data

The purpose of hazard assessment is to review and evaluate data pertinent to two questions: (1) whether an agent may pose a carcinogenic hazard to human beings and (2) under what circumstances an identified hazard may be expressed (NRC, 1994, p. 142). Hazard assessment is composed of analyses of a variety of data that may range from observations of tumor responses to analysis of structure-activity relationships. The purpose of the assessment is not simply to assemble these separate evaluations; its purpose is to construct a total case analysis examining the biological story the data reveal as a whole about carcinogenic effects, mode of action, and implications of these for human hazard and dose response evaluation. Weight of evidence conclusions come from the combined strength and coherence of inferences appropriately drawn from all of the available evidence. To the extent that data permit, hazard assessment addresses the mode of action question as both an initial step in considering appropriate approaches to dose response assessment and as a part of identifying human hazard potential.

The topics in this section include analysis of tumor data, both animal and human, and analysis of other key information about properties and effects that relate to carcinogenic potential. The section addresses how information can be used to evaluate potential modes of action. It also provides guidance on performing a weight of evidence evaluation.

2.1.2. Cross-Cutting Topics for Data Integration

Two topics are included in the analysis of each kind of available data: first, gathering information from available data about the conditions of expression of hazard and second, gathering perspectives on the agent's potential mode of action.

2.1.2.1. Conditions of Expression. Information on the significance of the route of exposure may be available from human or animal studies on the agent itself or on structural analogues. This information may be found in studies of the agent or analogue for toxicological endpoints other than cancer under acute or subchronic or chronic exposure regimens. Studies of metabolism or toxicokinetics of the agent similarly may provide pertinent data.

Each kind of data is also examined for information on conditions that affect expression of carcinogenic effect such as presence or absence of metabolic pathways. If carcinogenicity is secondary to another toxic effect, the physiological or tissue changes that mark the other toxicity are examined. Comparison of metabolic processes and toxicity processes in humans and animals also bears on the relevance of animal responses to human hazard. Included in the examination are the questions of the potential range of human variability and whether any special sensitivity may occur because of age, sex, preexisting disease, or other condition.

2.1.2.2. Mode of Action. Information on an agent's potential mode(s) of action is important in considering the relevance of animal effects to assessment of human hazard. It also plays an important role in selecting dose response approach(es), which are generally either biologically based models or case-specific models incorporating mode of action data or default procedures based on more limited data that support inferences about the likely shape of the dose response curve.

Each kind of data may provide some insight about mode of action and insights are gathered from each to be considered together as discussed in section 2.4. In Appendix C, is a background discussion of some of the development of views about carcinogenic processes.

2.1.3. Presentation of Results. Presentation of the results of hazard assessment follows Agency guidance as discussed in section 2.7. The results are presented in a technical hazard characterization that serves as a support to later risk characterization. It includes:

- a summary of the evaluations of hazard data,
- the rationales for its conclusions, and
- an explanation of the significant strengths or limitations of the conclusions.

Another presentation feature is the use of a weight of evidence narrative that includes both a conclusion about the weight of evidence of carcinogenic potential and a summary of the data on which the conclusion rests. This narrative is a brief summary that replaces the alphanumeric classification system used in EPA's previous guidelines.

2.2. Analysis of Tumor Data

Evidence of carcinogenicity comes from finding tumor increases in humans or laboratory animals exposed to a given

agent, or from finding tumors following exposure to structural analogues to the compound under review. The significance of observed or anticipated tumor effects is evaluated in reference to all of the other key data on the agent. This section contains guidance for analyzing human and animal studies to decide whether there is an association between exposure to an agent or a structural analogue and occurrence of tumors. Note that the use of the term "tumor" here is generic, meaning malignant neoplasms or a combination of malignant and corresponding benign neoplasms.

Observation of only benign neoplasias may or may not have significance. Benign tumors that are not observed to progress to malignancy are assessed on a case-by-case basis. There is a range of possibilities for their overall significance. They may deserve attention because they are serious health problems even though they are not malignant; for instance, benign tumors may be a health risk because of their effect on the function of a target tissue such as the brain. They may be significant indicators of the need for further testing of an agent if they are observed in a short term test protocol, or such an observation may add to the overall weight of evidence if the same agent causes malignancies in a long term study. Knowledge of the mode of action associated with a benign tumor response may aid in the interpretation of other tumor responses associated with the same agent. In other cases, observation of a benign tumor response alone may have no significant health hazard implications when other sources of evidence show no suggestion of carcinogenicity.

2.2.1. Human Data

Human data may come from epidemiologic studies or case reports. Epidemiology is the study of the distributions and causes of disease within human populations. The goals of cancer epidemiology are to identify differences in cancer risk between different groups in a population or between different populations, and then to determine the extent to which these differences in risk can be attributed causally to specific exposures to exogenous or endogenous factors. Epidemiologic data are extremely useful in risk assessment because they provide direct evidence that a substance produces cancer in humans, thereby avoiding the problem of species to species inference. Thus, when available human data are extensive and of good quality, they are generally preferable over animal data and should be given

greater weight in hazard characterization and dose response assessment, although both are utilized.

Null results from a single epidemiologic study cannot prove the absence of carcinogenic effects because they can arise either from being truly negative or from inadequate statistical power, inadequate design, imprecise estimates, or confounding factors. However, null results from a well-designed and well-conducted epidemiologic study that contains usable exposure data can help to define upper limits for the estimated dose of concern for human exposure if the overall weight of the evidence indicates that the agent is potentially carcinogenic in humans.

Epidemiology can also complement experimental evidence in corroborating or clarifying the carcinogenic potential of the agent in question. For example, observations from epidemiologic studies that elevated cancer incidence occurs at sites corresponding to those at which laboratory animals experience increased tumor incidence can strengthen the weight of evidence of human carcinogenicity. On the other hand, strong nonpositive epidemiologic data alone or in conjunction with compelling mechanistic information can lend support to a conclusion that animal responses may not be predictive of a human response. Furthermore, the advent of biochemical or molecular epidemiology may help improve understanding of the mechanisms of human carcinogenesis.

2.2.1.1. Types of Studies. The major types of cancer epidemiologic studies are analytical epidemiologic studies and descriptive or correlation epidemiologic studies. Each study type has well-known strengths and weaknesses that affect interpretation of study results as summarized below (Kelsey et al., 1986; Lilienfeld and Lilienfeld, 1979; Mausner and Kramer, 1985; Rothman, 1986).

Analytical epidemiologic studies are most useful for identifying an association between human exposure and adverse health effects. Analytical study designs include case-control studies and cohort studies. In case-control studies, groups of individuals with (cases) and without (controls) a particular disease are identified and compared to determine differences in exposure. In cohort studies, a group of "exposed" and "nonexposed" individuals are identified and studied over time to determine differences in disease occurrence. Cohort studies can either be performed prospectively or retrospectively from historical records.

Descriptive or correlation epidemiologic studies (sometimes called

ecological studies) examine differences in disease rates among populations in relation to age, gender, race, and differences in temporal or environmental conditions. In general, these studies can only identify patterns or trends in disease occurrence over time or in different geographical locations but cannot ascertain the causal agent or degree of exposure. These studies, however, are often very useful for generating hypotheses for further research.

Biochemical or molecular epidemiologic studies are studies in which laboratory methods are incorporated in analytical investigations. The application of techniques for measuring cellular and molecular alterations due to exposure to specific environmental agents may allow conclusions to be drawn about the mechanisms of carcinogenesis. The use of biological biomarkers in epidemiology may improve assessment of exposure and internal dose.

Case reports describe a particular effect in an individual or group of individuals who were exposed to a substance. These reports are often anecdotal or highly selected in nature and are of limited use for hazard assessment. However, reports of cancer cases can identify associations particularly when there are unique features such as an association with an uncommon tumor (e.g., vinyl chloride and angiosarcoma or diethylstilbestrol and clear-cell carcinoma of the vagina).

2.2.1.2. Criteria for Assessing Adequacy of Epidemiologic Studies. Criteria for assessing the adequacy of epidemiologic studies are well recognized. Characteristics that are desirable in these studies include (1) clear articulation of study objectives or hypothesis, (2) proper selection and characterization of the exposed and control groups, (3) adequate characterization of exposure, (4) sufficient length of follow-up for disease occurrence, (5) valid ascertainment of the causes of cancer morbidity and mortality, (6) proper consideration of bias and confounding factors, (7) adequate sample size to detect an effect, (8) clear, well-documented, and appropriate methodology for data collection and analysis, (9) adequate response rate and methodology for handling missing data, and (10) complete and clear documentation of results. Ideally, these conditions should be satisfied, where appropriate, but rarely can a study meet all of them. No single criterion determines the overall adequacy of a study. The following discussions highlight the major factors

included in an analysis of epidemiologic studies.

Population Issues. The ideal comparison would be between two populations that differ only in exposure to the agent in question. Because this is seldom the case, it is important to identify sources of bias inherent in a study's design or data collection methods. Bias can arise from several sources, including noncomparability between populations of factors such as general health (McMichael, 1976), diet, lifestyle, or geographic location; differences in the way case and control individuals recall past events; differences in data collection that result in unequal ascertainment of health effects in the populations; and unequal follow-up of individuals. Both acceptance of studies for assessment and judgment of their strengths or weaknesses depend on identifying their sources of bias and the effects on study results.

Exposure Issues. For epidemiologic data to be useful in determining whether there is an association between health effects and exposure to an agent, there must be adequate characterization of exposure information. In general, greater weight should be given to studies with more precise and specific exposure estimates.

Questions to address about exposure are: What can one reliably conclude about the level, duration, route, and frequency of exposure of individuals in one population as compared with another? How sensitive are study results to uncertainties in these parameters?

Actual exposure measurements are not available for many retrospective studies. Therefore, surrogates are often used to reconstruct exposure parameters when historical measurements are not available. These may involve attributing exposures to job classifications in a workplace or to broader occupational or geographic groupings. Use of surrogates carries a potential for misclassification in that individuals may be placed in the incorrect exposure group. Misclassification generally leads to reduced ability of a study to detect differences between study and referent populations.

When either current or historical monitoring data are available, the exposure evaluation includes consideration of the error bounds of the monitoring and analytic methods and whether the data are from routine or accidental exposures. The potentials for misclassification and measurement errors are amenable to both qualitative and quantitative analysis. These are essential analyses for judging a study's results because exposure estimation is

the most critical part of a retrospective study.

Biological markers potentially offer excellent measures of exposure (Hulka and Margolin, 1992; Peto and Darby, 1994). Validated markers of exposure such as alkylated hemoglobin from exposure to ethylene oxide (van Sittert et al., 1985) or urinary arsenic (Enterline et al., 1987) can greatly improve estimates of dose. Markers closely identified with effects promise to greatly increase the ability of studies to distinguish real effects from bias at low levels of relative risk between populations (Taylor et al., 1994; Biggs et al., 1993) and to resolve problems of confounding risk factors.

Confounding Factors. Because epidemiologic studies are mostly observational, it is not possible to guarantee the control of confounding variables, which may affect the study outcome. A confounding variable is a risk factor, independent of the putative agent, that is distributed unequally among the exposed and unexposed populations (e.g., smoking habits, lifestyle). Adjustment for possible confounding factors can occur either in the design of the study (e.g., matching on critical factors) or in the statistical analysis of the results. The influence of a potential confounding factor is limited by the effect of the exposure of interest. For example, a twofold effect of an exposure requires that the confounder effect be at least as big. The latter may not be possible due to the presentation of the data or because needed information was not collected during the study. In this case, indirect comparisons may be possible. For example, in the absence of data on smoking status among individuals in the study population, an examination of the possible contribution of cigarette smoking to increased lung cancer risk may be based on information from other sources such as the American Cancer Society's longitudinal studies (Hammond, 1966; Garfinkel and Silverberg, 1991). The effectiveness of adjustments contributes to the ability to draw inferences from a study.

Different studies involving exposure to an agent may have different confounding factors. If consistent increases in cancer risk are observed across a collection of studies with different confounding factors, the inference that the agent under investigation was the etiologic factor is strengthened, even though complete adjustment for confounding factors cannot be made and no single study supports a strong inference.

It also may be the case that the agent of interest is a risk factor in conjunction

with another agent. This relationship may be revealed in a collection of studies such as in the case of asbestos exposure and smoking.

Sensitivity. Sensitivity, or the ability of a study to detect real effects, is a function of several factors. Greater size of the study population(s) (sample size) increases sensitivity, as does greater exposure (levels and duration) of the population members. Because of the often long latency period in cancer development, sensitivity also depends on whether adequate time has elapsed since exposure began for effects to occur. A unique feature that can be ascribed to the effects of a particular agent (such as a tumor type that is seen only rarely in the absence of the agent) can increase sensitivity by permitting separation of bias and confounding factors from real effects. Similarly, a biomarker particular to the agent can permit these distinctions. Statistical reanalyses of data, particularly an examination of different exposure indices, can give insight on potential exposure-response relationships. These are all factors to explore in statistical analysis of the data.

Statistical Considerations. The analysis applies appropriate statistical methods to ascertain whether or not there is any significant association between exposure and effects. A description of the method or methods should include the reasons for their selection. Statistical analyses of the potential effects of bias or confounding factors are part of addressing the significance of an association, or lack of one, and whether a study is able to detect any effect.

The analysis augments examination of the results for the whole population with exploration of the results for groups with comparatively greater exposure or time since first exposure. This may support identifying an association or establishing a dose response trend. When studies show no association, such exploration may apply to determining an upper limit on potential human risk for consideration alongside results of animal tumor effects studies.

Combining Statistical Evidence Across Studies. Meta-analysis is a means of comparing and synthesizing studies dealing with similar health effects and risk factors. It is intended to introduce consistency and comprehensiveness into what otherwise might be a more subjective review of the literature. When utilized appropriately, meta-analysis can enhance understanding of associations between sources and their effects that may not be apparent from examination of

epidemiologic studies individually. Whether to conduct a meta-analysis depends on several issues. These include the importance of formally examining sources of heterogeneity, the refinement of the estimate of the magnitude of an effect, and the need for information beyond that provided by individual studies or a narrative review. Meta-analysis may not be useful in some circumstances. These include when the relationship between exposure and disease is obvious without a more formal analysis, when there are only a few studies of the key health outcomes, when there is insufficient information from available studies related to disease, risk estimate, or exposure classification, or when there are substantial confounding or other biases that cannot be adjusted for in the analysis (Blair et al., 1995; Greenland, 1987; Peto, 1992).

2.2.1.3. Criteria for Causality. A causal interpretation is enhanced for studies to the extent that they meet the criteria described below. None of the criteria is conclusive by itself, and the only criterion that is essential is the temporal relationship. These criteria are modeled after those developed by Bradford Hill in the examination of cigarette smoking and lung cancer (Rothman, 1986) and they need to be interpreted in the light of all other information on the agent being assessed.

- **Temporal relationship:** The development of cancers require certain latency periods, and while latency periods vary, existence of such periods is generally acknowledged. Thus, the disease has to occur within a biologically reasonable time after initial exposure. This feature must be present if causality is to be considered.

- **Consistency:** Associations occur in several independent studies of a similar exposure in different populations, or associations occur consistently for different subgroups in the same study. This feature usually constitutes strong evidence for a causal interpretation when the same bias or confounding is not also duplicated across studies.

- **Magnitude of the association:** A causal relationship is more credible when the risk estimate is large and precise (narrow confidence intervals).

- **Biological gradient:** The risk ratio (i.e., the ratio of the risk of disease or death among the exposed to the risk of the unexposed) increases with increasing exposure or dose. A strong dose response relationship across several categories of exposure, latency, and duration is supportive for causality given that confounding is unlikely to be correlated with exposure. The absence of a dose response relationship,

however, is not by itself evidence against a causal relationship.

- *Specificity of the association:* The likelihood of a causal interpretation is increased if an exposure produces a specific effect (one or more tumor types also found in other studies) or if a given effect has a unique exposure.

- *Biological plausibility:* The association makes sense in terms of biological knowledge. Information is considered from animal toxicology, toxicokinetics, structure-activity relationship analysis, and short-term studies of the agent's influence on events in the carcinogenic process considered.

- *Coherence:* The cause-and-effect interpretation is in logical agreement with what is known about the natural history and biology of the disease, i.e., the entire body of knowledge about the agent.

2.2.1.4. *Assessment of Evidence of Carcinogenicity from Human Data.* In the evaluation of carcinogenicity based on epidemiologic studies, it is necessary to critically evaluate each study for the confidence in findings and conclusions as discussed under section 2.2.1.2. All studies that are properly conducted, whether yielding positive or null results, or even suggesting protective carcinogenic effects, should be considered in assessing the totality of the human evidence. Although a single study may be indicative of a cause-effect relationship, confidence in inferring a causal relationship is increased when several independent studies are concordant in showing the association, when the association is strong, and when other criteria for causality are also met. Conclusions about the overall evidence for carcinogenicity from available studies in humans should be summarized along with a discussion of strengths or limitations of the conclusions.

2.2.2. Animal Data

Various kinds of whole animal test systems are currently used or are under development for evaluating potential carcinogenicity. Cancer studies involving chronic exposure for most of the life span of an animal are generally accepted for evaluation of tumor effects (Tomatis et al., 1989; Rall, 1991; Allen et al., 1988; but see Ames and Gold, 1990). Other studies of special design are useful for observing formation of preneoplastic lesions or tumors or investigating specific modes of action.

2.2.2.1. *Long-Term Carcinogenicity Studies.* The objective of long-term carcinogenesis bioassays is to determine the carcinogenic potential and dose response relationships of the test agent.

Long-term rodent studies are designed to examine the production of tumors as well as preneoplastic lesions and other indications of chronic toxicity that may provide evidence of treatment-related effects and insights into the way the test agent produces tumors. Current standardized long-term studies in rodents test at least 50 animals per sex per dose group in each of three treatment groups and in a concurrent control group, usually for 18 to 24 months, depending on the rodent species tested (OECD, 1981; U.S. EPA, 1983a; U.S. EPA, 1983b; U.S. EPA, 1983c). The high dose in long-term studies is generally selected to provide the maximum ability to detect treatment-related carcinogenic effects while not compromising the outcome of the study due to excessive toxicity or inducing inappropriate toxicokinetics (e.g., overwhelming detoxification or absorption mechanisms). The purpose of two or more lower doses is to provide some information on the shape of the dose response curve. Similar protocols have been and continue to be used by many laboratories worldwide.

All available studies of tumor effects in whole animals are considered, at least preliminarily. The analysis discards studies judged to be wholly inadequate in protocol, conduct, or results. Criteria for the technical adequacy of animal carcinogenicity studies have been published and should be used as guidance to judge the acceptability of individual studies (NTP, 1984; OSTP, 1985). Care is taken to include studies that provide some evidence bearing on carcinogenicity or help interpret effects noted in other studies even if they have some limitations of protocol or conduct. Such limited, but not wholly inadequate, studies can contribute as their deficiencies permit. The findings of long-term rodent bioassays are always interpreted in conjunction with results of prechronic studies along with toxicokinetic and metabolism studies and other pertinent information, if available. Evaluation of tumor effects requires consideration of both biological and statistical significance of the findings (Haseman, 1984, 1985, 1990, 1995). The following sections highlight the major issues in the evaluation of long-term carcinogenicity studies.

Dosing issues. In order to obtain the most relevant information from a long-term carcinogenicity study, it is important to require maximization of exposure to the test material. At the same time, there is a need for caution in using excessive high dose levels that would confound the interpretation of study results to humans. The high dose

is conventionally defined as a dose that produces some toxic effects without either unduly affecting mortality from effects other than cancer or producing significant adverse effects on the nutrition and health of the test animals (OECD, 1981; NRC, 1993b). It should be noted that practical upper limits have been established to avoid the use of excessive high doses in long-term carcinogenicity studies (e.g., 5% of the test substance in the feed for dietary studies [OECD, 1981]).

Evaluating the appropriateness of the high dose in carcinogenicity studies is based on scientific judgment using all available relevant information. In general, if the test agent does not appear to cause any specific target organ toxicity or perturbation of physiological function, an adequate high dose would be a dose that causes no more than 10% reduction of body weight gain over the life span of the animals. On the other hand, significant increases in mortality from effects other than cancer is accepted as clear evidence of frank toxicity, which indicates that an adequate high dose may have been exceeded. Other signs of treatment-related toxicity that may indicate that an adequate high dose has been exceeded include the following: (a) Reduction of body weight gain of 10% or greater, (b) significant increases in abnormal behavioral and clinical signs, (c) significant changes in hematology or clinical chemistry, (d) saturation of absorption and detoxification mechanisms, or (e) marked changes in organ weight, morphology, and histopathology.

For dietary studies, weight gain reductions should be evaluated as to whether there is a palatability problem or an issue with food efficiency; certainly, the latter is a toxic manifestation. In the case of inhalation studies with respirable particles, evidence of impairment of normal clearance of particles from the lung should be considered along with other signs of toxicity to the respiratory airways to determine whether the high exposure concentration has been appropriately selected. For dermal studies, evidence of skin irritation may indicate that an adequate high dose has been reached.

Interpretation of carcinogenicity study results is profoundly affected by exposure conditions, especially by inappropriate dose selection. This is particularly important in studies that are nonpositive for carcinogenicity, since failure to reach a sufficient dose reduces the sensitivity of a study. A lack of tumorigenic responses at exposure levels that cause significant impairment

of animal survival may also not be acceptable as negative findings because of the reduced sensitivity of the study. On the other hand, overt toxicity or inappropriate toxicokinetics due to excessive high doses may result in tumor effects that are secondary to the toxicity rather than directly attributable to the agent.

There are several possible outcomes regarding the study interpretation of the significance and relevance of tumorigenic effects associated with exposure or dose levels below, at, or above an adequate high dose. General guidance is given here that should not be taken as prescriptive; for each case, the information at hand is evaluated and a rationale should be given for the position taken.

- *Adequate high dose:* If an adequate high dose has been utilized, tumor effects are judged positive or negative depending on the presence or absence of significant tumor incidence increases, respectively.

- *Excessive high dose:* If toxicity or mortality is excessive at the high dose, interpretation depends on the finding of tumors or not.

- (a) Studies that show tumor effects only at excessive doses may be compromised and may or may not carry weight, depending on the interpretation in the context of other study results and other lines of evidence. Results of such studies, however, are generally not considered suitable for risk extrapolation.

- (b) Studies that show tumors at lower doses, even though the high dose is excessive and may be discounted, should be evaluated on their own merits.

- (c) If a study does not show an increase in tumor incidence at a toxic high dose and appropriately spaced lower doses are used without such toxicity or tumors, the study is generally judged as negative for carcinogenicity.

- *Inadequate high dose:* Studies of inadequate sensitivity where an adequate high dose has not been reached may be used to bound the dose range where carcinogenic effects might be expected.

Statistical Considerations. The main aim of statistical evaluation is to determine whether exposure to the test agent is associated with an increase of tumor development. Statistical analysis of a long-term study should be performed for each tumor type separately. The incidence of benign and malignant lesions of the same cell type, usually within a single tissue or organ, are considered separately and are combined when scientifically defensible (McConnell et al., 1986).

Trend tests and pairwise comparison tests are the recommended tests for determining whether chance, rather than a treatment-related effect, is a plausible explanation for an apparent increase in tumor incidence. A trend test such as the Cochran-Armitage test (Snedecor and Cochran, 1967) asks whether the results in all dose groups together increase as dose increases. A pairwise comparison test such as the Fisher exact test (Fisher, 1932) asks whether an incidence in one dose group is increased over the control group. By convention, for both tests a statistically significant comparison is one for which $p < 0.05$ that the increased incidence is due to chance. Significance in either kind of test is sufficient to reject the hypothesis that chance accounts for the result. A statistically significant response may or may not be biologically significant and vice versa. The selection of a significance level is a policy choice based on a trade-off between the risks of false positives and false negatives. A significance level of greater or less than 5% is examined to see if it confirms other scientific information. When the assessment departs from a simple 5% level, this should be highlighted in the risk characterization. A two-tailed test or a one-tailed test can be used. In either case a rationale is provided.

Considerations of multiple comparisons should also be taken into account. Haseman (1983) analyzes typical animal bioassays testing both sexes of two species and concludes that, because of multiple comparisons, a single tumor increase for a species-sex-site combination that is statistically significant at the 1% level for common tumors or 5% for rare tumors corresponds to a 7–8% significance level for the study as a whole.

Therefore, animal bioassays presenting only one significant result that falls short of the 1% level for a common tumor may be treated with caution.

Concurrent and Historical Controls. The standard for determining statistical significance of tumor incidence comes from a comparison of tumors in dosed animals as compared with concurrent control animals. Additional insights about both statistical and biological significance can come from an examination of historical control data (Tarone, 1982; Haseman, 1995). Historical control data can add to the analysis particularly by enabling identification of uncommon tumor types or high spontaneous incidence of a tumor in a given animal strain.

Identification of common or uncommon situations prompts further thought about the meaning of the response in the current study in context with other

observations in animal studies and with other evidence about the carcinogenic potential of the agent. These other sources of information may reinforce or weaken the significance given to the response in the hazard assessment. Caution should be exercised in simply looking at the ranges of historical responses because the range ignores differences in survival of animals among studies and is related to the number of studies in the database.

In analyzing results for uncommon tumors in a treated group that are not statistically significant in comparison to concurrent controls, the analyst can use the experience of historical controls to conclude that the result is in fact unlikely to be due to chance. In analyzing results for common tumors, a different set of considerations comes into play. Generally speaking, statistically significant increases in tumors should not be discounted simply because incidence rates in the treated groups are within the range of historical controls or because incidence rates in the concurrent controls are somewhat lower than average. Random assignment of animals to groups and proper statistical procedures provide assurance that statistically significant results are unlikely to be due to chance alone. However, caution should be used in interpreting results that are barely statistically significant or in which incidence rates in concurrent controls are unusually low in comparison with historical controls.

In cases where there may be reason to discount the biological relevance to humans of increases in common animal tumors, such considerations should be weighed on their own merits and clearly distinguished from statistical concerns.

When historical control data are used, the discussion needs to address several issues that affect comparability of historical and concurrent control data. Among these issues are the following: genetic drift in the laboratory strains; differences in pathology examination at different times and in different laboratories (e.g., in criteria for evaluating lesions; variations in the techniques for preparation or reading of tissue samples among laboratories); comparability of animals from different suppliers. The most relevant historical data come from the same laboratory and same supplier, gathered within 2 or 3 years one way or the other of the study under review; other data should be used only with extreme caution.

Assessment of Evidence of Carcinogenicity from Long-Term Animal Studies. In general, observation of tumor effects under different circumstances lends support to the

significance of the findings for animal carcinogenicity. Significance is a function of the number of factors present, and for a factor such as malignancy, the severity of the observed pathology. The following observations add significance to the tumor findings:

- uncommon tumor types
- tumors at multiple sites
- tumors by more than one route of administration
- tumors in multiple species, strains, or both sexes
- progression of lesions from preneoplastic to benign to malignant lesions
- reduced latency of neoplastic lesions
- metastases
- unusual magnitude of tumor response
- proportion of malignant tumors
- dose-related increases

These guidelines adopt the science policy position that tumor findings in animals indicate that an agent may produce such effects in humans. Moreover, the absence of tumor findings in well-conducted, long-term animal studies in at least two species provides reasonable assurance that an agent may not be a carcinogenic concern for humans. Each of these is a default assumption that may be adopted, when appropriate, after evaluation of tumor data and other key evidence.

Site concordance of tumor effects between animals and humans is an issue to be considered in each case. Thus far, there is evidence that growth control mechanisms at the level of the cell are homologous among mammals, but there is no evidence that these mechanisms are site concordant. Moreover, agents observed to produce tumors in both humans and animals have produced tumors either at the same (e.g., vinyl chloride) or different sites (e.g., benzene) (NRC, 1994). Hence, site concordance is not assumed a priori. On the other hand, certain processes with consequences for particular tissue sites (e.g., disruption of thyroid function) may lead to an anticipation of site concordance.

2.2.2.2. Other Studies. Various intermediate-term studies often use protocols that screen for carcinogenic or preneoplastic effects, sometimes in a single tissue. Some involve the development of various proliferative lesions, like foci of alteration in the liver (Goldsworthy et al., 1986). Others use tumor endpoints, like the induction of lung adenomas in the sensitive strain A mouse (Maronpot et al., 1986) or tumor induction in initiation-promotion studies using various organs such as the bladder, intestine, liver, lung, mammary gland, and thyroid (Ito et al., 1992). In

these tests, the selected tissue is, in a sense, the test system rather than the whole animal. Important information concerning the steps in the carcinogenic process and mode of action can be obtained from "start/stop" experiments. In these protocols, an agent is given for a period of time to induce particular lesions or effects, then stopped to evaluate the progression or reversibility of processes (Todd, 1986; Marsman and Popp, 1994).

Assays in genetically engineered rodents may provide insight into the chemical and gene interactions involved in carcinogenesis (Tennant et al., 1995a). These mechanistically based approaches involve activated oncogenes that are introduced (transgenic) or tumor suppressor genes that are deleted (knocked-out). If appropriate genes are selected, not only may these systems provide information on mechanisms, but the rodents typically show tumor development earlier than the standard bioassay. Transgenic mutagenesis assays also represent a mechanistic approach for assessing the mutagenic properties of agents as well as developing quantitative linkages between exposure, internal dose, and mutation related to tumor induction (Morrison and Ashby, 1994; Sisk et al., 1994; Hayward et al., 1995). These systems use a stable genomic integration of a lambda shuttle vector that carries a lacI target gene and a lacZ reporter gene.

The support that these studies give to a determination of carcinogenicity rests on their contribution to the consistency of other evidence about an agent. For instance, benzoyl peroxide has promoter activity on the skin, but the overall evidence may be less supportive (Kraus et al., 1995). These studies also may contribute information about mode of action. One needs to recognize the limitations of these experimental protocols such as short duration, limited histology, lack of complete development of tumors, or experimental manipulation of the carcinogenic process that may limit their contribution to the overall assessment. Generally, their results are appropriate as aids in the assessment for interpreting other toxicological evidence (e.g., rodent chronic bioassays), especially regarding potential modes of action. With sufficient validation, these studies may partially or wholly replace chronic bioassays in the future (Tennant et al., 1995).

2.2.3. Structural Analogue Data

For some chemical classes, there is significant information available on the carcinogenicity of analogues, largely in rodent bioassays. Analogue effects are

instructive in investigating carcinogenic potential of an agent as well as identifying potential target organs, exposures associated with effects, and potential functional class effects or modes of action. All appropriate studies are included and analyzed, whether indicative of a positive effect or not. Evaluation includes tests in various animal species, strains, and sexes; with different routes of administration; and at various doses, as data are available. Confidence in conclusions is a function of how similar the analogues are to the agent under review in structure, metabolism, and biological activity. This confidence needs to be considered to ensure a balanced position.

2.3. Analysis of Other Key Data

The physical, chemical, and structural properties of an agent, as well as data on endpoints that are thought to be critical elements of the carcinogenic process, provide valuable insights into the likelihood of human cancer risk. The following sections provide guidance for analyses of these data.

2.3.1. Physicochemical Properties

Physicochemical properties affect an agent's absorption, tissue distribution (bioavailability), biotransformation, and degradation in the body and are important determinants of hazard potential (and dose response analysis). Properties to analyze include, but are not limited to, the following: molecular weight, size, and shape; valence state; physical state (gas, liquid, solid); water or lipid solubility, which can influence retention and tissue distribution; and potential for chemical degradation or stabilization in the body.

An agent's potential for chemical reaction with cellular components, particularly with DNA and proteins, is also important. The agent's molecular size and shape, electrophilicity, and charge distribution are considered in order to decide whether they would facilitate such reactions.

2.3.2. Structure-Activity Relationships

Structure-activity relationship (SAR) analyses and models can be used to predict molecular properties, surrogate biological endpoints, and carcinogenicity. Overall, these analyses provide valuable initial information on agents, which may strengthen or weaken the concern for an agent's carcinogenic potential.

Currently, SAR analysis is useful for chemicals and metabolites that are believed to initiate carcinogenesis through covalent interaction with DNA (i.e., DNA-reactive, mutagenic, electrophilic, or proelectrophilic

chemicals) (Ashby and Tennant, 1991). For organic chemicals, the predictive capability of SAR analysis combined with other toxicity information has been demonstrated (Ashby and Tennant, 1994). The following parameters are useful in comparing an agent to its structural analogues and congeners that produce tumors and affect related biological processes such as receptor binding and activation, mutagenicity, and general toxicity (Woo and Arcos, 1989):

- nature and reactivity of the electrophilic moiety or moieties present,
- potential to form electrophilic reactive intermediate(s) through chemical, photochemical, or metabolic activation,
- contribution of the carrier molecule to which the electrophilic moiety(ies) is attached,
- physicochemical properties (e.g., physical state, solubility, octanol-water partition coefficient, half-life in aqueous solution),
- structural and substructural features (e.g., electronic, steric, molecular geometric),
- metabolic pattern (e.g., metabolic pathways and activation and detoxification ratio), and
- possible exposure route(s) of the agent.

Suitable SAR analysis of non-DNA-reactive chemicals and of DNA-reactive chemicals that do not appear to bind covalently to DNA requires knowledge or postulation of the probable mode(s) of action of closely related carcinogenic structural analogues (e.g., receptor-mediated, cytotoxicity-related). Examination of the physicochemical and biochemical properties of the agent may then provide the rest of the information needed in order to make an assessment of the likelihood of the agent's activity by that mode of action.

2.3.3. Comparative Metabolism and Toxicokinetics

Studies of the absorption, distribution, biotransformation, and excretion of agents permit comparisons among species to assist in determining the implications of animal responses for human hazard assessment, supporting identification of active metabolites, identifying changes in distribution and metabolic pathway or pathways over a dose range, and making comparisons among different routes of exposure.

If extensive data are available (e.g., blood/tissue partition coefficients and pertinent physiological parameters of the species of interest), physiologically based pharmacokinetic models can be constructed to assist in a determination of tissue dosimetry, species-to-species

extrapolation of dose, and route-to-route extrapolation (Connolly and Andersen, 1991; see section 3.2.2). If it is not contrary to available data, it is assumed as a default that toxicokinetic and metabolic processes are qualitatively comparable between species. Discussion of the defaults regarding quantitative comparison and their modifications appears in section 3.

The *qualitative* question of whether an agent is absorbed by a particular route of exposure is important for weight of evidence classification discussed in section 2.7.1. Decisions whether route of exposure is a limiting factor on expression of any hazard, in that absorption does not occur by a route, are based on studies in which effects of the agent, or its structural analogues, have been observed by different routes, on physical-chemical properties, or on toxicokinetics studies.

Adequate metabolism and pharmacokinetic data can be applied toward the following as data permit. Confidence in conclusions is enhanced when *in vivo* data are available.

- Identifying metabolites and reactive intermediates of metabolism and determining whether one or more of these intermediates are likely to be responsible for the observed effects. This information on the reactive intermediates will appropriately focus SAR analysis, analysis of potential modes of action, and estimation of internal dose in dose response assessment (D'Souza et al., 1987; Krewski et al., 1987).

• Identifying and comparing the relative activities of metabolic pathways in animals with those in humans. This analysis can provide insights for extrapolating results of animal studies to humans.

- Describing anticipated distribution within the body and possibly identifying target organs. Use of water solubility, molecular weight, and structure analysis can support qualitative inferences about anticipated distribution and excretion. In addition, describing whether the agent or metabolite of concern will be excreted rapidly or slowly or will be stored in a particular tissue or tissues to be mobilized later can identify issues in comparing species and formulating dose response assessment approaches.

• Identifying changes in toxicokinetics and metabolic pathways with increases in dose. These changes may result in important differences in disposition of the agent or its generation of active forms of the agent between high and low dose levels. These studies play an important role in providing a

rationale for dose selection in carcinogenicity studies.

- Determining bioavailability via different routes of exposure by analyzing uptake processes under various exposure conditions. This analysis supports identification of hazards for untested routes. In addition, use of physicochemical data (e.g., octanol-water partition coefficient information) can support an inference about the likelihood of dermal absorption (Flynn, 1990).

In all of these areas, attempts are made to clarify and describe as much as possible the variability to be expected because of differences in species, sex, age, and route of exposure. The analysis takes into account the presence of subpopulations of individuals who are particularly vulnerable to the effects of an agent because of toxicokinetic or metabolic differences (genetically or environmentally determined) (Bois et al., 1995).

2.3.4. Toxicological and Clinical Findings

Toxicological findings in experimental animals and clinical observations in humans are an important resource to the cancer hazard assessment. Such findings provide information on physiological effects, effects on enzymes, hormones, and other important macromolecules as well as on target organs for toxicity. Given that the cancer process represents defects in terminal differentiation, growth control, and cell death, developmental studies of agents may provide an understanding of the activity of an agent that carries over to cancer assessment. Toxicity studies in animals by different routes of administration support comparison of absorption and metabolism by those routes. Data on human variability in standard clinical tests may provide insight into the range of human sensitivity and common mechanisms to agents that affect the tested parameters.

2.3.5. Mode of Action-Related Endpoints and Short-Term Tests

A myriad of biochemical and biological endpoints relevant to the carcinogenic process provide important information in determining whether a cancer hazard exists and include, but are not limited to, mutagenesis, inhibition of gap junctional intercellular communication, increased cell proliferation, inhibition of programmed cell death, receptor activation, and immunosuppression. These precursor effects are discussed below.

2.3.5.1. *Direct DNA Effects.* Because cancer is the result of multiple genetic

defects in genes controlling proliferation and tissue homeostasis (Vogelstein et al., 1988), the ability of an agent to affect DNA is of obvious importance. It is well known that many carcinogens are electrophiles that interact directly with DNA, resulting in DNA damage and adducts, and subsequent mutations (referred to in these guidelines as direct DNA effects) that are thought to contribute to the carcinogenic process (Shelby and Zeiger, 1990; Tinwell and Ashby, 1991). Thus, studies of these phenomena continue to be important in the assessment of cancer hazard. The EPA has published testing guidelines for detecting the ability of agents to affect DNA or chromosomes (EPA, 1991a). Information on agents that induce mutations in animal germ cells also deserves attention; several human carcinogens have been shown to be positive in rodent tests for the induction of genetic damage in both somatic and germ cells (Shelby, 1995).

2.3.5.2. Secondary DNA Effects.

Similarly of interest are secondary mechanisms that either increase mutation rates or the number of dividing cells. An increase in mutations might be due to cytotoxic exposures causing regenerative proliferation or mitogenic influences, either of which could result in clonal expansion of initiated cells (Cohen and Ellwein, 1990). An agent might interfere with the enzymes involved in DNA repair and recombination (Barrett and Lee, 1992). Also, programmed cell death (apoptosis) can potentially be blocked by an agent, thereby permitting replication of damaged cells. For example, peroxisome proliferators may act by suppressing apoptosis pathways (Shulte-Hermann et al., 1993; Bayly et al., 1994). An agent may also generate reactive oxygen species that produce oxidative damage to DNA and other important macromolecules that become important elements of the carcinogenic process (Kehrer, 1993; Clayson et al., 1994; Chang et al., 1988). Damage to certain critical DNA repair genes or other genes (e.g., the p53 gene) may result in genomic instability, which predisposes cells to further genetic alterations and increases the probability of neoplastic progression independent of any exogenous agent (Harris and Hollstein, 1993; Levine, 1994).

The loss or gain of chromosomes (i.e., aneuploidy) is an effect that can result in genomic instability (Fearon and Vogelstein, 1990; Cavenee et al., 1986). Although the relationship between induced aneuploidy and carcinogenesis is not completely established, several carcinogens have been shown to induce aneuploidy (Gibson et al., 1995; Barrett,

1992). Agents that cause aneuploidy interfere with the normal process of chromosome segregation and lead to chromosomal losses, gains, or aberrations by interacting with the proteins (e.g., microtubules) needed for chromosome movement.

2.3.5.3. Nonmutagenic and Other Effects.

A failure to detect DNA damage and mutation induction in several test systems suggests that a carcinogenic agent may act by another mode of action.

It is possible for an agent to alter gene expression (transcriptional, translational, or post-translational modifications) by means not involving mutations (Barrett, 1995). For example, perturbation of DNA methylation patterns may cause effects that contribute to carcinogenesis (Jones, 1986; Goodman and Counts, 1993; Holliday, 1987). Overexpression of genes by amplification has been observed in certain tumors (Vainio et al., 1992). Other mechanisms may involve cellular reprogramming through hormonal mechanisms or receptor-mediated mechanisms (Ashby et al., 1994; Barrett, 1992).

Gap-junctional intercellular communication is widely believed to play a role in tissue and organ development and in the maintenance of a normal cellular phenotype within tissues. A growing body of evidence suggests that chemical interference with gap-junctional intercellular communication is a contributing factor in tumor development; many carcinogens have been shown to inhibit this communication. Thus, such information may provide useful mechanistic data in evaluating cancer hazard (Swierenga and Yamasaki, 1992; Yamasaki, 1995).

Both cell death and cell proliferation are mandatory for the maintenance of homeostasis in normal tissue. The balance between the two directly affects the survival and growth of initiated cells, as well as preneoplastic and tumor cell populations (i.e., increase in cell proliferation or decrease in cell death) (Bellamy et al., 1995; Cohen and Ellwein, 1990, 1991; Cohen et al., 1991). In studies of proliferative effects, distinctions should be made between mitogenesis and regenerative proliferation (Cohen and Ellwein, 1990, 1991; Cohen et al., 1991). In applying information from studies on cell proliferation and apoptosis to risk assessment, it is important to identify the tissues and target cells involved, to measure effects in both normal and neoplastic tissue, to distinguish between apoptosis and necrosis, and to

determine the dose that affects these processes.

2.3.5.4. Criteria for Judging Mode of Action.

Criteria that are applicable for judging the adequacy of mechanistically based data include the following:

- mechanistic relevance of the data to carcinogenicity,
- number of studies of each endpoint,
- consistency of results in different test systems and different species,
- similar dose response relationships for tumor and mode of action-related effects,
- tests conducted in accordance with generally accepted protocols, and
- degree of consensus and general acceptance among scientists regarding interpretation of the significance and specificity of the tests.

Although important information can be gained from in vitro test systems, a higher level of confidence is generally given to data that are derived from in vivo systems, particularly those results that show a site concordance with the tumor data.

2.4. Biomarker Information

Various endpoints can serve as biological markers of events in biological systems or samples. In some cases, these molecular or cellular effects (e.g., DNA or protein adducts, mutation, chromosomal aberrations, levels of thyroid stimulating hormone) can be measured in blood, body fluids, cells and tissues to serve as biomarkers of exposure in both animals and humans (Callemen et al., 1978; Birner et al., 1990). As such, they can do the following:

- act as an internal surrogate measure of chemical dose, representing as appropriate, either recent (e.g., serum concentration) or accumulated (e.g., hemoglobin adducts) exposure,
- help identify doses at which elements of the carcinogenic process are operating,
- aid in interspecies extrapolations when data are available from both experimental animal and human cells, and
- under certain circumstances, provide insights into the possible shape of the dose response curve below levels where tumor incidences are observed (e.g., Choy, 1993).

Genetic and other findings (like changes in proto-oncogenes and tumor suppressor genes in preneoplastic and neoplastic tissue or possibly measures of endocrine disruption) can indicate the potential for disease and as such serve as biomarkers of effect. They, too, can be used in different ways:

- The spectrum of genetic changes in proliferative lesions and tumors

following chemical administration to experimental animals can be determined and compared with those in spontaneous tumors in control animals, in animals exposed to other agents of varying structural and functional activities, and in persons exposed to the agent under study.

- They may provide a linkage to tumor response.
- They may help to identify subpopulations of individuals who may be at an elevated risk for cancer, e.g., cytochrome P450 2D6/debrisoquine sensitivity for lung cancer (Caporaso *et al.*, 1989) or inherited colon cancer syndromes (Kinzler *et al.*, 1991; Peltomäki *et al.*, 1993).
- As with biomarkers of exposure, it may be justified in some cases to use these endpoints for dose response assessment or to provide insight into the potential shape of the dose response curve at doses below those at which tumors are induced experimentally.

In applying biomarker data to cancer assessment (particularly assessments based on epidemiologic data), one should consider the following:

- routes of exposure
- exposure to mixtures
- time after exposure
- sensitivity and specificity of biomarkers
- dose response relationships.

2.5. Mode of Action—Implications for Hazard Characterization and Dose Response

The interaction of the biology of the organism and the chemical properties of the agent determine whether there is an adverse effect. Thus, mode of action analysis is based on physical, chemical, and biological information that helps to explain critical events in an agent's influence on development of tumors. The entire range of information developed in the assessment is reviewed to arrive at a reasoned judgment. An agent may work by more than one mode of action both at different sites and at the same tumor site. It is felt that at least some information bearing on mode of action (e.g., SAR, screening tests for mutagenicity) is present for most agents undergoing assessment of carcinogenicity, even though certainty about exact molecular mechanisms may be rare.

Inputs to mode of action analysis include tumor data in humans, animals, and among structural analogues as well as the other key data. The more complete the data package and generic knowledge about a given mode of action, the more confidence one has and the more one can replace or refine default science policy positions with

relevant information. Making reasoned judgments is generally based on a data-rich source of chemical, chemical class, and tumor type-specific information. Many times there will be conflicting data and gaps in the information base; one must carefully evaluate these uncertainties before reaching any conclusion.

Some of the questions that need to be addressed include the following:

- Has a body of data been developed on the agent that fits with a generally accepted mode of action?
- Has the mode of action been published and gained general scientific acceptance through peer-reviewed research or is it still speculative?
- Is the mode of action consistent with generally agreed-upon principles and understanding of carcinogenesis?
- Is the mode of action reasonably anticipated or assumed, in the absence of specific data, to operate in humans? How is this question influenced by information on comparative uptake, metabolism, and excretion patterns across animals and humans?
- Do humans appear to be more or less sensitive to the mode of action than are animals?
- Does the agent affect DNA, directly or indirectly?
- Are there important determinants in carcinogenicity other than effects on DNA, such as changes in cell proliferation, apoptosis, gene expression, immune surveillance, or other influences?

In making decisions about potential modes of action and the relevance of animal tumor findings to humans (Ashby *et al.*, 1990), very often the results of chronic animal studies may give important clues. Some of the important factors to review include the following:

- tumor types, e.g., those responsive to endocrine influence, those produced by reactive carcinogens (Ashby and Tennant, 1991),
- number of tumor sites, sexes, studies, and species affected or unaffected (Tennant, 1993),
- influence of route of exposure; spectrum of tumors; local or systemic sites,
- target organ or system toxicity, e.g., urinary chemical changes associated with stone formation, effects on immune surveillance,
- presence of proliferative lesions, e.g., hepatic foci, hyperplasias,
- progression of lesions from preneoplastic to benign to malignant with dose and time,
- ratio of malignant to benign tumors as a function of dose and time,
- time of appearance of tumors after commencing exposure,

- tumors invading locally, metastasizing, producing death,
- tumors at sites in laboratory animals with high or low spontaneous historical incidence,
- biomarkers in tumor cells, both induced and spontaneous, e.g., DNA or protein adducts, mutation spectra, chromosome changes, oncogene activation, and
- shape of the dose response in the range of tumor observation, e.g., linear vs. profound change in slope.

Some of the myriad of ways that information from chronic animal studies influences mode of action judgments include the following. Multisite and multispecies tumor effects are often associated with mutagenic agents. Tumors restricted to one sex/species may suggest an influence restricted to gender, strain, or species. Late onset of tumors that are primarily benign or are at sites with a high historical background incidence or show reversal of lesions on cessation of exposure may point to a growth-promoting mode of action. The possibility that an agent may act differently in different tissues or have more than one mode of action in a single tissue must also be kept in mind.

Simple knowledge of sites of tumor increase in rodent studies can give preliminary clues as to mode of action. Experience at the National Toxicology Program (NTP) indicates that substances that are DNA reactive and produce gene mutations may be unique in producing tumors in certain anatomical sites, while tumors at other sites may arise from both mutagenic or nonmutagenic influences (Ashby and Tennant, 1991; Huff *et al.*, 1991).

Effects on tumor sites in rodents and other mode of action information has been explored for certain agents (Alison *et al.*, 1994; Clayson, 1989; ECETOC, 1991; MacDonald *et al.*, 1994; McClain, 1994; Tischer *et al.*, 1991; ILSI, 1995; Cohen and Ellwein, 1991; FASEB, 1994; Havu *et al.*, 1990; U.S. EPA, 1991; Li *et al.*, 1987; Grasso and Hinton, 1991; Larson *et al.*, 1994; IARC, 1990; Jack *et al.*, 1983; Stitzel *et al.*, 1989; Ingram and Grasso, 1991; Bus and Popp, 1987; Prahalada *et al.*, 1994; Yamada *et al.*, 1994; Hill *et al.*, 1989; Burek *et al.*, 1988).

The selection of a dose response extrapolation procedure for cancer risk estimation considers mode of action information. When information is extensive and there is considerable certainty in a given mode of action, a biologically based or case-specific model that incorporates data on processes involved is preferred. Obviously, use of such a model requires

the existence of substantial data on component parameters of the mode of action, and judgments on its applicability must be made on a case-by-case basis.

In the absence of information to develop a biologically based or case-specific model, understanding of mode of action should be employed to the extent possible in deciding upon one of three science policy defaults: Low-dose linear extrapolation, nonlinear, and both procedures. The overall choice of the default(s) depends upon weighing the various inputs and deciding which best reflect the mode of action understanding. A rationale accompanies whichever default or defaults are chosen.

A default assumption of linearity is appropriate when the evidence supports a mode of action of gene mutation due to DNA reactivity or supports another mode of action that is anticipated to be linear. Other elements of empirical data may also support an inference of linearity, e.g., the background of human exposure to an agent might be such that added human exposure is on the linear part of a dose response curve that is sublinear overall. The default assumption of linearity is also appropriate as the ultimate default when evidence shows no DNA reactivity or other support for linearity, but neither is it sufficient evidence of a nonlinear mode of action to support a nonlinear procedure.

A default assumption of nonlinearity is appropriate when there is no evidence for linearity and sufficient evidence to support an assumption of nonlinearity and a nonlinear procedure. The mode of action may lead to a dose response relationship that is nonlinear, with response falling much more quickly than linearly with dose, or being most influenced by individual differences in sensitivity. Alternatively, the mode of action may theoretically have a threshold, e.g., the carcinogenicity may be a secondary

effect of toxicity that is itself a threshold phenomenon.

Both linear and nonlinear procedures may be used in particular cases. If a mode of action analysis finds substantial support for differing modes of action for different tumor sites, an appropriate procedure is used for each. Both procedures may also be appropriate to discuss implications of complex dose response relationships. For example, if it is apparent that an agent is both DNA reactive and is highly active as a promotor at high doses, and there are insufficient data for modeling, both linear and nonlinear default procedures may be needed to decouple and consider the contribution of both phenomena.

2.6. Weight of Evidence Evaluation for Potential Human Carcinogenicity

A weight of evidence evaluation is a collective evaluation of all pertinent information so that the full impact of biological plausibility and coherence are adequately considered. Identification and characterization of human carcinogenicity is based on human and experimental data, the nature, advantages and limitations of which have been discussed in the preceding sections.

The subsequent sections outline: (1) the basics of weighing individual lines of evidence and combining the entire body of evidence to make an informed judgment, (2) classification descriptors of cancer hazard, and (3) some case study examples to illustrate how the principles of guidance can be applied to arrive at a classification.

2.6.1. Weight of Evidence Analysis

Judgment about the weight of evidence involves considerations of the quality and adequacy of data and consistency of responses induced by the agent in question. The weight of evidence judgment requires combined input of relevant disciplines. Initial views of one kind of evidence may

change significantly when other information is brought to the interpretation. For example, a positive animal carcinogenicity finding may be diminished by other key data; a weak association in epidemiologic studies may be bolstered by consideration of other key data and animal findings. Factors typically considered are illustrated in figures below. Generally, no single weighing factor on either side determines the overall weight. The factors are not scored mechanically by adding pluses and minuses; they are judged in combination.

Human Evidence. Analyzing the contribution of evidence from a body of human data requires examining available studies and weighing them in the context of well-accepted criteria for causation (see section 2.2.1). A judgment is made about how closely they satisfy these criteria, individually and jointly, and how far they deviate from them. Existence of temporal relationships, consistent results in independent studies, strong association, reliable exposure data, presence of dose-related responses, freedom from biases and confounding factors, and high level of statistical significance are among the factors leading to increased confidence in a conclusion of causality.

Generally, the weight of human evidence increases with the number of adequate studies that show comparable results on populations exposed to the same agent under different conditions. The analysis takes into account all studies of high quality, whether showing positive associations or null results, or even protective effects. In weighing positive studies against null studies, possible reasons for inconsistent results should be sought, and results of studies that are judged to be of high quality are given more weight than those from studies judged to be methodologically less sound. See figure 2-1.

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Human Evidence Factors

Increase Weight	Decrease Weight
Number of independent studies with consistent results	Few studies Equally well designed and conducted studies with null results
Most causal criteria satisfied:	
Temporal relationship	
Strong association	
Reliable exposure data	Few causal criteria satisfied
Dose response relationship	
Freedom from bias and confounding	
Biological plausibility	
High statistical significance	



Figure 2-1. Factors for Weighing Human Evidence

Generally, no single factor is determinative. For example, the strength of association is one of the causal criteria. A strong association (i.e., a large relatively risk) is more likely to indicate causality than a weak association. However, finding of a large excess risk in a single study must be balanced against the lack of consistency as reflected by null results from other equally well designed and well conducted studies. In this situation, the positive association of a single study

may either suggest the presence of chance, bias or confounding, or reflect different exposure conditions. On the other hand, evidence of weak but consistent associations across several studies suggests either causality or the same confounder may be operating in all of these studies.

Animal Evidence. Evidence from long-term or other carcinogenicity studies in laboratory animals constitutes the second major class of information bearing on carcinogenicity. See figure 2-

2. As discussed in section 2.2.2., each relevant study must be reviewed and evaluated as to its adequacy of design and conduct as well as the statistical significance and biological relevance of its findings. Factors that usually increase confidence in the predictivity of animal findings are those of (1) multiplicity of observations in independent studies; (2) severity of lesions, latency, and lesion progression; (3) consistency in observations.

Animal Evidence Factors

Increase Weight	Decrease Weight
Number of independent studies with consistent results	Single study Inconsistent results
Same site across species, structural analogues	
Multiple observations Species Sites Sexes	Single site/species/sex
Severity and progression of lesions Early in life tumors/malignancy Dose response relationships Lesion progression Uncommon tumor	Benign tumors only High background of incidence tumors
Route of administration like human exposure	Route of administration unlike human exposure



Figure 2-2. Factors for Weighing Animal Evidence

Other Key Evidence. Additional information bearing on the qualitative assessment of carcinogenic potential may be gained from comparative pharmacokinetic and metabolism studies, genetic toxicity studies, SAR

analysis, and other studies of an agent's properties. See figure 2-3. Information from these studies helps to elucidate potential modes of action and biological fate and disposition. The knowledge gained supports interpretation of cancer

studies in humans and animals and provides a separate source of information about carcinogenic potential.

Other Key Evidence Factors

Increase Weight	Decrease Weight
A rich set of other key data are available	Few or poor data
Physicochemical data	or
Data indicate reactivity with macromolecules	Inadequate data necessitate use of default assumptions
Structure activity relationships support hazard potential	or
Comparable metabolism and toxicokinetics between species	Data show that animal findings are not relevant to humans
Toxicological and human clinical data support tumor findings	
Biomarker data support attribution of effects to agent	
Mode of action data support causal interpretation of human evidence or relevance of animal evidence	

△

Figure 2-3. Factors for Weighing Other Key Evidence

Totality of Evidence. In reaching a view of the entire weight of evidence, all data and inferences are merged. Figure 2-4 indicates the generalities. In

fact, possible weights of evidence span a broad continuum that cannot be capsulized. Most of the time the data in various lines of evidence fall in the

middle of the weights represented in the four figures in this section.

Totality of Evidence Factors

Increase Weight	Decrease Weight
Evidence of human causality	Data not available or do not show causality
Evidence of animal effects relevant to humans	Data not available or not relevant
Coherent inferences	Conflicting data
Comparable metabolism and toxicokinetics between species	Metabolism and toxicokinetics not comparable
Mode of action comparable across species	Mode of action not comparable across species



Figure 2-4. Factors for Weighing Totality of Evidence

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The following section and the weight of evidence narrative discussed in 2.7.2. provide a way to state a conclusion and capture this complexity in a consistent way.

2.6.2. Descriptors for Classifying Weight of Evidence

Hazard classification uses three categories of descriptors for human carcinogenic potential: "known/likely," "cannot be determined," and "not likely." Each category has associated subdescriptors to further define the conclusion. The descriptors are not meant to replace an explanation of the nuances of the biological evidence, but rather to summarize it. Each category spans a wide variety of potential data sets and weights of evidence. There will always be gray areas, gradations, and borderline cases. That is why the descriptors are presented only in the context of a weight of evidence narrative whose format is given in section 2.7.2. Using them within a narrative preserves and presents the complexity that is an essential part of the hazard classification. Applying a descriptor is a matter of judgment and cannot be reduced to a formula. Risk managers should consider the entire range of information included in the narrative rather than focusing simply on the descriptor.

A single agent may be categorized in more than one way if, for instance, the agent is likely to be carcinogenic by one route of exposure but not by another (section 2.3.3).

The descriptors and subdescriptors are standardized and are to be used consistently from case to case. The discussions below explain descriptors and subdescriptors which appear in italics, and along with Appendix A and section 2.6.3, illustrate their use.

"Known/Likely"

This category of descriptors is appropriate when the available tumor effects and other key data are adequate to convincingly demonstrate carcinogenic potential for humans; it includes:

- Agents known to be carcinogenic in humans based on either epidemiologic evidence or a combination of epidemiologic and experimental evidence, demonstrating causality between human exposure and cancer,
- Agents that should be treated as if they were known human carcinogens, based on a combination of epidemiologic data showing a plausible causal association (not demonstrating it definitively) and strong experimental evidence.
- Agents that are likely to produce cancer in humans due to the production or anticipated production of tumors by modes of action that are relevant or assumed to be relevant to human carcinogenicity.

Modifying descriptors for particularly high or low ranking in the "known/likely" group can be applied based on scientific judgment and experience and are as follows:

- Agents that are likely to produce cancer in humans based on data that are

at the high end of the weights of evidence typical of this group,

- Agents that are likely to produce cancer in humans based on data that are at the low end of the weights of evidence typical of this group.

"Cannot Be Determined"

This category of descriptors is appropriate when available tumor effects or other key data are suggestive or conflicting or limited in quantity and, thus, are not adequate to convincingly demonstrate carcinogenic potential for humans. In general, further agent specific and generic research and testing are needed to be able to describe human carcinogenic potential. The descriptor cannot be determined is used with a subdescriptor that captures the rationale:

- Agents whose carcinogenic potential cannot be determined, but for which there is suggestive evidence that raises concern for carcinogenic effects,
- Agents whose carcinogenic potential cannot be determined because the existing evidence is composed of conflicting data (e.g., some evidence is suggestive of carcinogenic effects, but other equally pertinent evidence does not confirm any concern),
- Agents whose carcinogenic potential cannot be determined because there are inadequate data to perform an assessment,
- Agents whose carcinogenic potential cannot be determined because no data are available to perform an assessment.

“Not Likely”

This is the appropriate descriptor when experimental evidence is satisfactory for deciding that there is no basis for human hazard concern, as follows (in the absence of human data suggesting a potential for cancer effects):

- Agents not likely to be carcinogenic to humans because they have been evaluated in at least two well conducted studies in two appropriate animal species without demonstrating carcinogenic effects,
- Agents not likely to be carcinogenic to humans because they have been appropriately evaluated in animals and show only carcinogenic effects that have been shown not to be relevant to humans (e.g., showing only effects in the male rat kidney due to accumulation of alpha_{2u}-globulin),
- Agents not likely to be carcinogenic to humans when carcinogenicity is dose or route dependent. For instance, not likely below a certain dose range (categorized as likely above that range) or not likely by a certain route of exposure (may be categorized as likely by another route of exposure). To qualify, agents will have been appropriately evaluated in animal studies and the only effects show a dose range or route limitation or a route limitation is otherwise shown by empirical data.
- Agents not likely to be carcinogenic to humans based on extensive human experience that demonstrates lack of effect (e.g., phenobarbital).

2.6.3. Case Study Examples

This section provides examples of substances that fit the three broad categories described above. These examples are based on available information about real substances and are selected to illustrate the principles for weight-of-evidence evaluation and the application of the classification scheme.

These case studies show the interplay of differing lines of evidence in making a conclusion. Some particularly illustrate the role that “other key data” can play in conclusions.

Example 1: “Known Human Carcinogen”—Route-Dependent/Linear Extrapolation**Human Data**

Substance 1 is an aluminosilicate mineral that exists in nature with a fibrous habit. Several descriptive epidemiologic studies have demonstrated very high mortality from malignant mesothelioma, mainly of the pleura, in three villages in Turkey, where there was a contamination of this mineral and where exposure had occurred from birth. Both sexes were equally affected and at an unusually young age.

Animal Data

Substance 1 has been studied in a single long-term inhalation study in rats at one exposure concentration that showed an extremely high incidence of pleural mesothelioma (98% in treated animals versus 0% in concurrent controls). This is a rare malignant tumor in the rat and the onset of tumors occurred at a very early age (as early as 1 year of age). Several studies involving injection into the body cavities of rats or mice (i.e., pleural or peritoneal cavities) also produced high incidences of pleural or peritoneal mesotheliomas. No information is available on the carcinogenic potential of substance 1 in laboratory animals via oral and dermal exposures.

Other Key Data

Information on the physical and chemical properties of substance 1 indicates that it is highly respirable to humans and laboratory rodents. It is highly insoluble and is not likely to be readily degraded in biological fluid.

No information is available on the deposition, translocation, retention, lung clearance, and excretion of the substance after inhalation exposure or ingestion. Lung burden studies have shown the presence of elevated levels of the substance in lung tissue samples of human cases of pleural mesotheliomas from contaminated villages compared with control villages.

No data are available on genetic or related effects in humans. The substance has been shown to induce unscheduled DNA synthesis in human cells in vitro and transformation and unscheduled DNA synthesis in mouse cells.

The mechanisms by which this substance causes cancer in humans and animals are not understood, but appear to be related to its unique physical, chemical, and surface properties. Its fiber morphology is similar to a known group of naturally occurring silicate minerals that have been known to cause respiratory cancers (including pleural mesothelioma) from inhalation exposure and genetic changes in humans.

Evaluation

Human evidence is judged to establish a causal link between exposure to substance 1 and human cancer. Even though the human evidence does not satisfy all criteria for causality, this judgment is based on a number of unusual observations: large magnitude of the association, specificity of the association, demonstration of environmental exposure, biological plausibility, and coherence based on the entire body of knowledge of the etiology of mesothelioma.

Animal evidence demonstrates a causal relationship between exposure and cancer in laboratory animals. Although available data are not optimal in terms of design (e.g., the use of single dose, one sex only), the judgment is based on the unusual findings from the only inhalation experiment in rats (i.e., induction of an uncommon tumor, an extremely high incidence of malignant neoplasms, and onset of tumors at an early age). Additional evidence is provided by consistent results from several injection studies showing an induction of the same

tumors by different modes of administration in more than one species.

Other key data, while limited, support the human and animal evidence of carcinogenicity. It can be inferred from human and animal data that this substance is readily deposited in the respiratory airways and deep lung and is retained for extended periods of time since first exposure. Information on related fibrous substances indicates that the modes of action are likely mediated by the physical and chemical characteristics of the substance (e.g., fiber shape, high aspect ratio, a high degree of insolubility in lung tissues).

Insufficient data are available to evaluate the human carcinogenic potential of substance 1 by oral exposure. Even though there is no information on its carcinogenic potential via dermal uptake, it is not expected to pose a carcinogenic hazard to humans by that route because it is very insoluble and is not likely to penetrate the skin.

Conclusion

It is concluded that substance 1 is a known human carcinogen by inhalation exposure. The weight of evidence of human carcinogenicity is based on (a) exceptionally increased incidence of malignant mesothelioma in epidemiologic studies of environmentally exposed human populations; (b) significantly increased incidence of malignant mesothelioma in a single inhalation study in rats and in several injection studies in rats and mice; and (c) supporting information on related fibrous substances that are known to cause cancer via inhalation and genetic damage in exposed mammalian and human mesothelial cells. The human carcinogenic potential of substance 1 via oral exposure cannot be determined on the basis of insufficient data. It is not likely to pose a carcinogenic hazard to humans via dermal uptake because it is not anticipated to penetrate the skin.

The mode of action of this substance is not understood. In addition to this uncertainty, dose response information is lacking for both human and animal data. Epidemiologic studies contain observations of significant excess cancer risks at relatively low levels of environmental exposure. The use of linear extrapolation in a dose response relationship assessment is appropriate as a default since mode of action data are not available.

Example 2: “As If Known Human Carcinogen”—Any Exposure Conditions/Linear Extrapolation**Human Data**

Substance 2 is an alkene oxide. Several cohort studies of workers using substance 2 as a sterilant have been conducted. In the largest and most informative study, mortality from lymphatic and hematopoietic cancer was marginally elevated, but a significant trend was found, especially for lymphatic leukemia and non-Hodgkin's lymphoma, in relation to estimated cumulative exposure to the substance. Nonsignificant excesses of lymphatic and hematopoietic cancer were

found in three other smaller studies of sterilization personnel.

In one cohort study of chemical workers exposed to substance 2 and other agents, mortality rate from lymphatic and hematopoietic cancer was elevated, but the excess was confined to a small subgroup with only occasional low-level exposure to substance 2. Six other studies of chemical workers are considered more limited due to a smaller number of deaths. Four studies found an excess of lymphatic and hematopoietic cancer (which were significant in two); no increase in mortality rate was observed in the other two studies.

Animal Data

Substance 2 was studied in an oral gavage study in rats. Treatment of substance 2 resulted in a dose-dependent increased incidence in forestomach tumors that were mainly squamous-cell carcinomas.

Substance 2 was also studied in two inhalation studies in mice and two inhalation studies in rats. In the first mouse study, dose-dependent increases in combined benign and malignant tumors at several tissue sites were induced in mice of both sexes (lung tumors and tumors of the Harderian gland in each sex, and uterine adenocarcinomas, mammary carcinomas, and malignant lymphomas in females). In a second study—a screening study for pulmonary tumors in mice— inhaled exposure to substance 2 resulted in a dose-dependent increase in lung tumors. In the two inhalation studies in rats, increased incidences of mononuclear-cell leukemia and brain tumors were induced in exposed animals of each sex; increased incidences of peritoneal tumors in the region of the testis and subcutaneous fibromas were induced in exposed male rats.

Substance 2 induced local sarcomas in mice following subcutaneous injection. No tumors were found in a limited skin painting study in mice.

Other Key Data

Substance 2 is a flammable gas at room temperature. The gaseous form is readily taken up in humans and rats, and in aqueous solution it can penetrate human skin. Studies in rats indicate that, once absorbed, substance 2 is uniformly distributed throughout the body. It is eliminated metabolically by hydrolysis and by conjugation with glutathione. The ability to form glutathione conjugate varies across animal species, with the rat being most active, followed by mice and rabbits.

Substance 2 is a directly acting alkylating agent. It has been shown to form adducts with hemoglobin in both humans and animals and with DNA in animals. The increased frequency of hemoglobin adducts, which have been used as markers of internal dose, has been found to correlate with the level and cumulative exposure to substance 2. Significant increases in chromosomal aberrations and sister chromatid exchanges in peripheral lymphocytes and induction of micronuclei in the bone marrow cells have been observed in exposed workers.

Substance 2 also induced chromosomal aberrations and sister chromatid exchanges in peripheral lymphocytes of monkeys

exposed *in vivo*. It also induced gene mutation, specific locus mutation, sister chromatid exchanges, chromosomal aberrations, micronuclei, dominant lethal mutations, and heritable translocation in rodents exposed *in vivo*. In human cells *in vitro*, it induced sister chromatid exchanges, chromosomal aberrations, and unscheduled DNA synthesis. Similar genetic and related effects were observed in rodent cells *in vitro* and in nonmammalian systems.

Evaluation

Available epidemiologic studies, taken together, suggest that a causal association between exposure to substance 2 and elevated risk of cancer is plausible. This judgment is based on small but consistent excesses of lymphatic and hematopoietic cancer in the studies of sterilization workers. Interpretation of studies of chemical workers is difficult because of possible confounding exposures. Nevertheless, findings of elevated risks of cancer at similar sites in chemical workers support the findings in studies of sterilization workers. Additional support is provided by observations of DNA damage in the same tissue in which elevated cancer was seen in exposed workers.

Extensive evidence indicates that substance 2 is carcinogenic to laboratory animals. Positive results were consistently observed in all well-designed and well-conducted studies. Substance 2 causes dose-related increased incidences of tumors at multiple tissue sites in rats and mice of both sexes by two routes of exposure (oral and inhalation). The only dermal study that yielded a nonpositive finding is considered of limited quality.

Other key data significantly add support to the potential carcinogenicity of substance 2. There is strong evidence of heritable mutations of exposed rodents and mutagenicity and clastogenicity both *in vivo* and *in vitro*. These findings are reinforced by observations of similar genetic damage in exposed workers. Additional support is based on SAR analysis that indicates that substance 2 is a highly DNA-reactive agent. Structurally related chemicals, *i.e.*, low-molecular-weight epoxides, also exhibit carcinogenic effects in laboratory animals.

Conclusion

Substance 2 should be considered as if it were a known human carcinogen by all routes of exposure. The weight of evidence of human carcinogenicity is based on (a) consistent evidence of carcinogenicity in rats and mice by oral and inhalation exposure; (b) epidemiologic evidence suggestive of a causal association between exposure and elevated risk of lymphatic and hematopoietic cancer; (c) evidence of genetic damage in blood lymphocytes and bone marrow cells of exposed workers; (d) mutagenic effects in numerous *in vivo* and *in vitro* test systems; (e) membership in a class of DNA-reactive compounds that have been shown to cause carcinogenic and mutagenic effects in animals; and (f) ability to be absorbed by all routes of exposure, followed by rapid distribution throughout the body.

Although the exact mechanisms of carcinogenic action of substance 2 are not

completely understood, available data strongly indicate a mutagenic mode of action. Linear extrapolation should be assumed in dose response assessment.

Example 3: "Likely Human Carcinogen"—Any Exposure Conditions/Linear Extrapolation

Human Data

Substance 3 is a brominated alkane. Three studies have investigated the cancer mortality of workers exposed to this substance. No statistically significant increase in cancer at any site was found in a study of production workers exposed to substance 3 and several other chemicals. Elevated cancer mortality was reported in a much smaller study of production workers. An excess of lymphoma was reported in grain workers who may have had exposure to substance 3 and other chemical compounds. These studies are considered inadequate due to their small cohort size; lack of, or poorly characterized, exposure concentrations; or concurrent exposure of the cohort to other potential or known carcinogens.

Animal Data

The potential carcinogenicity of substance 3 has been extensively studied in an oral gavage study in rats and mice of both sexes, two inhalation studies of rats of different strains of both sexes, an inhalation study in mice of both sexes, and a skin painting study in female mice.

In the oral study, increased incidences of squamous-cell carcinoma of the forestomach were found in rats and mice of both sexes. Additionally, there were increased incidences of liver carcinomas in female rats, hemangiosarcomas in male rats, and alveolar/bronchiolar adenoma of the lung of male and female mice. Excessive toxicity and mortality were observed in the rat study, especially in the high-dose groups, which resulted in early termination of study, and similar time-weighted average doses for the high- and low-treatment groups.

In the first inhalation study in rats and mice, increased incidences of carcinomas and adenocarcinomas of the nasal cavity and hemangiosarcoma of the spleen were found in exposed animals of each species of both sexes. Treated female rats also showed increased incidences of alveolar/bronchiolar carcinoma of the lung and mammary gland fibroadenomas. Treated male rats showed an increased incidence of peritoneal mesothelioma. In the second inhalation study in rats (single exposure only), significantly increased incidences of hemangiosarcoma of the spleen and adrenal gland tumors were seen in exposed animals of both sexes. Additionally, increased incidences of subcutaneous mesenchymal tumors and mammary gland tumors were induced in exposed male and female rats, respectively.

Lifetime dermal application of substance 3 to female mice resulted in significantly increased incidences of skin papillomas and lung tumors.

Several chemicals structurally related to substance 3 are also carcinogenic in rodents. The spectrum of tumor responses induced by related substances was similar to those seen with substance 3 (*e.g.*, forestomach, mammary gland, lung tumors).

Other Key Data

Substance 3 exists as a liquid at room temperature and is readily absorbed by ingestion, inhalation, and dermal contact. It is widely distributed in the body and is eliminated in the urine mainly as metabolites (e.g., glutathione conjugate).

Substance 3 is not itself DNA-reactive, but is biotransformed to reactive metabolites as inferred by findings of its covalent binding to DNA and induction of DNA strand breaks, both *in vivo* and *in vitro*. Substance 3 has been shown to induce sister chromatid exchanges, mutations, and unscheduled DNA synthesis in human and rodent cells *in vitro*. Reverse and forward mutations have been consistently produced in bacterial assays and *in vitro* assays using eukaryotic cells. Substance 3, however, did not induce dominant lethal mutations in mice or rats, or chromosomal aberrations or micronuclei in bone marrow cells of mice treated *in vivo*.

Evaluation

Available epidemiologic data are considered inadequate for an evaluation of a causal association of exposure to the substance and excess of cancer mortality due to major study limitations.

There is extensive evidence that substance 3 is carcinogenic in laboratory animals. Increased incidences of tumors at multiple sites have been observed in multiple studies in two species of both sexes with different routes of exposure. It induces tumors both at the site of entry (e.g., nasal tumors via inhalation, forestomach tumors by ingestion, skin tumor with dermal exposure) and at distal sites (e.g., mammary gland tumors). Additionally, it induced tumors at the same sites in both species and sexes via different routes of exposure (e.g., lung tumors). With the exception of the oral study in which the employed doses caused excessive toxicity and mortality, the other studies are considered adequately designed and well conducted. Overall, given the magnitude and extent of animal carcinogenic responses to substance 3, coupled with similar responses to structurally related substances, these animal findings are judged to be highly relevant and predictive of human responses.

Other key data, while not very extensive, are judged to be supportive of carcinogenic potential. Substance 3 has consistently been shown to be mutagenic in mammalian cells, including human cells, and nonmammalian cells; thus, mutation is likely a mode of action for its carcinogenic activity. However, the possible involvement of other modes of action has not been fully investigated. Furthermore, induction of genetic changes from *in vivo* exposure to substance 3 has not been demonstrated.

Conclusion

Substance 3 is likely to be a human carcinogen by any route of exposure. In comparison with other agents designated as likely human carcinogens, the overall weight of evidence for substance 3 puts it at the high end of the grouping.

The weight of evidence of human carcinogenicity is based on animal evidence and other key evidence. Human data are inadequate for an evaluation of human

carcinogenicity. The overall weight of evidence is based on (a) extensive animal evidence showing induction of increases of tumors at multiple sites in both sexes of two rodent species via three routes of administration relevant to human exposure; (b) tumor data of structural analogues exhibiting similar patterns of tumors in treated rodents; (c) *in vitro* evidence for mutagenic effects in mammalian cells and nonmammalian systems; and (d) its ability to be absorbed by all routes of exposure followed by rapid distribution throughout the body.

Some uncertainties are associated with the mechanisms of carcinogenicity of substance 3. Although there is considerable evidence indicating that mutagenic events could account for carcinogenic effects, there is still a lack of adequate information on the mutagenicity of substance 3 *in vivo* in animals or humans. Moreover, alternative modes of action have not been explored. Nonetheless, available data indicate a likely mutagenic mode of action. Linear extrapolation should be assumed in dose response assessment.

Example 4: "Likely Human Carcinogen"—All Routes/Linear and Nonlinear Extrapolation

Human Data

Substance 4 is a chlorinated alkene solvent. Several cohort studies of dry cleaning and laundry workers exposed to substance 4 and other solvents reported significant excesses of mortality due to cancers of the lung, cervix, esophagus, kidney, bladder, lymphatic and hematopoietic system, colon, or skin. No significant cancer risks were observed in a subcohort of one these investigations of dry cleaning workers exposed mainly to substance 4. Possible confounding factors such as smoking, alcohol consumption, or low socioeconomic status were not considered in the analyses of these studies.

A large case-control study of bladder cancer did not show any clear association with dry cleaning. Several case-control studies of liver cancer identified an increased risk of liver cancer with occupational exposure to organic solvents. The specific solvents to which workers were exposed and exposure levels were not identified.

Animal Data

The potential carcinogenicity of substance 4 has been investigated in two long-term studies in rats and mice of both sexes by oral administration and inhalation.

Significant increases in hepatocellular carcinomas were induced in mice of both sexes treated with substance 4 by oral gavage. No increases in tumor incidence were observed in treated rats. Limitations in both experiments included control groups smaller than treated groups, numerous dose adjustments during the study, and early mortality due to treatment-related nephropathy.

In the inhalation study, there were significantly increased incidences of hepatocellular adenoma and carcinoma in exposed mice of both sexes. In rats of both sexes, there were marginally significant increased incidences of mononuclear cell

leukemia (MCL) when compared with concurrent controls. The incidences of MCL in control animals, however, were higher than historical controls from the conducting laboratory. The tumor finding was also judged to be biologically significant because the time to onset of tumor was decreased and the disease was more severe in treated than in control animals. Low incidences of renal tubular cell adenomas or adenocarcinomas were also observed in exposed male rats. The tumor incidences were not statistically significant but there was a significant trend.

Other Key Data

Substance 4 has been shown to be readily and rapidly absorbed by inhalation and ingestion in humans and laboratory animals. Absorption by dermal exposure is slow and limited. Once absorbed, substance 4 is primarily distributed to and accumulated in adipose tissue and the brain, kidney, and liver. A large percentage of substance 4 is eliminated unchanged in exhaled air, with urinary excretion of metabolites comprising a much smaller percentage. The absorption and distribution profiles of substance 4 are similar across species including humans.

Two major metabolites (trichloroacetic acid (TCA), and trichloroethanol), which are formed by a P-450-dependent mixed-function oxidase enzyme system, have been identified in all studied species, including humans. There is suggestive evidence for the formation of an epoxide intermediate based on the detection of two other metabolites (oxalic acid and trichloroacetyl amide). In addition to oxidative metabolism, substance 4 also undergoes conjugation with glutathione. Further metabolism by renal beta-lyases could lead to two minor active metabolites (trichlorovinyl thiol and dichlorothiokente).

Toxicokinetic studies have shown that the enzymes responsible for the metabolism of substance 4 can be saturated at high exposures. The glutathione pathway was found to be a minor pathway at low doses, but more prevalent following saturation of the cytochrome P-450 pathway. Comparative *in vitro* studies indicate that mice have the greater capacity to metabolize to TCA than rats and humans. Inhalation studies also indicate saturation of oxidative metabolism of substance 4, which occurs at higher dose levels in mice than in rats and humans. Based on these findings, it has been postulated that the species differences in the carcinogenicity of substance 4 between rats and mice may be related to the differences in the metabolism to TCA and glutathione conjugates.

Substance 4 is a member of the class of chlorinated organics that often cause liver and kidney toxicity and carcinogenesis in rodents. Like many chlorinated organics, substance 4 itself does not appear to be mutagenic. Substance 4 was generally negative in *in vitro* bacterial systems and *in vivo* mammalian systems. However, a minor metabolite formed in the kidney by the glutathione conjugation pathway has been found to be a strong mutagen.

The mechanisms of induced carcinogenic effects of substance 4 in rats and mice are not completely understood. It has been

postulated that mouse liver carcinogenesis is related to liver peroxisomal proliferation and toxicity of the metabolite TCA. Information on whether or not TCA induces peroxisomal proliferation in humans is not definitive. The induced renal tumors in male rats may be related either to kidney toxicity or the activity of a mutagenic metabolite. The mechanisms of increases in MCL in rats are not known.

Evaluation

Available epidemiologic studies, taken together, provide suggestive evidence of a possible causal association between exposure to substance 4 and cancer incidence in the laundry and dry cleaning industries. This is based on consistent findings of elevated cancer risks in several studies of different populations of dry cleaning and laundry workers. However, each individual study is compromised by a number of study deficiencies including small numbers of cancers, confounding exposure to other solvents, and poor exposure characterization. Others may interpret these findings collectively as inconclusive.

There is considerable evidence that substance 4 is carcinogenic to laboratory animals. It induces tumors in mice of both sexes by oral and inhalation exposure and in rats of both sexes via inhalation. However, due to incomplete understanding of the mode of mechanism of action, the predictivity of animal responses to humans is uncertain.

Animal data of structurally related compounds showing common target organs of toxicity and carcinogenic effects (but lack of mutagenic effects) provide additional support for the carcinogenicity of substance 4. Comparative toxicokinetic and metabolism information indicates that the mouse may be more susceptible to liver carcinogenesis than rats and humans. This may indicate differences of the degree and extent of carcinogenic responses, but does not detract from the qualitative weight of evidence of human carcinogenicity. The toxicokinetic information also indicates that oral and inhalation are the major routes of human exposure.

Conclusion

Substance 4 is likely to be carcinogenic to humans by all routes of exposure. The weight of evidence of human carcinogenicity is based on: (a) Demonstrated evidence of carcinogenicity in two rodent species of both sexes via two relevant routes of human exposure; (b) the substance's similarity in structure to other chlorinated organics that are known to cause liver and kidney toxicity and carcinogenesis in rodents; (c) suggestive evidence of a possible association between exposure to the substance in the laundry and dry cleaning industries and increased cancer incidence; and (d) human and animal data indicating that the substance is absorbed by all routes of exposure.

In comparison with other agents designated as likely carcinogens, the overall weight of evidence places it the lower end of the grouping. This is because there is a lack of good evidence that observed excess cancer risk in exposed workers is due solely to substance 4. Moreover, there is considerable

scientific uncertainty about the human significance of certain rodent tumors associated with substance 4 and related compounds. In this case, the human relevance of the animal evidence of carcinogenicity relies on the default assumption.

Overall, there is not enough evidence to give high confidence in a conclusion about any single mode of action; it appears that more than one is plausible in different rodent tissues. Nevertheless, the lack of mutagenicity of substance 4 and its general growth-promoting effect on high background tumors as well as its toxicity toward mouse liver and rat kidney tissue support the view that the predominant mode is growth-promoting rather than mutagenic. A mutagenic contribution to carcinogenicity due to a metabolite cannot be ruled out. The dose response assessment should, therefore, adopt both default approaches, nonlinear and linear extrapolations. The latter approach is very conservative since it likely overestimates risk at low doses in this case, and is primarily useful for screening analyses.

Example 5: "Likely/Not Likely Human Carcinogen"—Range of Dose Limited, Margin-of-Exposure Extrapolation

Human Data

Substance 5 is a metal-conjugated phosphonate. No human tumor or toxicity data exist on this chemical.

Animal Data

Substance 5 caused a statistically significant increase in the incidence of urinary bladder tumors in male, but not female, rats at 30,000 ppm (3%) in the diet in a long-term study. Some of these animals had accompanying urinary tract stones and toxicity. No bladder tumors or adverse urinary tract effects were seen in two lower dose groups (2,000 and 8,000 ppm) in the same study. A chronic dietary study in mice at doses comparable to those in the rat study showed no tumor response or urinary tract effects. A 2-year study in dogs at doses up to 40,000 ppm showed no adverse urinary tract effects.

Other Key Data

Subchronic dosing of rats confirmed that there was profound development of stones in the male bladder at doses comparable to those causing cancer in the chronic study, but not at lower doses. Sloughing of the epithelium of the urinary tract accompanied the stones.

There was a lack of mutagenicity relevant to carcinogenicity. In addition, there is nothing about the chemical structure of substance 5 to indicate DNA-reactivity or carcinogenicity.

Substance 5 is composed of a metal, ethanol, and a simple phosphorus-oxygen-containing component. The metal is not absorbed from the gut, whereas the other two components are absorbed. At high doses, ethanol is metabolized to carbon dioxide, which makes the urine more acidic; the phosphorus level in the blood is increased and calcium in the urine is increased. Chronic testing of the phosphorus-oxygen-

containing component alone in rats did not show any tumors or adverse effects on the urinary tract.

Because substance 5 is a metal complex, it is not likely to be readily absorbed from the skin.

Evaluation

Substance 5 produced cancer of the bladder and urinary tract toxicity in male, but not female rats and mice, and dogs failed to show the toxicity noted in male rats. The mode of action developed from the other key data to account for the toxicity and tumors in the male rats is the production of bladder stones. At high but not lower subchronic doses in the male rat, substance 5 leads to elevated blood phosphorus levels; the body responds by releasing excess calcium into the urine. The calcium and phosphorus combine in the urine and precipitate into multiple stones in the bladder. The stones are very irritating to the bladder; the bladder lining is eroded, and cell proliferation occurs to compensate for the loss of the lining. Cell layers pile up, and finally, tumors develop. Stone formation does not involve the chemical per se but is secondary to the effects of its constituents on the blood and, ultimately, the urine. Bladder stones, regardless of their cause, commonly produce bladder tumors in rodents, especially the male rat.

Conclusion

Substance 5, a metal aliphatic phosphonate, is likely to be carcinogenic to humans only under high-exposure conditions following oral and inhalation exposure that lead to bladder stone formation, but is not likely to be carcinogenic under low-exposure conditions. It is not likely to be a human carcinogen via the dermal route, given that the compound is a metal conjugate that is readily ionized and its dermal absorption is not anticipated. The weight of evidence is based on (a) bladder tumors only in male rats; (b) the absence of tumors at any other site in rats or mice; (c) the formation of calcium-phosphorus-containing bladder stones in male rats at high, but not low, exposures that erode bladder epithelium and result in profound increases in cell proliferation and cancer; and (d) the absence of structural alerts or mutagenic activity.

There is a strong mode of action basis for the requirements of (a) high doses of substance 5, (b) which lead to excess calcium and increased acidity in the urine, (c) which result in the precipitation of stones and (d) the necessity of stones for toxic effects and tumor hazard potential. Lower doses fail to perturb urinary constituents, lead to stones, produce toxicity, or give rise to tumors. Therefore, dose response assessment should assume nonlinearity.

A major uncertainty is whether the profound effects of substance 5 may be unique to the rat. Even if substance 5 produced stones in humans, there is only limited evidence that humans with bladder stones develop cancer. Most often human bladder stones are either passed in the urine or lead to symptoms resulting in their removal. However, since one cannot totally dismiss the male rat findings, some hazard

potential may exist in humans following intense exposures. Only fundamental research could illuminate this uncertainty.

Example 6: "Cannot Be Determined"—Suggestive Evidence

Human Data

Substance 6 is an unsaturated aldehyde. In a cohort study of workers in a chemical plant exposed to a mixture of chemicals with substance 6 as a minor component, an elevated risk of cancer than was expected was reported. This study is considered inadequate because of multiple exposures, small cohort, and poor exposure characterization.

Animal Data

Substance 6 was tested for potential carcinogenicity in a drinking water study in rats, an inhalation study in hamsters, and a skin painting study in mice. No significant increases in tumors were observed in male rats treated with substance 6 at three dose levels in drinking water. However, a significant increase of adrenal cortical adenomas was found in the only treated female dose group administered a dose equivalent to the high dose of males. This study used a small number of animals (20 per dose group).

No significant finding was detected in the inhalation study in hamsters. This study is inadequate due to the use of too few animals, short duration of exposure, and inappropriate dose selection (use of a single exposure that was excessively toxic as reflected by high mortality).

No increase in tumors was induced in the skin painting study in mice. This study is of inadequate design for carcinogenicity evaluation because of several deficiencies: small number of animals, short duration of exposure, lack of reporting about the sex and age of animals, and purity of test material.

Substance 6 is structurally related to lowmolecularweight aldehydes that generally exhibit carcinogenic effects in the respiratory tracts of laboratory animals via inhalation exposure. Three skin painting studies in mice and two subcutaneous injection studies of rats and mice were conducted to evaluate the carcinogenic potential of a possible metabolite of substance 6 (identified *in vitro*). Increased incidences of either benign or combined benign and malignant skin tumors were found in the dermal studies. In the injection studies of rats and mice, increased incidences of local sarcomas or squamous cell carcinoma were found at the sites of injection. All of these studies are limited by the small number of test animals, the lack of characterization of test material, and the use of single doses.

Other Key Data

Substance 6 is a flammable liquid at room temperature. Limited information on its toxicokinetics indicates that it can be absorbed by all routes of exposure. It is eliminated in the urine mainly as glutathione conjugates. Substance 6 is metabolized *in vitro* by rat liver and lung microsomal preparations to a dihydroxylated aldehyde.

No data were available on the genetic and related effects of substance 6 in humans. It

did not induce dominant lethal mutations in mice. It induced sister chromatid exchanges in rodent cells *in vitro*. The mutagenicity of substance 6 is equivocal in bacteria. It did not induce DNA damage or mutations in fungi.

Evaluation

Available human data are judged inadequate for an evaluation of any causal relationship between exposure to substance 6 and human cancer.

The carcinogenic potential of substance 6 has not been adequately studied in laboratory animals due to serious deficiencies in study design, especially the inhalation and dermal studies. There is some evidence of carcinogenicity in the drinking water study in female rats. However, the significance and predictivity of that study to human response are uncertain since the finding is limited to occurrence of benign tumors, one sex, and at the high dose only. Additional suggestion for animal carcinogenicity comes from observation that a possible metabolite is carcinogenic at the site of administration. This metabolite, however, has not been studied *in vivo*. Overall, the animal evidence is judged to be suggestive for human carcinogenicity.

Other key data, taken together, do not add significantly to the overall weight of evidence of carcinogenicity. SAR analysis indicates that substance 6 would be DNA-reactive. However, mutagenicity data are inconclusive. Limited *in vivo* data do not support a mutagenic effect. While there is some evidence of DNA damage in rodent cells *in vitro*, there is either equivocal or no evidence of mutagenicity in nonmammalian systems.

Conclusion

The human carcinogenicity potential of substance 6 cannot be determined on the basis of available information. Both human and animal data are judged inadequate for an evaluation. There is evidence suggestive of potential carcinogenicity on the basis of limited animal findings and SAR considerations. Data are not sufficient to judge whether there is a mode of carcinogenic action. Additional studies are needed for a full evaluation of the potential carcinogenicity of substance 6. Hence, dose response assessment is not appropriate.

Example 7: "Not Likely Human Carcinogen"—Appropriately Studied Chemical in Animals Without Tumor Effects

Human Data

Substance 7, a plant extract, has not been studied for its toxic or carcinogenic potential in humans.

Animal Data

Substance 7 has been studied in four chronic studies in three rodent species. In a feeding study in rats, males showed a nonsignificant increase in benign tumors of the parathyroid gland in the high-dose group, where the incidence in concurrent controls greatly exceeded the historical control range. Females demonstrated a significant increase in various subcutaneous tumors in the low-dose group, but findings were not confirmed in the high-dose group, and there was no

dose response relationship. These effects were considered as not adding to the evidence of carcinogenicity. No tumor increases were noted in a second adequate feeding study in male and female rats. In a mouse feeding study, no tumor increases were noted in dosed animals. There was some question as to the adequacy of the dosing; however it was noted that in the mouse 90-d subchronic study, a dose of twice the high dose in the chronic study led to significant decrements in body weight. In a hamster study there were no significant increases in tumors at any site. No structural analogues of substance 7 have been tested for cancer.

Other Key Data

There are no structural alerts that would suggest that substance 7 is a DNA-reactive compound. It is negative for gene mutations in bacteria and yeast, but positive in cultured mouse cells. Tests for structural chromosome aberrations in cultured mammalian cells and in rats are negative; however, the animals were not tested at sufficiently high doses. Substance 7 binds to proteins of the cell division spindle; therefore, there is some likelihood for producing numerical chromosome aberrations, an endpoint that is sometimes noted in cancers. In sum, there is limited and conflicting information concerning the mutagenic potential of the agent.

The compound is absorbed via oral and inhalation exposure but only poorly via the skin.

Evaluation

The only indication of a carcinogenic effect comes from the finding of benign tumors in male rats in a single study. There is no confirmation of a carcinogenic potential from dosed females in that study, in males and females in a second rat study, or from mouse and hamster studies.

There is no structural indication that substance 7 is DNA-reactive, there is inconsistent evidence of gene mutations, and chromosome aberration testing is negative. The agent binds to cell division spindle proteins and may have the capacity to induce numerical chromosome anomalies. Further information on gene mutations and *in vivo* structural and numerical chromosome aberrations may be warranted.

Conclusion

Substance 7 is not likely to be carcinogenic to humans via all relevant routes of exposure. This weight of evidence judgment is largely based on the absence of significant tumor increases in chronic rodent studies. Adequate cancer studies in rats, mice, and hamsters fail to show any carcinogenic effect; a second rat study showed an increase in benign tumors at a site in dosed males, but not females.

2.7. Presentation of Results

The results of the hazard assessment are presented in the form of an overall technical hazard characterization. Additionally, a weight of evidence narrative is used when the conclusion as to carcinogenic potential needs to be

presented separately from the overall characterization.

2.7.1. Technical Hazard Characterization

The hazard characterization has two functions. First, it presents results of the hazard assessment and an explanation of how the weight of evidence conclusion was reached. It explains the potential for human hazard, anticipated attributes of its expression, and mode of action considerations for dose response. Second, it contains the information needed for eventual incorporation into a risk characterization consistent with EPA guidance on risk characterization (U.S. EPA, 1995).

The characterization qualitatively describes the conditions under which the agent's effects may be expressed in human beings. These qualitative hazard conditions are ones that are observable in the toxicity data without having done either quantitative dose response or exposure assessment. The description includes how expression is affected by route of exposure and dose levels and durations of exposure.

The discussion of limitations of dose as a qualitative aspect of hazard addresses the question of whether reaching a certain dose range appears to be a precondition for a hazard to be expressed; for example, when carcinogenic effects are secondary to another toxic effect that appears only when a certain dose level is reached. The assumption is made that an agent that causes internal tumors by one route of exposure will be carcinogenic by another route, if it is absorbed by the second route to give an internal dose. Conversely, if there is a route of exposure by which the agent is not absorbed (does not cross an absorption barrier; e.g., the exchange boundaries of skin, lung, and digestive tract through uptake processes) to any significant degree, hazard is not anticipated by that route. An exception to the latter statement would be when the site of contact is also the target tissue of carcinogenicity. Duration of exposure may be a precondition for hazard if, for example, the mode of action requires cytotoxicity or a physiologic change, or is mitogenicity, for which exposure must be sustained for a period of time before effects occur. The characterization could note that one would not anticipate a hazard from isolated, acute exposures. The above conditions are qualitative ones regarding preconditions for effects, not issues of relative absorption or potency at different dose levels. The latter are dealt with under dose response assessment (section 3), and their

implications can only be assessed after human exposure data are applied in the characterization of risk.

The characterization describes conclusions about mode of action information and its support for recommending dose response approaches.

The hazard characterization routinely includes the following in support of risk characterization:

- a summary of results of the assessment,
- identification of the kinds of data available to support conclusions and explanation of how the data fit together, highlighting the quality of the data in each line of evidence, e.g., tumor effects, short-term studies, structure-activity relationships), and highlighting the coherence of inferences from the different kinds of data,
- strengths and limitations (uncertainties) of the data and assessment, including identification of default assumptions invoked in the face of missing or inadequate data,
- identification of alternative interpretations of data that are considered equally plausible,
- identification of any subpopulations believed to be more susceptible to the hazard than the general population,
- conclusions about the agent's mode of action and recommended dose response approaches,
- significant issues regarding interpretation of data that arose in the assessment. Typical ones may include:
 - determining causality in human studies,
 - dosing (MTD), background tumor rates, relevance of animal tumors to humans,
 - weighing studies with positive and null results, considering the influence of other available kinds of evidence,
 - drawing conclusions based on mode of action data versus using a default assumption about the mode of action.

2.7.2. Weight of Evidence Narrative

The weight of evidence narrative summarizes the results of hazard assessment employing the descriptors defined in section 2.6.1. The narrative (about two pages in length) explains an agent's human carcinogenic potential and the conditions of its expression. If data do not allow a conclusion as to carcinogenicity, the narrative explains the basis of this determination. An example narrative appears below. More examples appear in Appendix A.

The items regularly included in a narrative are:

- name of agent and Chemical Abstracts Services number, if available,

- conclusions (by route of exposure) about human carcinogenicity, using a standard descriptor from section 2.6.1,

- summary of human and animal tumor data on the agent or its structural analogues, their relevance, and biological plausibility,

- other key data (e.g., structure-activity data, toxicokinetics and metabolism, short-term studies, other relevant toxicity or clinical data),

- discussion of possible mode(s) of action and appropriate dose response approach(es),

- conditions of expression of carcinogenicity, including route, duration, and magnitude of exposure.

Example Narrative

Aromatic Compound

CAS# XXX

CANCER HAZARD SUMMARY

Aromatic compound (AR) is known to be carcinogenic to humans by all routes of exposure.

The weight of evidence of human carcinogenicity is based on (a) consistent evidence of elevated leukemia incidence in studies of exposed workers and significant increases of genetic damage in bone marrow cells and blood lymphocytes of exposed workers; (b) significantly increased incidence of cancer in both sexes of several strains of rats and mice; (c) genetic damage in bone marrow cells of exposed rodents and effects on intracellular signals that control cell growth.

AR is readily absorbed by all routes of exposure and rapidly distributed throughout the body. The mode of action of AR is not understood. A dose response assessment that assumes linearity of the relationship is recommended as a default.

SUPPORTING INFORMATION

Data include numerous human epidemiologic and biomonitoring studies, long-term bioassays, and other data on effects of AR on genetic material and cell growth processes. The key epidemiologic studies and animal studies are well conducted and reliable. The other data are generally of good quality also.

Human Effects

Numerous epidemiologic and case studies have reported an increased incidence or a causal relationship associating exposure to AR and leukemia. Among the studies are five for which the design and performance as well as follow-up are considered adequate to demonstrate the causal relationship. Biomonitoring studies of exposed workers have found dose-related increases in chromosomal aberrations in bone marrow cells and blood lymphocytes.

Animal Effects

AR caused increased incidence of tumors in various tissues in both sexes of several rat and mouse strains. AR also caused chromosomal aberrations in rabbits, mice, and rats—as it does in humans.

Other Key Data

AR itself is not DNA-reactive and is not mutagenic in an array of test systems both in vitro and in vivo. Metabolism of AR yields several metabolites that have been separately studied for effects on carcinogenic processes. Some have mutagenic activity in test systems and some have other effects on cell growth controls inside cells.

MODE OF ACTION

No rodent tumor precisely matches human leukemia in pathology. The closest parallel is a mouse cancer of blood-forming tissue. Studies of the effects of AR at the cell level in this model system are ongoing. As yet, the mode of action of AR is unclear, but most likely the carcinogenic activity is associated with one or a combination of its metabolites. It is appropriate to apply a linear approach to the dose response assessment pending a better understanding because: (a) genetic damage is a typical effect of AR exposure in mammals and (b) metabolites of AR produce mutagenic effects in addition to their other effects on cell growth controls; AR is a multitissue carcinogen in mammals suggesting that it is affecting a common controlling mechanism of cell growth.

3. Dose Response Assessment

Dose response assessment first addresses the relationship of dose² to the degree of response observed in an experiment or human study. When environmental exposures are outside of the range of observation, extrapolations are necessary in order to estimate or characterize the dose relationship (ILSI, 1995). In general, three extrapolations may be made: from high to low doses, from animal to human responses, and from one route of exposure to another.

The dose response assessment proceeds in two parts. The first is assessment of the data in the range of empirical observation. This is followed by extrapolations either by modeling, if there are sufficient data to support a model, or by a default procedure based as much as possible on information about the agent's mode of action. The following discussion covers the assessment of observed data and extrapolation procedures, followed by sections on analysis of response data and analysis of dose data. The final section discusses dose response characterization.

²For this discussion, "exposure" means contact of an agent with the outer boundary of an organism. "Applied dose" means the amount of an agent presented to an absorption barrier and available for absorption. "Internal dose" means the amount crossing an absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. "Delivered dose" for an organ or cell means the amount available for interaction with that organ or cell (U.S. EPA, 1992a).

3.1. Dose Response Relationship

In the discussion that follows, reference to "response" data includes measures of tumorigenicity as well as other responses related to carcinogenicity. The other responses may include effects such as changes in DNA, chromosomes, or other key macromolecules, effects on growth signal transduction, induction of physiological or hormonal changes, effects on cell proliferation, or other effects that play a role in the process. Responses other than tumorigenicity may be considered part of the observed range in order either to extend the tumor dose response analysis or to inform it. The nontumor response or responses also may be used in lieu of tumor data if they are considered to be a more informative representation of the carcinogenic process for an agent (see section 3.2).

3.1.1. Analysis in the Range of Observation

Biologically Based and Case-Specific Models. A biologically based model is one whose parameters are calculated independently of curve-fitting of tumor data. If data are sufficient to support a biologically based model specific to the agent and the purpose of the assessment is such as to justify investing resources supporting use, this is the first choice for both the observed tumor and related response data and for extrapolation below the range of observed data in either animal or human studies. Examples are the two-stage models of initiation plus clonal expansion and progression developed by Moolgavkar and Knudson (1981) and Chen and Farland (1991). Such models require extensive data to build the form of the model as well as to estimate how well it conforms with the observed carcinogenicity data. Theoretical estimates of process parameters, such as cell proliferation rates, are not used to enable application of such a model (Portier, 1987).

Similarly preferred as a first choice are dose response models based on general concepts of mode of action and data on the agent. For a case-specific model, model parameters and data are obtained from studies on the agent.

In most cases, a biologically based or case-specific model will not be practicable, either because the necessary data do not exist or the decisions that the assessment are to support do not justify or permit, the time and resources required. In these cases, the analysis proceeds using curve-fitting models followed by default procedures for extrapolation, based, to the extent

possible, on mode of action and other biological information about the agent. These methods and assumptions are described below.

Curve-Fitting and Point of Departure for Extrapolation. Curve-fitting models are used that are appropriate to the kind of response data in the observed range. Any of several models can be used; e.g., the models developed for benchmark dose estimation for noncancer endpoints may be applied (Barnes et al., 1995).

For some data sets, particularly those with extreme curvature, the impact of model selection can be significant. In these cases, the choice is rationalized on biological grounds as possible. In other cases, the nature of the data or the way it is reported will suggest other types of models; for instance, when longitudinal data on tumor development are available, time to tumor or survival models may be necessary and appropriate to fit the data.

A point of departure for extrapolation is estimated. This is a point that is either a data point or an estimated point that can be considered to be in the range of observation, without any significant extrapolation. The LED₁₀—the lower 95% confidence limit on a dose associated with 10% extra risk—is such a point and is the standard point of departure, adopted as a matter of science policy to remain as consistent and comparable from case to case as possible.³ It is also a comparison point for noncancer endpoints (U.S. EPA, 1991f). The central estimate of the ED₁₀ also may be appropriate for use in relative hazard and potency ranking.

For some data sets, a choice of point of departure other than the LED₁₀ may be appropriate. For example, if the observed response is below the LED₁₀, then a lower point may be a better choice. Moreover, some forms of data may not be amenable to curve-fitting estimation, but to estimation of a "low-" or "no-observable-adverse-effect level" (LOAEL, NOAEL) instead, e.g., certain continuous data.

The rationale supporting the use of the LED₁₀ is that a 10% response is at or just below the limit of sensitivity of discerning a significant difference in most long-term rodent studies. The lower confidence limit on dose is used to appropriately account for experimental uncertainty (Barnes et al., 1995) and for consistency with the "benchmark dose" approach for noncancer assessment; it does not provide information about human

³It is appropriate to report the central estimate of the ED₁₀, the upper and lower 95% confidence limits, and a graphical representation of model fit.

variability. In laboratory studies of cancer or noncancer endpoints, the level of dose at which increased incidence of effects can be detected, as compared to controls, is a function of the size of the sample (e.g., number of animals), dose spacing, and other design aspects. In noncancer assessment, the dose at which significant effects are not observed is traditionally termed the NOAEL. This is not, in fact, a level of zero effect. The NOAEL in most study protocols is about the same as an LED₅ or LED₁₀—the lower 95% confidence limit on a dose associated with a 5% or 10% increased effect (Faustman et al., 1994; Haseman, 1983). Adopting parallel points of departure for cancer and noncancer assessment is intended to make discussion and comparison of the two kinds of assessment more comparable because of their similar science and science policy bases and similar analytic approaches.

Analysis of human studies in the observed range is designed case by case, depending on the type of study and how dose and response are measured in the study. In some cases the agent may have discernible interactive effects with another agent (e.g., asbestos and smoking), making possible estimation of contribution of the agent and others as risk factors. Also, in some cases, estimation of population risk in addition, or in lieu of, individual risk may be appropriate.

3.1.2. Analysis in the Range of Extrapolation

Extrapolation to lower doses is usually necessary, and in the absence of a biologically based or case-specific model, is based on one of the three default procedures described below. The Agency has adopted these three procedures as a matter of science policy based on current hypotheses of the likely shapes of dose response curves for differing modes of action. The choice of the procedure to be used in an individual case is a judgment based on the agent's modes of action.

Linear. A default assumption of linearity is appropriate when the evidence supports a mode of action of gene mutation due to DNA reactivity or supports another mode of action that is anticipated to be linear. Other elements of empirical support may also support an inference of linearity, e.g., the background of human exposure to an agent might be such that added human exposure is on the linear part of a dose response curve that is sublinear overall. The default assumption of linearity is also appropriate as the ultimate science policy default when evidence shows no DNA reactivity or other support for

linearity, but neither does it show sufficient evidence of a nonlinear mode of action to support a nonlinear procedure.

For linear extrapolation, a straight line is drawn from the point of departure to the origin—zero dose, zero response (Flamm and Winbush, 1984; Gaylor and Kodell, 1980; Krewski et al., 1984). This approach is generally conservative of public health, in the absence of information about the extent of human variability in sensitivity to effects. When a linear extrapolation procedure is used, the risk characterization summary displays the degree of extrapolation that is being made from empirical data and discusses its implications for the interpretation of the resulting quantitative risk estimates.

Nonlinear. A default assumption of nonlinearity is appropriate when there is no evidence for linearity and sufficient evidence to support an assumption of nonlinearity. The mode of action may lead to a dose response relationship that is nonlinear, with response falling much more quickly than linearly with dose, or being most influenced by individual differences in sensitivity. Alternatively, the mode of action may theoretically have a threshold, e.g., the carcinogenicity may be a secondary effect of toxicity or of an induced physiological change (see example 5, section 2.6.3) that is itself a threshold phenomenon.

As a matter of science policy under this analysis, nonlinear probability functions are not fitted to the response data to extrapolate quantitative low-dose risk estimates because different models can lead to a very wide range of results, and there is currently no basis, generally, to choose among them. Sufficient information to choose leads to a biologically based or case-specific model. In cases of nonlinearity, the risk is not extrapolated as a probability of an effect at low doses. A margin of exposure analysis is used, as described below, to evaluate concern for levels of exposure. The margin of exposure is the LED₁₀ or other point of departure divided by the environmental exposure of interest. The EPA does not generally try to distinguish between modes of action that might imply a "true threshold" from others with a nonlinear dose response relationship. Except in unusual cases where extensive information is available, it is not possible to distinguish between these empirically.

The environmental exposures of interest, for which margins of exposure are estimated, may be actual or projected future levels. The risk manager decides whether a given

margin of exposure is acceptable under applicable management policy criteria. The risk assessment provides supporting information to assist the decisionmaker.

The EPA often conducts margin of exposure analyses to accompany estimates of reference doses or concentrations (RfD, RfC) for noncancer endpoints.⁴ The procedure for a margin of exposure analysis for a response related to carcinogenicity is operationally analogous, the difference being that a threshold of cancer response is not necessarily presumed. If, in a particular case, the evidence indicates a threshold, as in the case of carcinogenicity being secondary to another toxicity that has a threshold, the margin of exposure analysis for the toxicity is the same as is done for a noncancer endpoint, and an RfD or RfC for that toxicity also may be estimated and considered in cancer assessment.

The analogy between margin of exposure analysis for noncancer and cancer responses begins with the analogy of points of departure; for both it is an effect level, either LED₁₀ or other point (presented as a human equivalent dose or concentration), as data support. For cancer responses, when animal data are used, the point of departure is a human equivalent dose or concentration arrived at by interspecies dose adjustment or toxicokinetic analysis. It is likely that many of the margin of exposure analyses for cancer will be for responses other than tumor incidence. This is because the impetus for considering a carcinogenic agent to have a nonlinear dose response will be a conclusion that there is sufficient evidence to support that view, and this evidence will often be information about a response that is a precursor to tumors.

To support a risk manager's consideration of the margin of exposure, information is provided in a risk assessment about current understanding of the phenomena that may be occurring as dose (exposure) decreases substantially below the observed data. The goal is to provide as much information as possible about the risk reduction that accompanies lowering of exposure. To this end, some important points to address include:

⁴ An RfD or RfC is an estimate with uncertainty spanning perhaps an order of magnitude of daily exposure to the human population (including sensitive subgroups) that is anticipated to be without appreciable deleterious effects during a lifetime. It is arrived at by dividing empirical data on effects by uncertainty factors that consider inter- and intraspecies variability, extent of data on all important chronic exposure toxicity endpoints, and availability of chronic as opposed to subchronic data.

- The slope of the observed dose response relationship at the point of departure and its uncertainties and implications for risk reduction associated with exposure reduction (a shallow slope suggests less reduction than a steep slope),
 - The nature of the response used for the dose response assessment,
 - The nature and extent of human variability in sensitivity to the phenomena involved,
 - Persistence of the agent in the body,
 - Human sensitivity to the phenomena as compared with experimental animals.
- As a default assumption for two of these points, a factor of no less than 10-fold each may be employed to account for human variability and for interspecies differences in sensitivity when humans may be more sensitive

than animals. When humans are found to be less sensitive than animals, a default factor of no smaller than a 1/10 fraction may be employed to account for this. If any information about human variability or interspecies differences is available, it is used instead of the default or to modify it as appropriate. In the case of analysis based on human studies, obviously, interspecies differences are not a factor. It should be noted that the dose response relationship and inter- or intraspecies variability in sensitivity are independent. That is, reduction of dose reduces risk; it does not change variability. To support consideration of acceptability of a margin of exposure by the risk manager, the assessment considers all of the hazard and dose response factors together; hence, the factors for inter- and intraspecies

differences alone are not to be considered a default number for an acceptable margin of exposure. (See Section 1.3.2.5.)

It is appropriate to provide a graphical representation of the data and dose response modeling in the observed range, also showing exposure levels of interest to the decisionmaker. (See figure 3-1.) In order to provide a frame of reference, by way of comparison, a straight line extrapolation may be displayed to show what risk levels would be associated with decreasing dose, if the dose response were linear. If this is done, the clear accompanying message is that, in this case of nonlinearity, the response falls disproportionately with decreasing dose.

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Linear and Nonlinear. Both linear and nonlinear procedures may be used in particular cases. If a mode of action analysis finds substantial support for differing modes of action for different tumor sites, an appropriate procedure is used for each. Both procedures may also be appropriate to discuss implications of complex dose response relationships. For example, if it is apparent that an agent is both DNA reactive and is highly active as a promotor at high doses, and there are insufficient data for modeling, both linear and nonlinear default procedures may be needed to decouple and consider the contribution of both phenomena.

3.1.3. Use of Toxicity Equivalence Factors and Relative Potency Estimates

A toxicity equivalence factor (TEF) procedure is one used to derive quantitative dose response estimates for agents that are members of a category or class of agents. TEFs are based on shared characteristics that can be used to order the class members by carcinogenic potency when cancer bioassay data are inadequate for this purpose (U.S. EPA, 1991c). The ordering is by reference to the characteristics and potency of a well-studied member or members of the class. Other class members are indexed to the reference agent(s) by one or more shared characteristics to generate their TEFs. The TEFs are usually indexed at increments of a factor of 10. Very good data may permit a smaller increment to be used. Shared characteristics that may be used are, for example, receptor-binding characteristics, results of assays of biological activity related to carcinogenicity, or structure-activity relationships.

TEFs are generated and used for the limited purpose of assessment of agents or mixtures of agents in environmental media when better data are not available. When better data become available for an agent, its TEF should be replaced or revised. Criteria for constructing TEFs are given in U.S. EPA (1991b). The criteria call for data that are adequate to support summing doses of the agents in mixtures. To date, adequate data to support use of TEF's has been found in only one class of compounds (dioxins) (U.S. EPA, 1989a).

Relative potencies can be similarly derived and used for agents with carcinogenicity or other supporting data. These are conceptually similar to TEFs, but they are less firmly based in science and do not have the same level of data to support them. They are used only when there is no better alternative.

The uncertainties associated with both TEFs and relative potencies are explained whenever they are used.

3.2. Response Data

Response data for analysis include tumor incidence data from human or animal studies as well as data on other responses as they relate to an agent's carcinogenicity, such as effects on growth control processes or cell macromolecules or other toxic effects. Tumor incidence data are ordinarily the basis of dose response assessment, but other response data can augment such assessment or provide separate assessments of carcinogenicity or other important effects.

Data on carcinogenic processes underlying tumor effects may be used to support biologically based or case-specific models. Other options for such data exist. If confidence is high in the linkage of a precursor effect and the tumor effect, the assessment of tumor incidence may be extended to lower dose levels by linking it to the assessment of the precursor effect (Swenberg et al., 1987). Even if a quantitative link is not appropriate, the assessment for a precursor effect may provide a view of the likely shape of the dose response curve for tumor incidence below the range of tumor observation (Cohen and Ellwein, 1990; Choy, 1993). If responses other than tumor incidence are regarded as better representations of the carcinogenicity of the agent, they may be used in lieu of tumor responses. For example, if it is concluded that the carcinogenic effect is secondary to another toxic effect, the dose response for the other effect will likely be more pertinent for risk assessment. As another example, if disruption of hormone activity is the key mode of action of an agent, data on hormone activity may be used in lieu of tumor incidence data.

If adequate positive human epidemiologic response data are available, they provide an advantageous basis for analysis since concerns about interspecies extrapolation do not arise. Adequacy of human exposure data for quantification is an important consideration in deciding whether epidemiologic data are the best basis for analysis in a particular case. If adequate exposure data exist in a well-designed and well-conducted epidemiologic study that detects no effects, it may be possible to obtain an upper-bound estimate of the potential human risk to provide a check on plausibility of available estimates based on animal tumor or other responses, e.g., do confidence limits on one overlap the point estimate of the other?

When animal studies are used, response data from a species that responds most like humans should be used if information to this effect exists. If this is unknown and an agent has been tested in several experiments involving different animal species, strains, and sexes at several doses and different routes of exposure, all of the data sets are considered and compared, and a judgment is made as to the data to be used to best represent the observed data and important biological features such as mode of action. Appropriate options for presenting results include:

- Use of a single data set,
- Combining data from different experiments (Stiteler et al., 1993; Vater et al., 1993),
- Showing a range of results from more than one data set,
- Showing results from analysis of more than one statistically significant tumor response based on differing modes of action,
- Representing total response in a single experiment by combining animals with statistically significant tumors at more than one site, or
- A combination of these options.

The approach judged to best represent the data is presented with the rationale for the judgment, including the biological and statistical considerations involved. The following are some points to consider:

- Quality of study protocol and execution,
- Proportion of malignant neoplasms,
- Latency of onset of neoplasia,
- Number of data points to define the relationship of dose and response,
- Background incidence in test animal,
- Differences in range of response among species, sexes, strains,
- Most sensitive responding species, and
- Availability of data on related precursor events to tumor development.

Analyses of carcinogenic effects other than tumor incidence are similarly presented and evaluated for their contribution to a best judgment on how to represent the biological data for dose response assessment.

3.3. Dose Data

Whether animal experiments or epidemiologic studies are the sources of data, questions need to be addressed in arriving at an appropriate measure of dose for the anticipated environmental exposure. Among these are:

- Whether the dose is expressed as an environmental concentration, applied dose, or delivered dose to the target organ,

- Whether the dose is expressed in terms of a parent compound, one or more metabolites, or both,
- The impact of dose patterns and timing where significant,
- Conversion from animal to human doses, where animal data are used, and
- The conversion metric between routes of exposure where necessary and appropriate.

In practice, there may be little or no information on the concentration or identity of the active form at a target; being able to compare the applied and delivered doses between routes and species is the ideal, but is rarely attained. Even so, the objective is to use available data to obtain as close to a measure of internal or delivered dose as possible.

The following discussion assumes that the analyst will have data of varying detail in different cases about toxicokinetics and metabolism. Discussed below are approaches to basic data that are most frequently available, as well as approaches and judgments for improving the analysis based on additional data. The estimation of dose in human studies is tailored to the form of dose data available.

3.3.1. Interspecies Adjustment of Dose

When adequate data are available, the doses used in animal studies can be adjusted to equivalent human doses using toxicokinetic information on the particular agent. The methods used should be tailored to the nature of the data on a case-by-case basis. In rare cases, it may also be possible to make adjustments based on toxicodynamic considerations. In most cases, however, there are insufficient data available to compare dose between species. In these cases, the estimate of human equivalent dose is based on science policy default assumptions. The defaults described below are modified or replaced whenever better comparative data on toxicokinetic or metabolic relationships are available. The availability and discussion of the latter also may permit reduction or discussion of uncertainty in the analysis.

For oral exposure, the default assumption is that delivered doses are related to applied dose by a power of body weight. This assumption rests on the similarities of mammalian anatomy, physiology, and biochemistry generally observed across species. This assumption is more appropriate at low applied dose concentrations where sources of nonlinearity, such as saturation or induction of enzyme activity, are less likely to occur. To derive an equivalent human oral dose from animal data, the default procedure

is to scale daily applied doses experienced for a lifetime in proportion to body weight raised to the 0.75 power ($W^{0.75}$). Equating exposure concentrations in parts per million units for food or water is an alternative version of the same default procedure because daily intakes of these are in proportion to $W^{0.75}$. The rationale for this factor rests on the empirical observation that rates of physiological processes consistently tend to maintain proportionality with $W^{0.75}$. A more extensive discussion of the rationale and data supporting the Agency's adoption of this scaling factor is in U.S. EPA, 1992b. Information such as blood levels or exposure biomarkers or other data that are available for interspecies comparison are used to improve the analysis when possible.

The default procedure to derive an human equivalent concentration of inhaled particles and gases is described in U.S. EPA (1994) and Jarabek (1995a,b). The methodology estimates respiratory deposition of inhaled particles and gases and provides methods for estimating internal doses of gases with different absorption characteristics. The method is able to incorporate additional toxicokinetics and metabolism to improve the analysis if such data are available.

3.3.2. Toxicokinetic Analyses

Physiologically based mathematical models are potentially the most comprehensive way to account for toxicokinetic processes affecting dose. Models build on physiological compartmental modeling and attempt to incorporate the dynamics of tissue perfusion and the kinetics of enzymes involved in metabolism of an administered compound.

A comprehensive model requires the availability of empirical data on the carcinogenic activity contributed by parent compound and metabolite or metabolites and data by which to compare kinetics of metabolism and elimination between species. A discussion of issues of confidence accompanies presentation of model results (Monro, 1992). This includes considerations of model validation and sensitivity analysis that stress the predictive performance of the model. When a delivered dose measure is used in animal to human extrapolation of dose response data, the assessment should discuss the confidence in the assumption that the toxicodynamics of the target tissue(s) will be the same in both species. Toxicokinetic data can improve dose response assessment by accounting for sources of change in proportionality of applied to internal or

delivered dose at various levels of applied dose. Many of the sources of potential nonlinearity involve saturation or induction of enzymatic processes at high doses. An analysis that accounts for nonlinearity (for instance, due to enzyme saturation kinetics) can assist in avoiding overestimation or underestimation of low dose response otherwise resulting from extrapolation from a sublinear or supralinear part of the experimental dose response curve (Gillette, 1983). Toxicokinetic processes tend to become linear at low doses, an expectation that is more robust than low-dose linearity of response (Hattis, 1990). Accounting for toxicokinetic nonlinearities allows better description of the shape of the curve at relatively high levels of dose in the range of observation, but cannot determine linearity or nonlinearity of response at low dose levels (Lutz, 1990a; Swenberg *et al.*, 1987).

Toxicokinetic modeling results may be presented as the preferred method of estimating human equivalent dose or in parallel discussion with default assumptions depending on relative confidence in the modeling.

3.3.3. Route-to-Route Extrapolation

Judgments frequently need to be made about the carcinogenicity of an agent through a route of exposure different than the one in the underlying studies. For example, exposures of interest may be through inhalation of an agent tested primarily through animal feeding studies or through ingestion of an agent that showed positive results in human occupational studies from inhalation exposure.

Route-to-route extrapolation has both qualitative and quantitative aspects. For the qualitative aspect, the assessor weighs the degree to which positive results through one route of exposure in human or animal studies support a judgment that similar results would have been observed in appropriate studies using the route of exposure of interest. In general, confidence in making such a judgment is strengthened when the tumor effects are observed at a site distant from the portal of entry and when absorption through the route of exposure of interest is similar to absorption via the tested routes. In the absence of contrary data, the qualitative default assumption is that, if the agent is absorbed by a route to give an internal dose, it may be carcinogenic by that route. (See section 2.7.1.)

When a qualitative extrapolation can be supported, quantitative extrapolation may still be problematic in the absence of adequate data. The differences in biological processes among routes of

exposure (oral, inhalation, dermal) can be great because of, for example, first-pass effects and differing results from different exposure patterns. There is no generally applicable method for accounting for these differences in uptake processes in quantitative route-to-route extrapolation of dose response data in the absence of good data on the agent of interest. Therefore, route-to-route extrapolation of dose data relies on a case-by-case analysis of available data. When good data on the agent itself are limited, an extrapolation analysis can be based on expectations from physical and chemical properties of the agent, properties and route-specific data on structurally analogous compounds, or in vitro or in vivo uptake data on the agent. Route-to-route uptake models may be applied if model parameters are suitable for the compound of interest. Such models are currently considered interim methods; further model development and validation is awaiting the development of more extensive data (see generally, Gerrity and Henry, 1990). For screening or hazard ranking, route-to-route extrapolation may be based on assumed quantitative comparability as a default, as long as it is reasonable to assume absorption by compared routes. When route-to-route extrapolation is used, the assessor's degree of confidence in both the qualitative and quantitative extrapolation should be discussed in the assessment and highlighted in the dose response characterization.

3.3.4. Dose Averaging

The cumulative dose received over a lifetime, expressed as lifetime average daily dose, is generally considered an appropriate default measure of exposure to a carcinogen (Monro, 1992). The assumption is made that a high dose of a carcinogen received over a short period of time is equivalent to a corresponding low dose spread over a lifetime. While this is a reasonable default assumption based on theoretical considerations, departures from it are expected. Another approach is needed in some cases, such as when dose-rate effects are noted (e.g., formaldehyde). Cumulative dose may be replaced, as appropriate and justified by the data, with other dose measures. In such cases, modifications to the default assumption are made to take account of these effects; the rationale for the selected approach is explained.

In cases where a mode of action or other feature of the biology has been identified that has special dose implications for sensitive subpopulations (e.g., differential effects by sex or disproportionate impacts of early-life exposure), these are explained

and are recorded to guide exposure assessment and risk characterization. Special problems arise when the human exposure situation of concern suggests exposure regimens (e.g., route and dosing schedule) that are substantially different from those used in the relevant animal studies. These issues are explored and pointed out for attention in the exposure assessment and risk characterization.

3.4. Discussion of Uncertainties

The exploration of significant uncertainties in data for dose and response and in extrapolation procedures is part of the assessment. The presentation distinguishes between model uncertainty and parameter uncertainty. Model uncertainty is an uncertainty about a basic biological question. For example, a default, linear dose response extrapolation may have been made based on tumor and other key evidence supporting the view that the model for an agent's mode of action is a DNA-reactive process. Discussion of the confidence in the extrapolation is appropriately done qualitatively or by showing results for alternatives that are equally plausible. It is not useful, for example, to conduct quantitative uncertainty analysis running multiple forms of linear models. This would obviate the function of the policy default.

Parameter uncertainties deal with numbers representing statistical or analytical measures of variance or error in data or estimates. Uncertainties in parameters are described quantitatively, if practicable, through sensitivity analysis and statistical uncertainty analysis. With the recent expansion of readily available computing capacity, computer methods are being adapted to create simulated biological data that are comparable with observed information. These simulations can be used for sensitivity analysis, for example, to analyze how small, plausible variations in the observed data could affect dose response estimates. These simulations can also provide information about experimental uncertainty in dose response estimates, including a distribution of estimates that are compatible with the observed data. Because these simulations are based on the observed data, they cannot assist in evaluating the extent to which the observed data as a whole are idiosyncratic rather than typical of the true situation. If quantitative analysis is not possible, significant parameter uncertainties are described qualitatively. In either case, the discussion highlights uncertainties that are specific to the agent being assessed,

as distinct from those that are generic to most assessments.

Estimation of the applied dose in a human study has numerous uncertainties such as the exposure fluctuations that humans experience compared with the controlled exposures received by animals on test. In a prospective cohort study, there is opportunity to monitor exposure and human activity patterns for a period of time that supports estimation of applied dose (U.S. EPA, 1992a). In a retrospective study, exposure may be based on monitoring data but is often based on human activity patterns and levels reconstructed from historical data, contemporary data, or a combination of the two. Such reconstruction is accompanied by analysis of uncertainties considered with sensitivity analysis in the estimation of dose (Wyzga, 1988; U.S. EPA, 1986a). These uncertainties can also be assessed for any confounding factor for which a quantitative adjustment of dose response data is made (U.S. EPA, 1984).

3.5. Technical Dose Response Characterization

As with hazard characterization, the dose response characterization serves the dual purposes of presenting a technical characterization of the assessment results and supporting the risk characterization.

The characterization presents the results of analyses of dose data, of response data, and of dose response. When alternative approaches are plausible and persuasive in selecting dose data, response data, or extrapolation procedures, the characterization follows the alternative paths of analysis and presents the results. The discussion covers the question of whether any should be preferred over others because it (or they) better represents the available data or corresponds to the view of the mechanism of action developed in the hazard assessment. The results for different tumor types by sex and species are provided along with the one(s) preferred. Similarly, results for responses other than tumor incidence are shown if appropriate.

Numerical dose response estimates are presented to one significant figure. Numbers are qualified as to whether they represent central tendency or upper bounds and whether the method used is inherently more likely to overestimate or underestimate (Krewski et al., 1984).

In cases where a mode of action or other feature of the biology has been identified that has special implications

for early-life exposure, differential effects by sex, or other concerns for sensitive subpopulations, these are explained. Similarly, any expectations that high dose-rate exposures may alter the risk picture for some portion of the population are described. These and other perspectives are recorded to guide exposure assessment and risk characterization. Whether the lifetime average daily dose or another measure of dose should be considered for differing exposure scenarios is discussed.

Uncertainty analyses, qualitative or quantitative if possible, are highlighted in the characterization.

The dose response characterization routinely includes the following, as appropriate for the data available:

- Identification of the kinds of data available for analysis of dose and response and for dose response assessment,
- Results of assessment as above,
- Explanation of analyses in terms of quality of data available,
- Selection of study/response and dose metric for assessment,
- Discussion of implications of variability in human susceptibility, including for susceptible subpopulation,
- Applicability of results to varying exposure scenarios—issues of route of exposure, dose rate, frequency, and duration,
- Discussion of strengths and limitations (uncertainties) of the data and analyses that are quantitative as well as qualitative, and
- Special issues of interpretation of data, such as:
 - Selecting dose data, response data, and dose response approach(es),
 - Use of meta-analysis,
 - Uncertainty and quantitative uncertainty analysis.

4. Technical Exposure Characterization

Guidelines for exposure assessment of carcinogenic and other agents are published (U.S. EPA, 1992a) and are used in conjunction with these cancer risk assessment guidelines. Presentation of exposure descriptors is a subject of discussion in EPA risk characterization guidance (U.S. EPA, 1995). The exposure characterization is a technical characterization that presents the assessment results and supports risk characterization.

The characterization provides a statement of purpose, scope, level of detail, and approach used in the assessment, identifying the exposure scenario(s) covered. It estimates the distribution of exposures among members of the exposed population as the data permit. It identifies and

compares the contribution of different sources and routes and pathways of exposure. Estimates of the magnitude, duration, and frequency of exposure are included as available monitoring or modeling results or other reasonable methods permit. The strengths and limitations (uncertainties) of the data and methods of estimation are made clear.

The exposure characterization routinely includes the following, as appropriate and possible for the data available:

- Identification of the kinds of data available,
- Results of assessment as above,
- Explanation of analyses in terms of quality of data available,
- Uncertainty analyses as discussed in Exposure Assessment Guidelines, distinguishing uncertainty from variability, and
- Explanation of derivation of estimators of “high end” or central tendency of exposure and their appropriate use.

5. Risk Characterization

5.1. Purpose

The risk characterization process includes an integrative analysis followed by a presentation in a Risk Characterization Summary, of the major results of the risk assessment. The Risk Characterization Summary is a nontechnical discussion that minimizes the use of technical terms. It is an appraisal of the science that supports the risk manager in making public health decisions, as do other decisionmaking analyses of economic, social, or technology issues. It also serves the needs of other interested readers. The summary is an information resource for preparation of risk communication information, but being somewhat technical, is not itself the usual vehicle for communication with every audience.

The integrative analysis brings together the assessments and characterizations of hazard, dose response, and exposure to make risk estimates for the exposure scenarios of interest. This analysis is generally much more extensive than the Risk Characterization Summary. It may be peer-reviewed or subject to public comment along with the summary in preparation for an Agency decision. The integrative analysis may be titled differently by different EPA programs (e.g., “Staff Paper” for criteria air pollutants), but it typically will identify exposure scenarios of interest in a decisionmaking and present risk analyses associated with them. Some of

the analyses may concern scenarios in several media, others may examine, for example, only drinking water risks. It also may be the document that contains quantitative analyses of uncertainty.

The values supported by a risk characterization throughout the process are transparency in environmental decisionmaking, clarity in communication, consistency in core assumptions and science policies from case to case, and reasonableness. While it is appropriate to err on the side of protection of health and the environment in the face of scientific uncertainty, common sense and reasonable application of assumptions and policies are essential to avoid unrealistic estimates of risk (U.S. EPA, 1995). Both integrative analyses and the Risk Characterization Summary present an integrated and balanced picture of the analysis of the hazard, dose response, and exposure. The risk analyst should provide summaries of the evidence and results and describe the quality of available data and the degree of confidence to be placed in the risk estimates. Important features include the constraints of available data and the state of knowledge, significant scientific issues, and significant science and science policy choices that were made when alternative interpretations of data existed (U.S. EPA, 1995). Choices made about using default assumptions or data in the assessment are explicitly discussed in the course of analysis, and if a choice is a significant issue, it is highlighted in the summary.

5.2. Application

Risk characterization is a necessary part of generating any Agency report on risk, whether the report is preliminary to support allocation of resources toward further study or comprehensive to support regulatory decisions. In the former case, the detail and sophistication of the characterization are appropriately small in scale; in the latter case, appropriately extensive. Even if a document covers only parts of a risk assessment (hazard and dose response analyses for instance), the results of these are characterized.

Risk assessment is an iterative process that grows in depth and scope in stages from screening for priority-making, to preliminary estimation, to fuller examination in support of complex regulatory decisionmaking. Default assumptions are used at every stage because no database is ever complete, but they are predominant at screening stages and are used less as more data are gathered and incorporated at later stages. Various provisions in EPA-administered statutes require decisions

based on findings that represent all stages of iteration. There are close to 30 provisions within the major statutes that require decisions based on risk, hazard, or exposure assessment. For example, Agency review of premanufacture notices under section 5 of the Toxic Substances Control Act relies on screening analyses, while requirements for industry testing under section 4 of that Act rely on preliminary analyses of risk or simply of exposure. At the other extreme, air quality criteria under the Clean Air Act rest on a rich data collection required by statute to undergo reassessment every few years. There are provisions that require ranking of hazards of numerous pollutants—by its nature a screening level of analysis—and other provisions that require a full assessment of risk. Given this range in the scope and depth of analyses, not all risk characterizations can or should be equal in coverage or depth. The risk assessor must carefully decide which issues in a particular assessment are important to present, choosing those that are noteworthy in their impact on results. For example, health effect assessments typically rely on animal data since human data are rarely available. The objective of characterization of the use of animal data is not to recount generic issues about interpreting and using animal data. Agency guidance documents cover these. Instead, the objective is to call out any significant issues that arose within the particular assessment being characterized and inform the reader about significant uncertainties that affect conclusions.

5.3. Presentation of Risk Characterization Summary

The presentation is a nontechnical discussion of important conclusions, issues, and uncertainties that uses the hazard, dose-response, exposure, and integrative analyses for technical support. The primary technical supports within the risk assessment are the hazard characterization, dose response characterization, and exposure characterization described in this guideline. The risk characterization is derived from these. The presentation should fulfill the aims outlined in the purpose section above.

5.4. Content of Risk Characterization Summary

Specific guidance on hazard, dose response, and exposure characterization appears in previous sections. Overall, the risk characterization routinely includes the following, capturing the important items covered in hazard, dose

response, and exposure characterization.

- Primary conclusions about hazard, dose response, and exposure, including equally plausible alternatives,
- Nature of key supporting information and analytic methods,
- Risk estimates and their attendant uncertainties, including key uses of default assumptions when data are missing or uncertain,
- Statement of the extent of extrapolation of risk estimates from observed data to exposure levels of interest (i.e., margin of exposure) and its implications for certainty or uncertainty in qualifying risk,
- Significant strengths and limitations of the data and analyses, including any major peer reviewers' issues,
- Appropriate comparison with similar EPA risk analyses or common risks with which people may be familiar, and
- Comparison with assessment of the same problem by another organization.

Appendix A

This appendix contains several general illustrations of weight of evidence narratives. In addition, after narrative #5 is an example of a briefing summary format.

NARRATIVE #1 Chlorinated Alkene CAS# XXX

CANCER HAZARD SUMMARY

Chlorinated alkene (cl-alkene) is likely to be carcinogenic to humans by all routes of exposure. The weight of evidence of human carcinogenicity of cl-alkene is based on (a) findings of carcinogenicity in rats and mice of both sexes by oral and inhalation exposures; (b) its similarity in structure to other chlorinated organics that are known to cause liver and kidney damage, and liver and kidney tumors in rats and mice; (c) suggestive evidence of a possible association between cl-alkene exposure of workers in the laundry and dry cleaning industries and increased cancer risk in a number of organ systems; and (d) human and animal data indicating that cl-alkene is absorbed by all routes of exposure.

In comparison with other agents designated as likely carcinogens, the overall weight of evidence for cl-alkene places it at the low end of the grouping. This is because one cannot attribute observed excess cancer risk in exposed workers solely to cl-alkene. Moreover, there is considerable scientific uncertainty about the human significance and relevance of certain rodent tumors associated with exposure to cl-alkene and other chlorinated organics, but insufficient evidence about mode of action for the animal tumors. Hence, the human relevance of the animal evidence of carcinogenicity relies on a default assumption of relevance.

There is no clear evidence about the mode of action for each tumor type induced in rats and mice. Available evidence suggests that

cl-alkene induces cancer mainly by promoting cell growth rather than via direct mutagenic action, although a mutagenic mode of action for rat kidney tumors cannot be ruled out. The dose response assessment should, therefore, adopt both default approaches, nonlinear and linear. It is recognized that the latter approach likely overestimates risk at low doses if the mode of action is primarily growth-promoting. This approach, however, may be useful for screening analyses.

SUPPORTING INFORMATION

Human Data

A number of epidemiologic studies of dry cleaning and laundry workers that have reported elevated incidences of lung, cervix, esophagus, kidney, blood and lymphoid cancers. Many of these studies are confounded by co-exposure to other petroleum solvents, making them limited for determining whether the observed increased cancer risks are causally related to cl-alkene. The only investigation of dry cleaning workers with no known exposure to other chemicals did not evaluate other confounding factors such as smoking, alcohol consumption, and low socioeconomic status to exclude the possible contribution of these factors to cancer risks.

Animal Data

The carcinogenic potential of cl-alkene has been adequately investigated in two chronic studies in two rodent species, the first study by gavage and the second study by inhalation. Cl-alkene is carcinogenic in the liver in both sexes of mice when tested by either route of exposure. It causes marginally increased incidences of mononuclear cell leukemia (MCL) in both sexes of rats and low incidences of a rare kidney tumor in male rats by inhalation. No increases in tumor incidence were found in rats treated with cl-alkene by gavage. This rat study was considered limited because of high mortality of the animals.

Although cl-alkene causes increased incidences of tumors at multiple sites in two rodent species, controversy surrounds each of the tumor endpoints concerning their relevance and/or significance to humans (see discussion under Mode of Action).

Other Key Data

Cl-alkene is a member of a class of chlorinated organics that often cause liver and kidney toxicity and carcinogenesis in rodents. Like many chlorinated hydrocarbons, cl-alkene itself is tested negative in a battery of standard genotoxicity tests using bacterial and mammalian cells systems including human lymphocytes and fibroblast cells. There is evidence, however, that a minor metabolite generated by an enzyme found in rat kidney tissue is mutagenic. This kidney metabolite has been hypothesized to be related to the development of kidney tumors in the male rat. This metabolic pathway appears to be operative in the human kidney.

Human data indicate that cl-alkene is readily absorbed via inhalation but to a much lesser extent by skin contact. Animal data show that cl-alkene is absorbed well by the oral route.

MODE OF ACTION

The mechanisms of *cl*-alkene-induced mouse liver tumors are not completely understood. One mechanism has been hypothesized to be mediated by a genotoxic epoxide metabolite generated by enzymes found in the mouse liver, but there is a lack of direct evidence in support of this mechanism. A more plausible mechanism that still needs to be further defined is related to liver peroxisomal proliferation and toxicity by TCA (trichloroacetic acid), a major metabolite of *cl*-alkene. However, there are no definitive data indicating that TCA induces peroxisomal proliferation in humans.

The mechanisms by which *cl*-alkene induces kidney tumors in male rats are even less well understood. The rat kidney response may be related to either kidney toxicity or the activity of a mutagenic metabolite of the parent compound.

The human relevance of *cl*-alkene-induced MCL in rats is unclear. The biological significance of marginally increased incidences of MCL has been questioned by some, since this tumor occurs spontaneously in the tested rat strain at very high background rates. On the other hand, it has been considered by others to be a true finding because there was a decreased time to onset of the disease and the disease was more severe in treated as compared with untreated control animals. The exact mechanism by which *cl*-alkene increases incidences of MCL in rats is not known.

Overall, there is not enough evidence to give high confidence in a conclusion about any single mode of action; it would appear that more than a single mode operates in different rodent tissues. The apparent lack of mutagenicity of *cl*-alkene itself and its general growth-promoting effect on high background tumors as well as its toxicity toward mouse liver and rat kidney tissue support the view that its predominant mode of action is cell growth promoting rather than mutagenic. A mutagenic contribution to the renal carcinogenicity due to a metabolite cannot be entirely ruled out.

NARRATIVE #2

Unsaturated Aldehyde

CAS# XXX

CANCER HAZARD SUMMARY

The potential human hazard of unsaturated aldehyde (UA) cannot be determined, but there are suggestive data for carcinogenicity.

The evidence on carcinogenicity consists of (a) data from an oral animal study showing a response only at the highest dose in female rats, with no response in males and (b) the fact that other low-molecular-weight aldehydes have shown tumorigenicity in the respiratory tract after inhalation. The one study of UA effects by the inhalation route was not adequately performed. The available evidence is too limited to describe human carcinogenicity potential or support dose response assessment.

SUPPORTING INFORMATION

Human Data

An elevated incidence of cancer was reported in a cohort of workers in a chemical

plant who were exposed to a mixture of chemicals including UA as a minor component. The study is considered inadequate because of the small size of the cohort studied and the lack of adequate exposure data.

Animal Data

In a long-term drinking water study in rats, an increased incidence of adrenal cortical adenomas was found in the highest-dosed females. No other significant finding was made. The oral rat study was well conducted by a standard protocol. In a 1-year study in hamsters at one inhalation dose, no tumors were seen. This study was inadequate due to high mortality and consequent short duration. The chemical is very irritating and is a respiratory toxicant in mammals. The animal data are too limited for conclusions to be drawn.

Structural Analogue Data

UA's structural analogues, formaldehyde and acetaldehyde, both have carcinogenic effects on the rat respiratory tract.

Other Key Data

The weight of results of mutagenicity tests in bacteria, fungi, fruit flies, and mice result in an overall conclusion of not mutagenic; UA is lethal to bacteria to a degree that makes testing difficult and test results difficult to interpret. The chemical is readily absorbed by all routes.

MODE OF ACTION

Data are not sufficient to judge whether there is a carcinogenic mode of action.

NARRATIVE #3

Alkene Oxide

CAS# XXX

CANCER HAZARD SUMMARY

Alkene oxide (AO) should be dealt with as if it were a known human carcinogen by all routes of exposure. Several studies in workers, when considered together, suggest an elevated risk of leukemia and lymphoma after long-term exposure to AO, even though no single study conclusively demonstrates that AO caused the cancer. In addition, animal cancer and mutagenicity studies as well as short-term tests of mutagenicity have strongly consistent results that support a level of concern equal to having conclusive human studies.

The weight of evidence of human carcinogenicity is based on (a) consistent evidence of carcinogenicity of AO in rats and mice by both oral and inhalation exposure; (b) studies in workers that taken together suggest elevated risk of leukemia and lymphoma to workers exposed to AO and show genetic damage in blood lymphocytes in exposed workers; (c) mutagenic effects in numerous test systems and heritable gene mutations in animals; and (d) membership in a class of DNA-reactive compounds that are regularly observed to cause cancer in animals.

Due to its ready absorption by all routes of exposure and rapid distribution throughout the body, AO is expected to pose a risk by any route of exposure. The strong evidence of a mutagenic mode of action supports dose

response assessment that assumes linearity of the relationship.

SUPPORTING INFORMATION

Human Data

Elevated risks of lymphatic cancer and cancer of blood-forming tissue have been reported in exposed workers in several studies. The interpretation of the studies separately is complicated by exposures to other agents in each so there is no single study that demonstrates that AO caused the effects; nevertheless, several of the studies together are considered suggestive of AO carcinogenicity because they consistently show cancer elevation in the same tissues. Biomonitoring studies of exposed workers find DNA damage in blood lymphocytes and the degree of DNA damage correlates with the level and duration of AO exposure. Finding this damage in the same tissue in which elevated cancer was seen in workers adds further weight to the positive suggestion from the worker cancer studies. The human data are from well-conducted studies.

Animal Data

AO causes cancer in multiple tissue sites in rats and mice of both sexes by oral and inhalation exposure. The database is more extensive than usual and the studies are good. The observation of multisite, multispecies carcinogenic activity by an agent is considered to be very strong evidence and is often the case with highly mutagenic agents. There are also good studies showing that AO causes heritable germ cell mutations in mice after inhalation exposure—a property that is very highly correlated with carcinogenicity.

Structural Analogue Data

Organic epoxides are commonly found to have carcinogenic effects in animals, particularly the low-molecular-weight ones.

Other Key Data

The structure and DNA reactivity of AO support potential carcinogenicity. Both properties are highly correlated with carcinogenicity. Positive mutagenicity tests *in vitro* and *in vivo* add to this support and are reinforced by observation of similar genetic damage in exposed workers.

AO is experimentally observed to be readily absorbed by all routes and rapidly distributed through the body.

MODE OF ACTION

All of the available data are strongly supportive of a mutagenic mode of action, with a particular human target in lymphatic and blood-forming tissue. The current scientific consensus is that there is virtually complete correspondence between ability of an agent to cause heritable germ cell mutations, as AO does, and carcinogenicity. All of this points to a mutagenic mode of action and supports assuming linearity of the dose response relationship.

NARRATIVE #4

Bis-benzenamine

CAS# XXX

CANCER HAZARD SUMMARY

This chemical is likely to be carcinogenic to humans by all routes of exposure. Its

carcinogenic potential is indicated by (a) tumor and toxicity studies on structural analogues, which demonstrate the ability of the chemical to produce thyroid follicular cell tumors in rats and hepatocellular tumors in mice following ingestion and (b) metabolism and hormonal information on the chemical and its analogues, which contributes to a working mode of action and associates findings in animals with those in exposed humans. In comparison with other agents designated as likely carcinogens, the overall weight of evidence for this chemical places it at the lower end of the grouping. This is because there is a lack of tumor response data on this agent itself.

Biological information on the compound is contradictory in terms of how to quantitate potential cancer risks. The information on disruption on thyroid-pituitary status argues for using a margin of exposure evaluation. However, the chemical is an aromatic amine, a class of agents that are DNA-reactive and induce gene mutation and chromosome aberrations, which argues for low-dose linearity. Additionally, there is a lack of mode of action information on the mouse liver tumors produced by the structural analogues, also pointing toward a low-dose linear default approach. In recognition of these uncertainties, it is recommended to quantitate tumors using both nonlinear (to place a lower bound on the risks) and linear (to place an upper bound on the risks) default approaches. Given the absence of tumor response data on the chemical per se, it is recommended that tumor data on close analogues be used to possibly develop toxicity equivalent factors or relative potencies.

Overall, this chemical is an inferential case for potential human carcinogenicity. The uncertainties associated with this assessment include (1) the lack of carcinogenicity studies on the chemical, (2) the use of tumor data on structural analogues, (3) the lack of definitive information on the relevance of thyroid-pituitary imbalance for human carcinogenicity, and (4) the different potential mechanisms that may influence tumor development and potential risks.

SUPPORTING INFORMATION

Human Data

Worker exposure has not been well characterized or quantified, but recent medical monitoring of workers exposed over a period of several years has uncovered alterations in thyroid-pituitary hormones (a decrease in T3 and T4 and an increase in TSH) and symptoms of hypothyroidism. A urinary metabolite of the chemical has been monitored in workers, with changes in thyroid and pituitary hormones noted, and the changes were similar to those seen in an animal study.

Animal Data

The concentration of the urinary metabolite in rats receiving the chemical for 28 days was within twofold of that in exposed workers, a finding associated with comparable changes in thyroid hormones and TSH levels. In addition, the dose of the chemical given to rats in this study was essentially the same as that of an analogue

that had produced thyroid and pituitary tumors in rats. The human thyroid responds in the same way as the rodent thyroid following short-term, limited exposure. Although it is not well established that thyroid-pituitary imbalance leads to cancer in humans as it does in rodents, information in animals and in exposed humans suggests similar mechanisms of disrupting thyroid-pituitary function and the potential role of altered TSH levels in leading to thyroid carcinogenesis.

Structural Analogue Data

This chemical is an aromatic amine, a member of a class of chemicals that has regularly produced carcinogenic effects in rodents and gene and structural chromosome aberrations in short-term tests. Some aromatic amines have produced cancer in humans.

Close structural analogues produce thyroid follicular cell tumors in rats and hepatocellular tumors in mice following ingestion. The thyroid tumors are associated with known perturbations in thyroid-pituitary functioning. These compounds inhibit the use of iodide by the thyroid gland, apparently due to inhibition of the enzyme that synthesizes the thyroid hormones (T3, T4). Accordingly, blood levels of thyroid hormones decrease, which induce the pituitary gland to produce more TSH, a hormone that stimulates the thyroid to produce more of its hormones. The thyroid gland becomes larger due to increases in the size of individual cells and their proliferation and upon chronic administration, tumors develop. Thus, thyroid tumor development is significantly influenced by disruption in the thyroid-pituitary axis.

Other Key Data

The chemical can be absorbed by the oral, inhalation, and dermal routes of exposure.

MODE OF ACTION

Data on the chemical and on structural analogues indicate the potential association of carcinogenesis with perturbation of thyroid-pituitary homeostasis. Structural analogues are genotoxic, thus raising the possibility of different mechanisms by which this chemical may influence tumor development.

NARRATIVE #5

Brominated Alkane (BA)

CAS# XXX

CANCER HAZARD SUMMARY

Brominated alkane (BA) is likely to be a human carcinogen by all routes of exposure. The weight of evidence for human carcinogenicity is at the high end of agents in the "likely" group. Findings are based on very extensive and significant experimental findings that include (a) tumors at multiple sites in both sexes of two rodent species via three routes of administration relevant to human exposure, (b) close structural analogues that produce a spectrum of tumors like BA, (c) significant evidence for the production of reactive BA metabolites that readily bind to DNA and produce gene mutations in many systems including cultured mammalian and human cells, and

(d) two null and one positive epidemiologic study; in the positive study, there may have been exposure to BA. These findings support a decision that BA might produce cancer in exposed humans. In comparison to other agents considered likely human carcinogens, the overall weight of evidence for BA puts it near the top of the grouping. Given the agent's mutagenicity, which can influence the carcinogenic process, a linear dose-response extrapolation is recommended.

Uncertainties include the lack of adequate information on the mutagenicity of BA in mammals or humans *in vivo*, although such effects would be expected.

SUPPORTING INFORMATION

Human Data

The information on the carcinogenicity of BA from human studies is inadequate. Two studies of production workers have not shown significant increases in cancer from exposure to BA and other chemicals. An increase in lymphatic cancer was reported in a mortality study of grain elevator workers who may have been exposed to BA (and other chemicals).

Animal Data

BA produced tumors in four chronic rodent studies. Tumor increases were noted in males and females of rats and mice following oral dermal and inhalation exposure (rat—oral and two inhalation, mouse—oral and dermal). It produces tumors both at the site of application (e.g., skin with dermal exposure) and at sites distal to the portal of entry into the body (e.g., mammary gland) following exposure from each route. Tumors at the same site were noted in both sexes of a species (blood vessel), both species (forestomach) and via different routes of administration (lung). Some tumors developed after very short latency, metastasized extensively, and produced death, an uncommon findings in rodents. The rodent studies were well designed and conducted except for the oral studies, in which the doses employed caused excessive toxicity and mortality. However, given the other rodent findings, lower doses would also be anticipated to be carcinogenic.

Structural Analogue Data

Several chemicals structurally related to BA are also carcinogenic in rodents. Among four that are closest in structure, tumors like those seen for BA were often noted (e.g., forestomach, mammary, lung), which helps to confirm the findings for BA itself. In sum, all of the tumor findings help to establish animal carcinogenicity and support potential human carcinogenicity for BA.

Other Key Data

BA itself is not reactive, but from its structure it was expected to be metabolized to reactive forms. Extensive metabolism studies have confined this presumption and have demonstrated metabolites that bind to DNA and cause breaks in the DNA chain. These lesions are readily converted to gene mutations in bacteria, fungi, higher plants, insects and mammalian and human cells in culture. There are only a limited number of reports on the induction of chromosome aberrations in mammals and humans; thus far they are negative.

MODE OF ACTION

Human carcinogens often produce cancer in multiple sites of multiple animal species and both sexes and are mutagenic in multiple test systems. BA satisfies these findings. It produces cancer in males and females of rats and mice. It produces gene mutations in cells across all life forms—plants, bacteria and animals—including mammals and humans. Given the mutagenicity of BA exposure and the multiplicity and short latency of BA tumor induction, it is reasonable to use a linear approach for cancer dose-response extrapolation.

BRIEFING SUMMARY

Route(s)	Class	Designation or rationale	Dose response
All	Likely	High end	Default-linear.

Basis for classification/dose response

1. Human data: Two studies of production workers show no increase in cancer (one had a small sample size; the other had mixed chemical exposures). An increase in lymphatic cancer is seen among grain elevator workers who may have been exposed to other chemicals.

2. Animal data: BA produces tumors at multiple sites in male and female rats and mice following oral, dermal, and inhalation exposure. Tumors are seen at the site of administration and distally and are often consistent across sex, species, and route of administration; some develop early, metastasize, and cause death.

3. Structural analogue data: Close analogues produce some of the same tumors as are seen with BA.

4. Other key data: BA is metabolized to a reactive chemical that binds DNA and produces gene mutations in essentially every test system including cultured human cells.

5. Mode of action: Like most known human carcinogens, BA is mutagenic in most test systems.

6. Hazard classification/uncertainties: There is a rich database on BA demonstrating its potential ability to cause tumors in humans, including (a) multiple animal tumors, (b) by appropriate routes of exposure, (c) a mode of action relevant to human carcinogenicity, and (d) some information in humans. Together they lead to a designation near the high end of the *likely* human carcinogen class.

7. Dose response: Given the anticipated mode of action, a linear default dose response relationship should be assumed.

Appendix B

This appendix contains responses to the National Academy of Sciences National Research Council report *Science and Judgment in Risk Assessment* (NRC, 1994).

Recommendations of the National Academy of Sciences National Research Council

In 1994, the National Academy of Sciences published a report *Science and Judgment in Risk Assessment*. The 1994 report was

written by a Committee on Risk Assessment of Hazardous Air Pollutants formed under the Academy's Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council. The report was called for under Section 112(o)(1)(A,B) of the Clean Air Act Amendments of 1990, which provided for the EPA to arrange for the Academy to review:

- risk assessment methodology used by the EPA to determine the carcinogenic risk associated with exposure to hazardous air pollutants from source categories and subcategories subject to the requirements of this section and

- improvements in such methodology.

Under Section 112(o)(2)(A,B), the Academy was to consider the following in its review:

- the techniques used for estimating and describing the carcinogenic potency to humans of hazardous air pollutants and
- the techniques used for estimating exposure to hazardous air pollutants (for hypothetical and actual maximally exposed individuals as well as other exposed individuals).

To the extent practicable, the Academy was also to review methods of assessing adverse human health effects other than cancer for which safe thresholds of exposure may not exist [Section 112(o)(3)]. The Congress further provided that the EPA Administrator should consider, but need not adopt, the recommendations in the report and the views of the EPA Science Advisory Board with respect to the report. Prior to the promulgation of any standards under Section 112(f), the Administrator is to publish revised guidelines for carcinogenic risk assessment or a detailed explanation of the reasons that any recommendations contained in the report will not be implemented [Section 112(o)(6)].

The following discussion addresses the recommendations of the 1994 report that are pertinent to the EPA cancer risk assessment guidelines. Guidelines for assessment of exposure, of mixtures, and of other health effects are separate EPA publications. Many of the recommendations were related to practices specific to the exposure assessment of hazardous air pollutants, which are not covered in cancer assessment guidelines. Recommendations about these other guidelines or practices are not addressed here.

Hazard Classification

The 1994 report contains the following recommendation about classifying cancer hazard:

- The EPA should develop a two-part scheme for classifying evidence on carcinogenicity that would incorporate both a simple classification and a narrative evaluation. At a minimum, both parts should include the strength (quality) of the evidence, the relevance of the animal model and results to humans, and the relevance of the experimental exposures (route, dose, timing, and duration) to those likely to be encountered by humans.

The report also presented a possible matrix of 24 boxes that would array weights of evidence against low, medium, or high relevance, resulting in 24 codes for expressing the weight and relevance.

These guidelines adopt a set of descriptors and subdescriptors of weight of evidence in three categories: "known/likely," "cannot be determined," and "not likely," and a narrative for presentation of the weight of evidence findings. The descriptors are used within the narrative. There is no matrix of alphanumeric weight of evidence boxes.

The issue of an animal model that is not relevant to humans has been dealt with by not including an irrelevant response in the weighing of evidence, rather than by creating a weight of evidence then appending a discounting factor as the NRC scheme would do. The issue is more complex than the NRC matrix makes apparent. Often the question of relevance of the animal model applies to a single tumor response, but one encounters situations in which there are more tumor responses in animals than the questioned one. Dealing with this complexity is more straightforward if it is done during the weighing of evidence rather than after as in the NRC scheme. Moreover, the same experimental data are involved in deciding on the weight of evidence and the relevance of a response. It would be awkward to go over the same data twice.

In recommending that the relevance of circumstances of human exposure also be taken into account, the NRC appears to assume that all of the actual conditions of human exposure will be known when the classification is done. This is not the case. More often than not, the hazard assessment is applied to assessment of risks associated with exposure to different media or environments at different times. In some cases, there is no priority to obtaining exposure data until the hazard assessment has been done. The approach of these guidelines is to characterize hazards as to whether their expression is intrinsically limited by route of exposure or by reaching a particular dose range based strictly on toxicological and other biological features of the agent. Both the use of descriptors and the narrative specifically capture this information. Other aspects of appropriate application of the hazard and dose response assessment to particular human exposure scenarios are dealt with in the characterization of the dose response assessment, e.g., the applicability of the dose response assessment to scenarios with differing frequencies and durations.

The NRC scheme apparently intended that the evidence would be weighed, then given a low, medium, or high code for some combination of relevance of the animal response, route of exposure, timing, duration, or frequency. The 24 codes contain none of this specific information, and in fact, do not communicate what the conclusion is about. To make the codes communicate the information apparently intended would require some multiple of the 24 in the NRC scheme. As the number of codes increases, their utility for communication decreases.

Another reason for declining to use codes is that they tend to become outdated as research reveals new information that was not contemplated when they were adopted. This has been the case with the classification system under the EPA, 1986 guidelines.

Even though these guidelines do not adopt a matrix of codes, the method they provide

of using descriptors and narratives captures the information the NRC recommended as the most important, and in the EPA's view, in a more transparent manner.

Dose Response

• The 1994 report contains the following recommendations about dose response issues:

- EPA should continue to explore, and when scientifically appropriate, incorporate toxicokinetic models of the link between exposure and biologically effective dose (i.e., dose reaching the target tissue).

- Despite the advantages of developing consistent risk assessments between agencies by using common assumptions (e.g., replacing surface area with body weight to the 0.75 power), EPA should indicate other methods, if any, that would be more accurate.

- EPA should continue to use the linearized multistage model as a default option but should develop criteria for determining when information is sufficient to use an alternative extrapolation model.

- EPA should continue to use as one of its risk characterization metrics upper-bound potency estimates of the probability of developing cancer due to lifetime exposure. Whenever possible, this metric should be supplemented with other descriptions of cancer potency that might more adequately reflect the uncertainty associated with the estimates.

- EPA should adopt a default assumption for differences in susceptibility among humans in estimating individual risks.

- In the analysis of animal bioassay data on the occurrence of multiple tumor types, the cancer potencies should be estimated for each relevant tumor type that is related to exposure and the individual potencies should be summed for those tumors.

The use of toxicokinetic models is encouraged in these guidelines with discussion of appropriate considerations for their use. When there are questions as to whether such a model is more accurate in a particular case than the default method for estimating the human equivalent dose, both alternatives may be used. It should be noted that the default method for inhalation exposure is a toxicokinetic model.

The rationale for adopting the oral scaling factor of body weight to the 0.75 power has been discussed above in the explanation of major defaults. The empirical basis is further explored in U.S. EPA, 1992b. The more accurate approach is to use a toxicokinetic model when data become available or to modify the default when data are available as encouraged under these guidelines. As the U.S. EPA, 1992b discussion explores in depth, data on the differences among animals in response to toxic agents are basically consistent with using a power of 1.0, 0.75, or 0.66. The Federal agencies chose the power of 0.75 for the scientific reasons given in the previous discussion of major defaults; these were not addressed specifically in the NRC report. It was also considered appropriate, as a matter of policy, for the agencies to agree on one factor. Again, the default for inhalation exposure is a model that is constructed to become better as more agent-specific data become available.

The EPA proposes not to use a computer model such as the linearized multistage model as a default for extrapolation below the observed range. The reason is that the basis for default extrapolation is a theoretical projection of the likely shape of the curve considering mode of action. For this purpose, a computer model looks more sophisticated than a straight line extrapolation, but is not. The extrapolation will be by straight line as explained in the explanation of major defaults. This was also recommended by workshop reviewers of a previous draft of these guidelines (U.S. EPA, 1994b). In addition, a margin of exposure analysis is proposed to be used in cases in which the curve is thought to be nonlinear, based on mode of action. In both cases, the observed range of data will be modeled by curve fitting in the absence of supporting data for a biologically based or case-specific model.

The result of using straight line extrapolation is thought to be an upper bound on low-dose potency to the human population in most cases, but as discussed in the major defaults section, it may not always be. Exploration and discussion of uncertainty of parameters in curve-fitting a model of the observed data or in using a biologically based or case-specific model is called for in the dose response assessment and characterization sections of these guidelines.

The issue of a default assumption for human differences in susceptibility has been addressed under the major defaults discussion in section 1.3 with respect to margin of exposure analysis. The EPA has considered but decided not to adopt a quantitative default factor for human differences in susceptibility when a linear extrapolation is used. In general, the EPA believes that the linear extrapolation is sufficiently conservative to protect public health. Linear approaches (both LMS and straight line extrapolation) from animal data are consistent with linear extrapolation on the same agents from human data (Goodman and Wilson, 1991; Hoel and Portier, 1994). If actual data on human variability in sensitivity are available they will, of course, be used.

In analyzing animal bioassay data on the occurrence of multiple tumor types, these guidelines outline a number of biological and other factors to consider. The objective is to use these factors to select response data (including nontumor data as appropriate) that best represent the biology observed. As stated in section 3 of the guidelines, appropriate options include use of a single data set, combining data from different experiments, showing a range of results from more than one data set, showing results from analysis of more than one tumor response based on differing modes of action, representing total response in a single experiment by combining animals with tumors, or a combination of these options. The approach judged to best represent the data is presented with the rationale for the judgment, including the biological and statistical considerations involved. The EPA has considered the approach of summing tumor incidences and decided not to adopt it. While multiple tumors may be independent, in the sense of not arising from

metastases of a single malignancy, it is not clear that they can be assumed to represent different effects of the agent on cancer processes. In this connection, it is not clear that summing incidences provides a better representation of the underlying mode(s) of action of the agent than combining animals with tumors or using another of the several options noted above. Summing incidences would result in a higher risk estimate, a step that appears unnecessary without more reason.

Risk Characterization

- When EPA reports estimates of risk to decisionmakers and the public, it should present not only point estimates of risk, but also the sources and magnitudes of uncertainty associated with these estimates.

- Risk managers should be given characterizations of risk that are both qualitative and quantitative, i.e., both descriptive and mathematical.

- EPA should consider in its risk assessments the limits of scientific knowledge, the remaining uncertainties, and the desire to identify errors of either overestimation or underestimation.

In part as a response to these recommendations, the Administrator of EPA issued guidelines for risk characterization and required implementation plans for all programs in EPA (U.S. EPA, 1995). The Administrator's guidance is followed in these cancer guidelines. The assessments of hazard, dose response, and exposure will all have accompanying technical characterizations covering issues of strengths and limitations of data and current scientific understanding, identification of defaults utilized in the face of gaps in the former, discussions of controversial issues, and discussions of uncertainties in both their qualitative, and as practicable, their quantitative aspects.

Appendix C

Overview of Cancer Processes

The following picture is changing as research reveals more about carcinogenic processes. Nevertheless, it is apparent that several general modes of action are being elucidated from direct reaction with DNA to hormonal or other growth-signaling processes. While the exact mechanism of action of an agent at the molecular level may not be clear from existing data, the available data will often provide support for deducing the general mode of action. Under these guidelines, using all of the available data to arrive at a view of the mode of action supports both characterization of human hazard potential and assessment of dose response relationships.

Cancers are diseases of somatic mutation affecting cell growth and differentiation. The genes that control cell growth, programmed cell death, and cell differentiation are critical to normal development of tissues from embryo to adult metazoan organisms. These genes continue to be critical to maintenance of form and function of tissues in the adult (e.g., Meyn, 1993) and changes in them are essential elements of carcinogenesis (Hsu et al., 1991; Kakizuka et al., 1991; Bottaro et al., 1991; Sidransky et al., 1991; Salomon et al.,

1990; Srivastava et al., 1990). The genes involved are among the most highly conserved in evolution as evidenced by the great homology of many of them in DNA sequence and function in organisms as phylogenetically distant as worms, insects, and mammals (Auger et al., 1989a, b; Hollstein et al., 1991; Herschman, 1991; Strausfeld et al., 1991; Forsburg and Nurse, 1991).

Mutations affecting three general categories of genes have been implicated in carcinogenesis. Over 100 oncogenes have been found in human and animal tumors that act as dominant alleles, whereas there are about 10 known tumor suppressor genes that are recessive in action. The normal alleles of these genes are involved with control of cell division and differentiation; mutated alleles lead to a disruption in these functions. The third class are mutator genes that predispose the genome to enhanced mutagenic events that contribute further to the carcinogenic process.

Adult tissues, even those that are composed of rapidly replicating cells, maintain a constant size and cell number (Nunez et al., 1991) by balancing three cell fates: (1) continued replication, (2) differentiation to take on specialized functions, or (3) programmed cell death (apoptosis) (Raff, 1992; Maller, 1991; Naeve et al., 1991; Schneider et al., 1991; Harris, 1990). Neoplastic growth through clonal expansion can result from somatic mutations that inactivate control over cell fate (Kakizuka et al., 1991; deThe et al., 1991; Sidransky et al., 1992; Nowell, 1976).

Cancers may also be thought of as diseases of the cell cycle. For example, genetic diseases that cause failure of cells to repair DNA damage prior to cell replication predispose people to cancer. These changes are also frequently found in tumor cells in sporadic cancers. These changes appear to be particularly involved at points in cell replication called "checkpoints" where DNA synthesis or mitosis is normally stopped until DNA damage is repaired or cell death induced (Tobey, 1975). A cell that bypasses a checkpoint may acquire a heritable growth advantage. Similar effects on the cell cycle occur when mitogens such as hormones or growth factors stimulate cell growth. Rapid replication in response to tissue injury may also lead to unrepaired DNA damage that is a risk factor for carcinogenesis.

Normally a cell's fate is determined by a timed sequence of biochemical signals. Signal transduction in the cell involves chemical signals that bind to receptors, generating further signals in a pathway whose target in many cases is control of transcription of a specific set of genes (Hunter, 1991; Cantley et al., 1991; Collum and Alt, 1990). Cells are subject to growth signals from the same and distant tissues, e.g., endocrine tissues (Schuller, 1991). In addition to hormones produced by endocrine tissues, numerous soluble polypeptide growth factors have been identified that control normal growth and differentiation (Cross and Dexter, 1991; Wellstein et al., 1990). The cells responsive to a particular growth factor are those that express transmembrane receptors that specifically bind the growth factor.

Solid tumors develop in stages operationally defined as initiation, promotion, and progression (see, for example, Pitot and Dragan, 1991). These terms, which were coined in the context of specific experimental designs, are used for convenience in discussing concepts, but they refer to complex events that are not completely understood. During initiation, the cell acquires a genetic change that confers a potential growth advantage. During promotion, clonal expansion of this altered cell occurs. Later, during progression, a series of genetic and other biological events both enhance the growth advantage of the cells and enlist normal host processes to support tumor development and cells develop the ability to invade locally and metastasize distally, taking on the characteristics of malignancy. Many endogenous and exogenous factors are known to participate in the process as a whole. These include specific genetic predispositions or variations in ability to detoxify agents, medical history (Harris, 1989; Nebreda et al., 1991), infections, exposure to chemicals or ionizing radiation, hormones and growth factors, and immune suppression. Several such risk factors likely work together to cause individual human cancers.

A cell that has been transformed, acquiring the potential to establish a line of cells that grow to a tumor, will probably realize that potential only rarely. The process of tumorigenesis in animals and humans is a multistep one (Bouk, 1990; Fearon and Vogelstein, 1990; Hunter, 1991; Kumar et al., 1990; Sukumar, 1989; Sukumar, 1990) and normal physiological processes appear to be arrayed against uncontrolled growth of a transformed cell (Weinberg, 1989). Powerful inhibition by signals from contact with neighboring normal cells is one known barrier (Zhang et al., 1992). Another is the immune system (at least for viral infection). How a cell with tumorigenic potential acquires additional properties that are necessary to enable it to overcome these and other inhibitory processes is a subject of ongoing research. For known human carcinogens studied thus far, there is an often decades-long latency between exposure to carcinogenic agents and development of tumors (Fidler and Radinsky, 1990; Tanaka et al., 1991; Thompson et al., 1989). This latency is also typical of tumor development in individuals with genetic diseases that make them prone to cancer (Meyn, 1993; Srivastava et al., 1990).

The importance of genetic mutation in the carcinogenic process calls for special attention to assessing agents that cause such mutations. Heritable genetic defects that predispose humans to cancer are well known and the number of identified defects is growing. Examples include xeroderma pigmentosum (DNA repair defect) and Li Fraumeni and retinoblastoma (both are tumor suppressor gene mutations). Much of the screening and testing of agents for carcinogenic potential has been driven by the idea of identifying this mode of action. Cognizance of and emphasis on other modes of action such as ones that act at the level of growth signalling within or between cells, through cell receptors, or that indirectly

cause genetic change, comes from more recent research. There are not yet standardized tests for many modes of action, but pertinent information may be available in individual cases.

Agents of differing characteristics influence cancer development: inorganic and organic, naturally occurring and synthetic, of inanimate or animate origin, endogenous or exogenous, dietary and nondietary. The means by which these agents act to influence carcinogenesis are variable, and reasoned hazard assessment requires consideration of the multiple ways that chemicals influence cells in experimental systems and in humans. Agents exert mutagenic effects either by interacting directly with DNA or by indirect means through intermediary substances (e.g., reactive oxygen species) or processes. Most DNA-reactive chemicals are electrophilic or can become electrophilic when metabolically activated. Electrophilic molecules may bind covalently to DNA to form adducts, and this may lead to depurination, depyrimidation, or produce DNA strand breaks; such lesions can be converted to mutations with a round of DNA synthesis and cell division. Other DNA-interactive chemicals may cause the same result by intercalation into the DNA helix. Still other chemicals may methylate DNA, changing gene expression. Non-DNA-reactive chemicals produce genotoxic effects by many different processes. They may affect spindle formation or chromosome proteins, interfere with normal growth control mechanisms, or affect enzymes involved with ensuring the fidelity of DNA synthesis (e.g., topoisomerase), recombination, or repair.

The "classical" chemical carcinogens in laboratory rodent studies are agents that consistently produce gene mutations and structural chromosome aberrations in short-term tests. A large database reveals that these mutagenic substances commonly produce tumors at multiple sites and in multiple species (Ashby and Tennant, 1991). Most of the carcinogens identified in human studies, aside from hormones, are also gene or structural chromosome mutagens (Tennant and Ashby, 1991). Most of these compounds or their metabolites contain electrophilic moieties that react with DNA.

Numerical chromosome aberrations, gene amplification, and the loss of gene heterozygosity are also found in animal and human tumor cells and may arise from initiating events or during progression. There is reason to believe that accumulation of additional genetic changes is favored by selection in the evolution of tumor cells because they confer additional growth advantages (Hartwell and Kastan, 1994). Exogenous agents may function at any stage of carcinogenesis (Barrett, 1993). Some aberrations may arise as a consequence of genomic instability arising from tumor suppressor gene mutation, e.g., p53 (Harris and Hollstein, 1993). The frequent observation in tumor cells that both of a pair of homologous chromosomes have identical mutation spectra in tumor suppressor genes suggests an ongoing, endogenous process of gene conversion. Currently, there is a paucity of routine test methods to screen for events such as gene conversion or gene amplification and knowledge regarding the

ability of particular agents of environmental interest to induce them is, for the most part, wanting. Work is under way to characterize, measure, and evaluate their significance (Travis et al., 1991).

Several kinds of mechanistic studies aid in risk assessment. Comparison of DNA lesions in tumor cells taken from humans with the lesions that a tumorigenic agent causes in experimental systems can permit inferences about the association of exposure to the agent and an observed human effect (Vahakangas et al., 1992; Hollstein et al., 1991; Hayward et al., 1991). An agent that is observed to cause mutations experimentally may be inferred to have potential for carcinogenic activity (U.S. EPA, 1991a). If such an agent is shown to be carcinogenic in animals, the inference that its mode of action is through mutagenicity is strong. A carcinogenic agent that is not mutagenic in experimental systems but is mitogenic or affects hormonal levels or causes toxic injury followed by compensatory growth may be inferred to have effects on growth signal transduction or to have secondary carcinogenic effects. The strength of these inferences depends in each case on the nature and extent of all the available data.

Differing modes of action at the molecular level have different dose response implications for the activity of agents. The carcinogenic activity of a direct-acting mutagen should be a function of the probability of its reaching and reacting with DNA. The carcinogenic activity of an agent that interferes at the level of signal pathways with many potential receptor targets should be a function of multiple reactions. The carcinogenic activity of an agent that acts by causing cell toxicity followed by compensatory growth should be a function of the toxicity.

References

- Alison, R.H.; Capen, C.C.; Prentice, D.E. (1994) Neoplastic lesions of questionable significance to humans. *Toxicol. Pathol.* 22: 179-186.
- Allen, B.C.; Crump, K.S.; Shipp, A.M. (1988) Correlation between carcinogenic potency of chemicals in animals and humans. *Risk Anal.* 8: 531-544.
- Ames, B.N.; Gold, L.S. (1990) Too many rodent carcinogens: mitogenesis increases mutagenesis. *Science* 249: 970-971.
- Anderson, E.; Deisler, P.F.; McCallum, D.; St. Helaire, C.; Spitzer, H.L.; Strauss, H.; Wilson, J.D.; Zimmerman, R. (1993) Key issues in carcinogen risk assessment guidelines. Society for Risk Analysis.
- Ashby, J.; Tennant, R.W. (1991) Definitive relationships among chemical structure, carcinogenicity and mutagenicity for 301 chemicals tested by the U.S. NTP. *Mutat. Res.* 257: 229-306.
- Ashby, J.; Tennant, R.W. (1994) Prediction of rodent carcinogenicity for 44 chemicals: results. *Mutagenesis* 9: 7-15.
- Ashby, J.; Doerr, N.G.; Flamm, F.G.; Harris, J.E.; Hughes, D.H.; Johannsen, F.R.; Lewis, S.C.; Krivanek, N.D.; McCarthy, J.F.; Moolenaar, R.J.; Raabe, G.K.; Reynolds, R.C.; Smith, J.M.; Stevens, J.T.; Teta, M.J.; Wilson, J.D. (1990) A scheme for classifying carcinogens. *Regul. Toxicol. Pharmacol.* 12: 270-295.
- Ashby, J.; Brady, A.; Elcombe, C.R.; Elliott, B.M.; Ishmael, J.; Odum, J.; Tugwood, D.; Kettle, S.; Purchase, I.F.H. (1994) Mechanistically based human hazard assessment of peroxisome proliferator-induced hepatocarcinogenesis. *Hum. Exper. Toxicol.* 13: 1-117.
- Auger, K.R.; Carpenter, C.L.; Cantley, L.C.; Varticovski, L. (1989a) Phosphatidylinositol 3-kinase and its novel product, phosphatidylinositol 3-phosphate, are present in *Saccharomyces cerevisiae*. *J. Biol. Chem.* 264: 20181-20184.
- Auger, K.R.; Sarunian, L.A.; Soltoff, S.P.; Libby, P.; Cantley, L.C. (1989b) PDGF-dependent tyrosine phosphorylation stimulates production of novel polyphosphoinositides in intact cells. *Cell* 57: 167-175.
- Barnes, D.G.; Daston, G.P.; Evans, J.S.; Jarabek, A.M.; Kavlock, R.J.; Kimmel, C.A.; Park, C.; Spitzer, H.L. (1995) Benchmark dose workshop: criteria for use of a benchmark dose to estimate a reference dose. *Regul. Toxicol. Pharmacol.* 21: 296-306.
- Barrett, J.C. (1992) Mechanisms of action of known human carcinogens. In: Mechanisms of carcinogenesis in risk identification. IARC Sci. Pubs. No. 116, Lyon, France: International Agency for Research on Cancer; 115-134.
- Barrett, J.C. (1993) Mechanisms of multistep carcinogenesis and carcinogen risk assessment. *Environ. Health Perspect.* 100: 9-20.
- Barrett, J.C. (1995) Role of mutagenesis and mitogenesis in carcinogenesis. *Environ. Mutagenesis*, in press.
- Barrett, J. C.; Lee, T. C. (1992) Mechanisms of arsenic-induced gene amplification. In: Gene amplification in mammalian cells: A comprehensive guide (ed. R. E. Kellems), Marcel Dekker, New York: 441-446.
- Bayly, A.C.; Roberts, R.A.; Dive, C. (1994) Suppression of liver cell apoptosis in vitro by the nongenotoxic hepatocarcinogen and peroxisome proliferator nafenopin. *J. Cell. Biol.* 125: 197-203.
- Bellamy, C.O.C.; Malcomson, R.D.G.; Harrison, D.J.; Wyllie, A.H. (1995) Cell death in health and disease: The biology and regulation of apoptosis. *Seminars in cancer biology, Apoptosis in oncogenesis and chemotherapy* 6: 3-16.
- Bianchi, A.B.; Navone, N.M.; Alda, C.M.; Conti, C.J. (1991) Overlapping loss of heterozygosity by mitotic recombination on more chromosome 7F1-ter in skin carcinogenesis. *Proc. Nat. Acad. Sci.* 88: 7590-7594.
- Biggs, P.J.; Warren, W.; Venitt, S.; Stratton, M.R. (1993) Does a genotoxic carcinogen contribute to human breast cancer? The value of mutational spectra in unraveling the etiology of cancer. *Mutagenesis* 8: 275-283.
- Birner et al. (1990) Biomonitoring of aromatic amines. III: Hemoglobin binding and benzidine and some benzidine congeners. *Arch. Toxicol.* 64(2): 97-102.
- Blair, A.; Burg, J.; Foran, J.; Gibb, H.; Greenland, S.; Morris, R.; Raabe, G.; Savitz, D.; Teta, J.; Wartenberg, D.; Wong, O.; Zimmerman, R. (1995) Guidelines for application of meta-analysis in environmental epidemiology. *Regul. Toxicol. Pharmacol.* 22: 189-197.
- Bois, F.Y.; Krowech, G.; Zeise, L. (1995) Modeling human interindividual variability in metabolism and risk: the example of 4-aminobiphenyl. 15: 205-213.
- Bottaro, D.P.; Rubin, J.S.; Faletto, D.L.; Chan, A.M.L.; Kmiec, T.E.; Vande Woude, G.F.; Aaronson, S.A. (1991) Identification of the hepatocyte growth factor receptor as the c-met proto-oncogene product. *Science* 251: 802-804.
- Bouck, N. (1990) Tumor angiogenesis: the role of oncogenes and tumor suppressor genes. *Cancer Cells* 2: 179-183.
- Burek, J.D.; Patrick, D.H.; Gerson, R.J. (1988) Weight-of-biological evidence approach for assessing carcinogenicity. In: Grice, H.C.; Cimino, J.L., eds. *Carcinogenicity*. New York, NY: Springer Verlag; pp. 83-95.
- Bus, J.S.; Popp, J.A. (1987) Perspectives on the mechanism of action of the splenic toxicity of aniline and structurally related compounds. *Fd. Chem. Toxicol.* 25: 619-626.
- Callemen, C.J.; Ehrenberg, L.; Jansson, B.; Osterman-Golkar, S.; Segerback, D.; Svensson, K.; Wachtmeister, C.A. (1978) Monitoring and risk assessment by means of alkyl groups in hemoglobin in persons occupationally exposed to ethylene oxide. *J. Environ. Pathol. Toxicol.* 2: 427-442.
- Cantley, L.C.; Auger, K.R.; Carpenter, C.; Duckworth, B.; Graziani, A.; Kapeller, R.; Soltoff, S. (1991) Oncogenes and signal transduction. *Cell* 64: 281-302.
- Caporaso, N.; Hayes, R.B.; Dosemeci, M.; Hoover, R.; Ayesh, R.; Hetzel, M.; Idle, J. (1989) Lung cancer risk, occupational exposure, and the debrisoquine metabolic phenotype. *Cancer Res.* 49: 3675-3679.
- Cavene, W.K.; Koufos, A.; Hansen, M. F. (1986) Recessive mutant genes predisposing to human cancer. *Mutation Research* 168: 3-14.
- Chang, C.C.; Jone, C.; Trosko, J. E.; Peterson, A. R.; Sevanian, A. (1988) Effect of cholesterol epoxides on the inhibition of intercellular communication and on mutation induction in Chinese hamster V79 cells. *Mutation Research* 206: 471-478.

- Chen, C.; Farland, W. (1991) Incorporating cell proliferation in quantitative cancer risk assessment: approaches, issues, and uncertainties. In: Butterworth, B.; Slaga, T.; Farland, W.; McClain, M., eds. Chemical induced cell proliferation: Implications for risk assessment. New York, NY: Wiley-Liss; pp. 481–499.
- Choy, W.N. (1993) A review of the dose-response induction of DNA adducts by aflatoxin B₂ and its implications to quantitative cancer-risk assessment. *Mutat. Res.* 296: 181–198.
- Clayson, D.B. (1989) Can a mechanistic rationale be provided for non-genotoxic carcinogens identified in rodent bioassays? *Mutat. Res.* 221: 53–67.
- Clayson, D.B.; Mehta, R.; Iverson, F. (1994) Oxidative DNA damage—The effects of certain genotoxic and operationally non-genotoxic carcinogens. *Mutat. Res.* 317: 25–42.
- Cogliano, V.J. (1986) The U.S. EPA's methodology for adjusting the reportable quantities of potential carcinogens. Proceedings of the 7th National Conference on Management of Uncontrollable Hazardous Wastes (Superfund '86). Washington, DC: Hazardous Wastes Control Institute, 182–185.
- Cohen, S.W.; Ellwein, L.B. (1990) Cell proliferation in carcinogenesis. *Science* 249: 1007–1011.
- Cohen, S.M.; Ellwein, L.B. (1991) Genetic errors, cell proliferation and carcinogenesis. *Cancer Res.* 51: 6493–6505.
- Cohen, S.M.; Purtilo, D.T.; Ellwein, L.B. (1991) Pivotal role of increased cell proliferation in human carcinogenesis. *Mod. Pathol.* 4: 371–375.
- Collum, R.G.; Alt, F.W. (1990) Are myc proteins transcription factors? *Cancer Cells* 2: 69–73.
- Connolly, R.B.; Andersen, M.E. (1991) Biologically based pharmacodynamic models: tools for toxicological research and risk assessment. *Ann. Rev. Pharmacol. Toxicol.* 31: 503–523.
- Cross, M.; Dexter, T. (1991) Growth factors in development, transformation, and tumorigenesis. *Cell* 64: 271–280.
- D'Souza, R.W.; Francis, W.R.; Bruce, R.D.; Andersen, M.E. (1987) Physiologically based pharmacokinetic model for ethylene chloride and its application in risk assessment. In: Pharmacokinetics in risk assessment. Drinking Water and Health. Vol. 8. Washington, DC: National Academy Press.
- deThe, H.; Lavau, C.; Marchio, A.; Chomienne, C.; Degos, L.; Dejean, A. (1991) The PML-RAR α fusion mRNA generated by the t(15;17) translocation in acute promyelocytic leukemia encodes a functionally altered RAR. *Cell* 66: 675–684.
- Enterline, P.E.; Henderson, V.L.; Marsh, G.M. (1987) Exposure to arsenic. *Amer. J. Epidemiol.* 125: 929–938.
- European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). (1991) Early indicators of non-genotoxic carcinogenesis. ECETOC Monograph No. 16. Brussels: ECETOC. Printed in *Mutat. Res.* 248: 211–374.
- Faustman, E.M.; Allen, B.C.; Kavlock, R.J.; Kimmel, C.A. (1994) Dose-response assessment for developmental toxicity. *Fund. Appl. Toxicol.* 23: 478–486.
- Fearon, E.; Vogelstein, B. (1990) A genetic model for colorectal tumorigenesis. *Cell* 61: 959–967.
- Federated Association of Societies of Experimental Biology (FASEB) (1994) Evaluation of evidence for the carcinogenicity of butylated hydroxyanisole (BHA). Life Sciences Research Office, Bethesda, MD. Letter from Hamilton Brown (FDA) to John Rice (FASEB), July 28, 1994. Letter from John Rice (FASEB) to Ed Arnold (FDA), August 4, 1994.
- Fidler, I.J.; Radinsky, R. (1990) Genetic control of cancer metastasis. *J. Natl. Cancer Inst.* 82: 166–168.
- Fisher, R.A. (1950) Statistical methods for research workers. Edinborough, Scotland: Oliver and Boyd.
- Flamm, W.G.; Winbush, J.S. (1984) Role of mathematical models in assessment of risk and in attempts to define management strategy. *Fund. Appl. Toxicol.* 4: S395–S401.
- Flynn, G.L. (1990) Physicochemical determinants of skin absorption. In: Gerrity, T.R.; Henry, C.J., eds. Principles of route to route extrapolation for risk assessment. New York, NY: Elsevier Science Publishing Co.; pp. 93–127.
- Forsburg, S.L.; Nurse, P. (1991) Identification of a G1-type cyclin pug1+ in the fission yeast *Schizosaccharomyces pombe*. *Nature* 351: 245–248.
- Garfinkel, L.; Silverberg, E. (1991) Lung cancer and smoking trends in the United States over the past 25 years. *Cancer* 41: 137–145.
- Gaylor, D.W.; Kodell, R.L. (1980) Linear interpolation algorithm for low-dose risk assessment of toxic substances. *J. Environ. Pathol. Toxicol.* 4: 305–312.
- Gerrity, T.R.; Henry, C., eds. (1990) Principles of route to route extrapolation for risk assessment. New York, NY: Elsevier Science Publishing Co.
- Gibson, D.P.; Aardema, M.J.; Kerckaert, G.A.; Carr, G.J.; Brauning, R.M.; LeBoeuf, R.A. (1995) Detection of aneuploidy-inducing carcinogens in the Syrian hamster embryo (SHE) cell transformation assay. *Mutat. Res.; Genet. Toxicol.* 343: 7–24.
- Gillette, J.R. (1983) The use of pharmacokinetics in safety testing. In: Homburger, ed. Safety evaluation and regulation of chemicals 2. 2nd Int. Conf., Cambridge, MA: Karger, Basel; pp. 125–133.
- Goldsworthy, T.L.; Hanigan, M.H.; and Pitot, H.C. (1986) Models of hepatocarcinogenesis in the rat—contrasts and comparisons. *CRC Crit. Rev. Toxicol.* 17: 61–89.
- Goodman, G.; Wilson, R. (1991) Predicting the carcinogenicity of chemicals in humans from rodent bioassay data. *Environ. Health Perspect.* 94: 195–218.
- Goodman, J.I.; Counts, J.L. (1993) Hypomethylation of DNA: A possible nongenotoxic mechanism underlying the role of cell proliferation in carcinogenesis. *Environ. Health Perspect.* 101 Suppl. 5: 169–172.
- Goodman, J.I.; Ward, J.M.; Popp, J.A.; Klaunig, J.E.; Fox, T.R. (1991) Mouse liver carcinogenesis: Mechanisms and relevance. *Fund. Appl. Toxicol.* 17: 651–665.
- Grasso, P.; Hinton, R.H. (1991) Evidence for and possible mechanisms of non-genotoxic carcinogenesis in rodent liver. *Mutat. Res.* 248: 271–290.
- Greenland, S. (1987) Quantitative methods in the review of epidemiologic literature. *Epidemiol. Rev.* 9: 1–29.
- Hammond, E.C. (1966) Smoking in relation to the death rates of one million men and women. In: Haenzel, W., ed. Epidemiological approaches to the study of cancer and other chronic diseases. National Cancer Institute Monograph No. 19. Washington, DC.
- Harris, C.C. (1989) Interindividual variation among humans in carcinogen metabolism, DNA adduct formation and DNA repair. *Carcinogenesis* 10: 1563–1566.
- Harris, C.C.; Hollstein, M. (1993) Clinical implications of the p53 tumor suppressor gene. *N. Engl. J. Med.* 329: 1318–1327.
- Harris, H. (1990) The role of differentiation in the suppression of malignancy. *J. Cell Sci.* 97: 5–10.
- Hartwell, L.H.; Kastan, M.B. (1994) Cell cycle control and cancer. *Science* 266: 1821–1828.
- Haseman, J.K. (1983) Issues: a reexamination of false-positive rates for carcinogenesis studies. *Fund. Appl. Toxicol.* 3: 334–339.
- Haseman, J.K. (1984) Statistical issues in the design, analysis and interpretation of animal carcinogenicity studies. *Environ. Health Perspect.* 58: 385–392.
- Haseman, J.K. (1985) Issues in carcinogenicity testing: dose selection. *Fund. Appl. Toxicol.* 5: 66–78.
- Haseman, J.K. (1990) Use of statistical decision rules for evaluating laboratory animal carcinogenicity studies. *Fund. Appl. Toxicol.* 14: 637–648.
- Haseman, J.K. (1995) Data analysis: Statistical analysis and use of historical control data. *Regul. Toxicol. Pharmacol.* 21: 52–59.
- Haseman, J.K.; Huff, J.; Boorman, G.A. (1984) Use of historical control data in carcinogenicity studies in rodents. *Toxicol. Pathol.* 12: 126–135.
- Hattis, D. (1990) Pharmacokinetic principles for dose-rate extrapolation of carcinogenic risk from genetically active agents. *Risk Anal.* 10: 303–316.
- Havu, N.; Mattsson, H.; Ekman, L.; Carlsson, E. (1990) Enterochromaffin-like cell carcinoids in the rat gastric mucosa following long-term administration of ranitidine. *Digestion* 45: 189–195.

- Hayward, N.K.; Walker, G.J.; Graham, W.; Cooksley, E. (1991) Hepatocellular carcinoma mutation. *Nature* 352: 764.
- Hayward, J.J.; Shane, B.S.; Tindall, K.R.; Cunningham, M.L. (1995) Differential in vivo mutagenicity of the carcinogen-narcarcinogen pair 2,4- and 2,6-diaminotoluene. *Carcinogenesis*. In press.
- Herschman, H.R. (1991) Primary response genes induced by growth factors or promoters. *Ann. Rev. Biochem.* 60: 281–319.
- Hill, R.N.; Erdreich, L.S.; Paynter, O.E.; Roberts, P.A.; Rosenthal, S.L.; Wilkinson, C.F. (1989) Thyroid follicular cell carcinogenesis. *Fund. Appl. Toxicol.* 12: 629–697.
- Hoel, D.G.; Portier, C.J. (1994) Nonlinearity of dose-response functions for carcinogenicity. *Environ. Health Perspect.* 102 Suppl 1: 109–113.
- Hoel, D.G.; Haseman, J.K.; Hogam, M.D.; Huff, J.; McConnell, E.E. (1988) The impact of toxicity on carcinogenicity studies: Implications for risk assessment. *Carcinogenesis* 9: 2045–2052.
- Holliday, R. (1987) DNA methylation and epigenetic defects in carcinogenesis. *Mutation Research* 181: 215–217.
- Hollstein, M.; Sidransky, D.; Vogelstein, B.; Harris, C.C. (1991) p53 mutations in human cancers. *Science* 253: 49–53.
- Hsu, I.C.; Metcalf, R.A.; Sun, T.; Welsh, J.A.; Wang, N.J.; Harris, C.C. (1991) Mutational hotspot in human hepatocellular carcinomas. *Nature* 350: 427–428.
- Huff, J.E. (1993) Chemicals and cancer in humans: first evidence in experimental animals. *Environ. Health Perspect.* 100: 201–210.
- Huff, J.E. (1994) Chemicals causally associated with cancers in humans and laboratory animals. A perfect concordance. In: *Carcinogenesis*. Waalkes, M.P.; Ward, J.M., eds., New York, NY: Raven Press; pp. 25–37.
- Hulka, B.S.; Margolin, B.H. (1992) Methodological issues in epidemiologic studies using biological markers. *Am. J. Epidemiol.* 135: 122–129.
- Hunter, T. (1991) Cooperation between oncogenes. *Cell* 64: 249–270.
- Ingram, A.J.; Grasso, P. (1991) Evidence for and possible mechanisms of non-genotoxic carcinogenesis in mouse skin. *Mutat. Res.* 248: 333–340.
- International Agency for Research on Cancer (IARC). (1990) *Ciclosporin*. IARC monographs on the evaluation of carcinogenic risks to humans. Vol. 50. Lyon, France: IARC; pp. 77–114.
- IARC. (1994) IARC monographs on the evaluation of carcinogenic risks to humans. Vol. 60, *Some industrial chemicals*. Lyon, France: IARC; pp. 13–33.
- International Life Science Institute (ILSI). (1995) The use of biological data in cancer risk assessment. In: Olin, S.; Farland, W.; Park, C.; Rhomberg, L.; Scheuplein, R.; Starr, T.; Wilson, J., eds. *Low-dose extrapolation of cancer risks: Issues and Perspectives*. Washington, DC: ILSI Press; pp. 45–60.
- Ito, N.; Shirai, T.; and Hasegawa, R. (1992) Medium-term bioassays for carcinogens. In “Mechanisms of Carcinogenesis in Risk Identifications” (eds., H. Vainio, P.N. Magee, DB McGregor and AJ McMichael), Lyon, International Agency for Research on Cancer, pp. 353–388.
- Jack, D.; Poynter, D.; Spurling, N.W. (1983) Beta-adrenoreceptor stimulants and mesoovarian leiomyomas in the rat. *Toxicology* 2: 315–320.
- Jarabek, A.M. (1995a) The application of dosimetry models to identify key processes and parameters for default dose-response assessment approaches. *Toxicol. Lett.* 79:171–184.
- Jarabek, A.M. (1995b) Interspecies extrapolation based on mechanistic determinants of chemical disposition. *Human Eco. Risk Assess.* 1(5):641–662.
- Jones, P.A. (1986) DNA methylation and cancer. *Cancer Res.* 46: 461–466.
- Kehrer, J.P. (1993) Free radicals as mediators of tissue injury and disease. *Crit. Rev. Toxicol.* 23: 21–48.
- Kelsey, J.L.; Thompson, W.D.; Evans, A.S. (1986) *Methods in observational epidemiology*. New York, NY: Oxford University Press.
- Mr. Kinzler, K.W.; Nilbert, M.C.; Su, L.-K.; Vogelstein, B.; Bryan, T.M.; Levy, D.B.; Smith, K.J.; Preisinger, A.C.; Hedge, P.; McKechnie, D.; Finniear, R.; Markham, A.; Groffen, J.; Boguski, M.S.; Altschul, S.J.; Horii, A.; Ando, H.; Miyoshi, Y.; Miki, Y.; Nishisho, I.; Nakamura, Y. (1991) Identification of FAP locus genes from chromosome 5q21. *Science* 253: 661–665.
- Kodell, R.L.; Park, C.N. (1995) *Linear extrapolation in cancer risk assessment*. ILSI Risk Science Institute: Washington, D.C. In press.
- Kraus, A.L.; Munro, I.C.; Orr, J.C.; Binder, R.L.; LeBoeuf, R.A.; Williams, G.M. (1995) *Benzoyl peroxide: An integrated human safety assessment for carcinogenicity*. *Regul. Toxicol. Pharmacol.* 21: 87–107.
- Krewski, D.; Brown, C.; Murdoch, D. (1984) Determining “safe” levels of exposure: Safety factors of mathematical models. *Fund. Appl. Toxicol.* 4: S383–S394.
- Krewski, D.; Murdoch, D.J.; Withey, J.R. (1987) The application of pharmacokinetic data in carcinogenic risk assessment. In: *Pharmacokinetics in risk assessment. Drinking water and health*. Vol. 8. Washington, DC: National Academy Press; pp. 441–468.
- Kripke, M.L. (1988) Immunoregulation of carcinogenesis: Past, present, and future. *J. Natl. Cancer Inst.* 80: 722–727.
- Kumar, R.; Sukumar, S.; Barbacid, M. (1990) Activation of ras oncogenes preceding the onset of neoplasia. *Science* 248: 1101–1104.
- Larson, J.L.; Wolf, D.C.; Butterworth, B.E. (1994) Induced cytotoxicity and cell proliferation in the hepatocarcinogenicity of chloroform in female B6C3F1 mice: comparison of administration by gavage in corn oil vs. ad libitum in drinking water. *Fundam. Appl. Toxicol.* 22: 90–102.
- Levine, A.M. (1993) AIDs-related malignancies: The emerging epidemic. *J. Natl. Cancer Inst.* 85: 1382–1397.
- Levine, P.H.; Hoover, R.N., eds. (1992) *The emerging epidemic of non-Hodgkin’s lymphoma: Current knowledge regarding etiological factors*. *Cancer Res.* 52: 5426s–5574s.
- Levine, A. J.; Momand, J.; Finlay, C. A. (1991) The p53 tumour suppressor gene. *Nature* 351: 453–456.
- Levine, A.J.; Perry, M.E.; Chang, A., et al. (1994) The 1993 Walter Hubert Lecture: The role of the p53 tumor-suppressor gene in tumorigenesis. *Brit. J. Cancer* 69: 409–416.
- Li, J.L.; Okada, S.; Hamazaki, S.; Ebina, Y.; Midorikawa, O. (1987) Subacute nephrotoxicity and induction of renal cell carcinoma in mice treated with ferric nitrilotriacetate. *Cancer Res.* 47: 1867–1869.
- Lijinsky, W. (1993) Species differences in carcinogenesis. *In Vivo* 7: 65–72.
- Lilienfeld, A.M.; Lilienfeld, D. (1979) *Foundations of epidemiology*, 2nd ed. New York, NY: Oxford University Press.
- Loeb, L.A. (1991) Mutator phenotype may be required for multistage carcinogenesis. *Cancer Res.* 51: 3075–3079.
- Lutz, W.K. (1990a) Endogenous genotoxic agents and processes as a basis of spontaneous carcinogenesis. *Mutat. Res.* 238: 287–295.
- Lutz, W.K. (1990b) Dose-response relationship and low dose extrapolation in chemical carcinogenesis. *Carcinogenesis* 11: 1243–1247.
- MacDonald, J.S.; Lankas, G.R.; Morrissey, R.E. (1994) Toxicokinetic and mechanistic considerations in the interpretation of the rodent bioassay. *Toxicol. Pathol.* 22: 124–140.
- Maller, J.L. (1991) Mitotic control. *Curr. Opin. Cell Biol.* 3: 269–275.
- Maronpot, R.R.; Shimkin, M.B.; Witschi, H.P.; Smith, L.H.; and Cline, J.M. (1986) Strain A mouse pulmonary tumor test results for chemicals previously tested in National Cancer Institute carcinogenicity test. *J. Natl. Cancer Inst.* 76: 1101–1112.
- Marsman, D.S.; Popp, J.A. (1994) Biological potential of basophilic hepatocellular foci and hepatic adenoma induced by the peroxisome proliferator, Wy-14,643. *Carcinogenesis* 15: 111–117.
- Mausner, J.S.; Kramer, S. (1985) *Epidemiology*, 2nd ed. Philadelphia: W.B. Saunders Company.
- McClain, R.M. (1994) Mechanistic considerations in the regulation and classification of chemical carcinogens. In: Kotsonis, F.N.; Mackey, M.; Hjelle, J., eds. *Nutritional toxicology*. New York, NY: Raven Press; pp. 273–304.
- McConnell, E.E.; Sollefeld, H.A.; Swenberg, J.A.; Boorman, G.A. (1986) Guidelines for combining neoplasms for evaluation of rodent carcinogenesis studies. *J. Natl. Cancer Inst.* 76: 283–289.
- McMichael, A.J. (1976) Standardized mortality ratios and the “healthy worker effect”: scratching beneath the surface. *J. Occup. Med.* 18: 165–168.

- Melnick, R.L.; Huff, J.E.; Barrett, J.C.; Maronpot, R.R.; Lucier, G.; Portier, C.J. (1993a) Cell proliferation and chemical carcinogenesis: A symposium overview. *Molecular Carcinogenesis* 7: 135-138.
- Melnick, R.L.; Huff, J.E.; Barrett, J.C.; Maronpot, R.R.; Lucier, G.; Portier, C.J. (1993b) Cell proliferation and chemical carcinogenesis. *Molecular Carcinogenesis* 7: 135-138.
- Meyn, M.S. (1993) High spontaneous intrachromosomal recombination rates in ataxia-telangiectasia. *Science* 260: 1327-1330.
- Modrich, P. (1994) Mismatch repair, genetic stability, and cancer. *Science* 266: 1959-1960.
- Monro, A. (1992) What is an appropriate measure of exposure when testing drugs for carcinogenicity in rodents? *Toxicol. Appl. Pharmacol.* 112: 171-181.
- Moolgavkar, S.H.; Knudson, A.G. (1981) Mutation and cancer: A model for human carcinogenesis. *J. Natl. Cancer Inst.* 66: 1037-1052.
- Morrison, V.; Ashby, J. (1994) A preliminary evaluation of the performance of the muta™ mouse (lacZ) and Big Blue™ (lacI) transgenic mouse mutation assays. *Mutagenesis* 9: 367-375.
- Naeve, G.S.; Sharma, A.; Lee, A.S. (1991) Temporal events regulating the early phases of the mammalian cell cycle. *Curr. Opin. Cell Biol.* 3: 261-268.
- National Research Council (NRC). (1983) Risk Assessment in the federal government: Managing the process. Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, NRC. Washington, DC: National Academy Press.
- NRC. (1993a) Pesticides in the diets of infants and children. Committee on Pesticides in the Diets of Infants and Children, Commission on Life Sciences, NRC. Washington, DC: National Academy Press.
- NRC. (1993b) Issues in risk Assessment. Committee on Risk Assessment Methodology, Commission on Life Sciences, NRC. Washington, DC: National Academy Press.
- NRC. (1994) Science and judgment in risk assessment. Committee on Risk Assessment of Hazardous Air Pollutants, Commission on Life Sciences, NRC. Washington, DC: National Academy Press.
- National Toxicology Program (NTP). (1984) Report of the Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation of the National Toxicology Program, Board of Scientific Counselors. Washington, DC: U.S. Government Printing Office. 1984-421-132: 4726.
- Nebreda, A.R.; Martin-Zanca, D.; Kaplan, D.R.; Parada, L.F.; Santos, E. (1991) Induction by NGF of meiotic maturation of xenopus oocytes expressing the trk proto-oncogene product. *Science* 252: 558-561.
- Nowell, P. (1976) The clonal evolution of tumor cell populations. *Science* 194: 23-28.
- Nunez, G.; Hockenberry, D.; McDonnell, J.; Sorenson, C.M.; Korsmeyer, S.J. (1991) Bcl-2 maintains B cell memory. *Nature* 353: 71-72.
- Office of Science and Technology Policy (OSTP). (1985) Chemical carcinogens: Review of the science and its associated principles. *Federal Register* 50: 10372-10442.
- Organization for Economic Cooperation and Development (OECD). (1981) Guidelines for testing of chemicals. Carcinogenicity studies. No. 451. Paris, France.
- Peltonmäki, P.; Aaltonen, L.A.; Sisonen, P.; Pylkkänen, L.; Mecklin, J.-P.; Järvinen, H.; Green, J.S.; Jass, J.R.; Weber, J.L.; Leach, F.S.; Petersen, G.M.; Hamilton, S.R.; de la Chapelle, A.; Vogelstein, B. (1993) Genetic mapping of a locus predisposing human colorectal cancer. *Science* 260: 810-812.
- Peto, J. (1992) Meta-analysis of epidemiological studies of carcinogenesis. In: Mechanisms of carcinogenesis in risk assessment. IARC Sci. Pubs. No. 116, Lyon, France: IARC; pp. 571-577.
- Peto, J.; Darby, S. (1994) Radon risk reassessed. *Nature* 368: 97-98.
- Pitot, H.; Dragan, Y.P. (1991) Facts and theories concerning the mechanisms of carcinogenesis. *FASEB J.* 5: 2280-2286.
- Portier, C. (1987) Statistical properties of a two-stage model of carcinogenesis. *Environ. Health Perspect.* 76: 125-131.
- Prahalada, S.; Majka, J.A.; Soper, K.A.; Nett, T.M.; Bagdon, W.J.; Peter, C.P.; Burek, J.D.; MacDonald, J.S.; van Zwieten, M.J. (1994) Leydig cell hyperplasia and adenomas in mice treated with finasteride, 5 α -reductase inhibitor: A possible mechanism. *Fund. Appl. Toxicol.* 22: 211-219.
- Raff, M.C. (1992) Social controls on cell survival and cell death. *Nature* 356: 397-400.
- Rall, D.P. (1991) Carcinogens and human health: Part 2. *Science* 251: 10-11.
- Rothman, K.T. (1986) Modern epidemiology. Boston: Little, Brown and Company.
- Salomon, D.S.; Kim, N.; Saeki, T.; Ciardiello, F. (1990) Transforming growth factor α —an oncogene developmental growth factor. *Cancer Cells* 2: 389-397.
- Schneider, C.; Gustincich, S.; DelSal, G. (1991) The complexity of cell proliferation control in mammalian cells. *Curr. Opin. Cell Biol.* 3: 276-281.
- Schuller, H.M. (1991) Receptor-mediated mitogenic signals and lung cancer. *Cancer Cells* 3: 496-503.
- Schulte-Hermann, R.; Bursch, W.; Kraupp-Grasl, B.; Oberhammer, F.; Wagner, A.; Jirtle, R. (1993) Cell proliferation and apoptosis in normal liver and preneoplastic foci. *Environ. Health Perspect.* 101 (Supp. 5): 87-90.
- Shelby, M.D.; Zeiger, E. (1990) Activity of human carcinogens in the Salmonella and rodent bone-marrow cytogenetics tests. *Mutat. Res.* 234: 257-261.
- Shelby, M.D. (1994) Human germ cell mutations. *Environ. Molec. Mutagen.* 23 (Supp. 24): 30-34.
- Sidransky, D.; Von Eschenbach, A.; Tsai, Y.C.; Jones, P.; Summerhayes, I.; Marshall, F.; Paul, M.; Green, P.; Hamilton, P.F.; Vogelstein, B. (1991) Identification of p53 gene mutations in bladder cancers and urine samples. *Science* 252: 706-710.
- Sidransky, D.; Mikkelsen, T.; Schwachheimer, K.; Rosenblum, M.L.; Cavane, W.; Vogelstein, B. (1992) Clonal expansion of p53 mutant cells is associated with brain tumor progression. *Nature* 355: 846-847.
- Sisk, S.C.; Pluta, L.J.; Bond, J.A.; Recio, L. (1994) Molecular analysis of lacI mutants from bone marrow of B6C3F1 transgenic mice following inhalation exposure to 1,3-butadiene. *Carcinogenesis* 15(3): 471-477.
- Snedecor, G.W.; Cochran, W.G. (1978) Statistical methods, Sixth ed. Ames, Iowa: Iowa State University Press; 593 pp.
- Srivastava, S.; Zou, Z.; Pirolo, K.; Blattner, W.; Chang, E. (1990) Germ-line transmission of a mutated p53 gene in a cancer-prone family with Li-Fraumeni syndrome. *Nature* 348(6303): 747-749.
- Stewart, B.W. (1994) Mechanisms of apoptosis: Integration of genetic, biochemical, and cellular indicators. *J. Natl. Cancer Inst.* 86: 1286-1296.
- Stiteler, W.H.; Knauf, L.A.; Hertzberg, R.C.; Schoeny, R.S. (1993) A statistical test of compatibility of data sets to a common dose-response model. *Reg. Tox. Pharmacol.* 18: 392-402.
- Stitzel, K.A.; McConnell, R.F.; Dierckman, T.A. (1989) Effects of nitrofurantoin on the primary and secondary reproductive organs of female B6C3F1 mice. *Toxicol. Pathol.* 17: 774-781.
- Strausfeld, U.; Labbe, J.C.; Fesquet, D.; Cavadore, J.C.; Dicard, A.; Sadhu, K.; Russell, P.; Dor'ee, M. (1991) Identification of a G1-type cyclin puc1+ in the fission yeast *Schizosaccharomyces pombe*. *Nature* 351: 242-245.
- Sukumar, S. (1989) ras oncogenes in chemical carcinogenesis. *Curr. Top. Microbiol. Immunol.* 148: 93-114.
- Sukumar, S. (1990) An experimental analysis of cancer: Role of ras oncogenes in multistep carcinogenesis. *Cancer Cells* 2: 199-204.
- Swenberg, J.A.; Richardson, F.C.; Boucheron, J.A.; Deal, F.H.; Belinsky, S.A.; Charbonneau, M.; Short, B.G. (1987) High to low dose extrapolation: Critical determinants involved in the dose-response of carcinogenic substances. *Environ. Health Perspect.* 76: 57-63.
- Swierenga, S.H.H.; Yamasaki, H. (1992) Performance of tests for cell transformation and gap junction intercellular communication for detecting nongenotoxic carcinogenic activity. In: Mechanisms of carcinogenesis in risk identification. IARC Sci. Pubs. No. 116, Lyon, France: International Agency for Research on Cancer; pp. 165-193.

- Tanaka, K.; Oshimura, M.; Kikiuchi, R.; Seki, M.; Hayashi, T.; Miyaki, M. (1991) Suppression of tumorigenicity in human colon carcinoma cells by introduction of normal chromosome 5 or 18. *Nature* 349: 340-342.
- Tarone, R.E. (1982) The use of historical control information in testing for a trend in proportions. *Biometrics* 38: 215-220.
- Taylor, J.H.; Watson, M.A.; Devereux, T.R.; Michels, R.Y.; Saccomanno, G.; Anderson, M. (1994) *Lancet* 343: 86-87.
- Tennant, R.W. (1993) Stratification of rodent carcinogenicity bioassay results to reflect relative human hazard. *Mutat. Res.* 286: 111-118.
- Tennant, R.W.; Ashby, J. (1991) Classification according to chemical structure, mutagenicity to *Salmonella* and level of carcinogenicity of a further 39 chemicals tested for carcinogenicity by the U.S. National Toxicology Program. *Mutat. Res.* 257: 209-277.
- Tennant, R.W.; Elwell, M.R.; Spalding, J.W.; Griesemer, R.A. (1991) Evidence that toxic injury is not always associated with induction of chemical carcinogenesis. *Molec. Carcinogen.* 4: 420-440.
- Tennant, R.W.; French, J.E.; Spalding, J.W. (1995) Identifying chemical carcinogens and assessing potential risk in short-term bioassays using transgenic mouse models. *Environ. Health Perspect.* 103:942-950.
- Thompson, T.C.; Southgate, J.; Kitchener, G.; Land, H. (1989) Multistage carcinogenesis induced by ras and myc oncogenes in a reconstituted organ. *Cell* 56: 917-3183.
- Tinwell, H.; Ashby, J. (1991) Activity of the human carcinogen MeCCNU in the mouse bone marrow micronucleus test. *Environ. Molec. Mutagen.* 17: 152-154.
- Tischler, A.S.; McClain, R.M.; Childers, H.; Downing, J. (1991) Neurogenic signals regulate chromaffin cell proliferation and mediate the mitogenic effect of reserpine in the adult rat adrenal medulla. *Lab. Invest.* 65: 374-376.
- Tobey, R.A. (1975) Different drugs arrest cells at a number of distinct stages in G2. *Nature* 254: 245-247.
- Todd, G.C. (1986) Induction of reversibility of thyroid proliferative changes in rats given an antithyroid compound. *Vet. Pathol.* 23: 110-117.
- Tomatis, L.; Aitio, A.; Wilbourn, J.; Shuker, L. (1989) Human carcinogens so far identified. *Jpn. J. Cancer Res.* 80: 795-807.
- Travis, C.C.; McClain, T.W.; Birkner, P.D. (1991) Diethylnitrosamine-induced hepatocarcinogenesis in rats: A theoretical study. *Toxicol. Appl. Pharmacol.* 109: 289-309.
- U.S. Environmental Protection Agency. (1983a) Good laboratory practices standards—toxicology testing. *Federal Register* 48: 53922.
- U.S. Environmental Protection Agency. (1983b) Hazard evaluations: Humans and domestic animals. Subdivision F. Available from: NTIS, Springfield, VA; PB 83-153916.
- U.S. Environmental Protection Agency. (1983c) Health effects test guidelines. Available from: NTIS, Springfield, VA; PB 83-232984.
- U.S. Environmental Protection Agency. (1984) Estimation of the public health risk from exposure to gasoline vapor via the gasoline marketing system. Office of Health and Environmental Assessment, Washington, DC.
- U.S. Environmental Protection Agency. (1986a) Health assessment document for beryllium. Office of Health and Environmental Assessment, Washington, DC.
- U.S. Environmental Protection Agency. (1986b) Guidelines for carcinogen risk assessment. *Federal Register* 51(185):33992-34003.
- U.S. Environmental Protection Agency. (1989a) Interim procedures for estimating risks associated with exposures to mixtures of chlorinated dibenzo-p-dioxins and -dibenzofurans (CDDs and CDFs) and 1989 update. *Risk Assessment Forum*, Washington, DC. EPA/625/3-89/016.
- U.S. Environmental Protection Agency. (1989b) Workshop on EPA guidelines for carcinogen risk assessment. *Risk Assessment Forum*, Washington, DC. EPA/625/3-89/015.
- U.S. Environmental Protection Agency. (1989c) Workshop on EPA guidelines for carcinogen risk assessment: use of human evidence. *Risk Assessment Forum*, Washington, DC. EPA/625/3-90/017.
- U.S. Environmental Protection Agency. (1991a) Pesticide assessment guidelines: Subdivision F, hazard evaluation, human and domestic animals. Series 84, Mutagenicity. Addendum 9. Office of Pesticide Programs, Washington, DC. PB91-158394, 540/09-91-122.
- U.S. Environmental Protection Agency. (1991b) Alpha-2u-globulin: Association with chemically induced renal toxicity and neoplasia in the male rat. *Risk Assessment Forum*, Washington, DC. EPA/625/3-91/019F.
- U.S. Environmental Protection Agency. (1991c) Workshop report on toxicity equivalency factors for polychlorinated biphenyl congeners. *Risk Assessment Forum*, Washington, DC. EPA/625/3-91/020.
- U.S. Environmental Protection Agency. (1991f) Guidelines for developmental toxicity risk assessment. *Federal Register* 56(234): 63798-63826.
- U.S. Environmental Protection Agency. (1992a) Guidelines for exposure assessment. *Federal Register* 57(104): 22888-22938.
- U.S. Environmental Protection Agency. (1992b) Draft report: A cross-species scaling factor for carcinogen risk assessment based on equivalence of mg/kg^{3/4}/day. *Federal Register* 57(109): 24152-24173.
- U.S. Environmental Protection Agency. (1992c) Health assessment for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and related compounds (Chapters 1 through 8). *Workshop Review Drafts*. EPA/600/AP-92/001a through 001h.
- U.S. Environmental Protection Agency. (1994) Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Research Triangle Park, NC. EPA/600/8-90/066F.
- U.S. Environmental Protection Agency. (1994a) Estimating exposure to dioxin-like compounds. Office of Health and Environmental Assessment, Office of Research and Development, Washington, DC. External Review Draft, 3 vol. EPA/600/6-88/005Ca, Cb, Cc.
- U.S. Environmental Protection Agency. (1994b) Report on the workshop on cancer risk assessment guidelines issues. Office of Research and Development, Risk Assessment Forum, Washington, DC. EPA/630/R-94/005a.
- U.S. Environmental Protection Agency. (1995) Policy for risk characterization. Memorandum of Carol M. Browner, Administrator, March 21, 1995, Washington, D.C.
- U.S. Food and Drug Administration (1987) Sponsored compounds in food-producing animals; criteria and procedures for evaluating the safety of carcinogenic residues. final rule. 21 CFR Parts 70, 500, 514 and 571.
- Vahakangas, K.H.; Samet, J.M.; Metcalf, R.A.; Welsh, J.A.; Bennett, W.P.; Lane, D.P.; Harris, C.C. (1992) Mutation of p53 and ras genes in radon-associated lung cancer from uranium miners. *Lancet* 339: 576-578.
- Vainio, H.; Magee, P.; McGregor, D.; McMichael, A.J. (1992) Mechanisms of carcinogenesis in risk identification. *IARC Sci. Pubs.* No. 116. Lyon, France: IARC.
- Van Sittert, N.J.; De Jong, G.; Clare, M.G.; Davies, R.; Dean, B.J.; Wren, L.R.; Wright, A.S. (1985) Cytogenetic, immunological, and hematological effects in workers in an ethylene oxide manufacturing plant. *Br. J. Indust. Med.* 42:19-26.
- Vater, S.T.; McGinnis, P.M.; Schoeny, R.S.; Velazquez, S. (1993) Biological considerations for combining carcinogenicity data for quantitative risk assessment. *Reg. Toxicol. Pharmacol.* 18: 403-418.
- Vogelstein, B.; Fearon, E. R.; Hamilton, S. R.; Kern, S. E.; Presinger, A. C.; Leppert, M.; Nakamura, Y.; White, R.; Smits, A. M. M.; Bos, J. L. (1988) Genetic alterations during colorectal-tumor development. *New England Journal of Medicine* 319: 525-532.
- Weinberg, R.A. (1989) Oncogenes, antioncogenes, and the molecular bases of multistep carcinogenesis. *Cancer Res.* 49: 3713-3721.

- Wellstein, A.; Lupu, R.; Zugmaier, G.; Flamm, S.L.; Cheville, A.L.; Bovi, P.D.; Basicico, C.; Lippman, M.E.; Kern, F.G. (1990) Autocrine growth stimulation by secreted Kaposi fibroblast growth factor but not by endogenous basic fibroblast growth factor. *Cell Growth Differ.* 1: 63-71.
- Woo, Y.T.; Arcos, J.C. (1989) Role of structure-activity relationship analysis in evaluation of pesticides for potential carcinogenicity. In: Ragsdale, N.N.; Menzer, R.E., eds. *Carcinogenicity and pesticides: Principles, issues, and relationship.* ACS Symposium Series No. 414. San Diego: Academic Press; pp. 175-200.
- Wyzga, R.E. (1988) The role of epidemiology in risk assessments of carcinogens. *Adv. Mod. Environ. Toxicol.* 15: 189-208.
- Yamada, T.; Nakamura, J.; Murakami, M.; Okuno, Y.; Hosokawa, S.; Matsuo, M.; Yamada, H. (1994) The correlation of serum luteinizing hormone levels with the induction of Leydig cell tumors in rats by oxolinic acid. *Toxicol. Appl. Pharmacol.* 129: 146-154.
- Yamasaki, H. (1990) Gap junctional intercellular communication and carcinogenesis. *Carcinogenesis* 11: 1051-1058.
- Yamasaki, H. (1995) Non-genotoxic mechanisms of carcinogenesis: Studies of cell transformation and gap junctional intercellular communication. *Toxicol. Lett.* 77: 55-61.
- Zhang, K.; Papageorge, A.G.; Lowry, D.R. (1992) Mechanistic aspects of signalling through ras in NIH 3T3 cells. *Science* 257: 671-674.

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Part III

**Department of
Transportation**

Federal Highway Administration
49 CFR Part 393

**Department of
Housing and Urban
Development**

24 CFR Part 3280

**Manufactured Home Tires, Parts and
Accessories Necessary for Safe
Operation; and Manufactured Home
Construction and Safety Standards;
Proposed Rule**

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****49 CFR Part 393**

[FHWA Docket No. MC-95-1]

RIN 2125-AD41

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**24 CFR Part 3280**

[Docket No. FR-3943]

RIN 2502-AG54

Manufactured Home Tires, Parts and Accessories Necessary for Safe Operation; and Manufactured Home Construction and Safety Standards

AGENCIES: Federal Highway Administration (FHWA), DOT; Office of the Assistant Secretary for Housing, Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice of proposed rulemaking; proposed change in HUD interpretative bulletin.

SUMMARY: The FHWA and HUD are proposing amendments to the Federal Motor Carrier Safety Regulations and an interpretation of the Manufactured Home Construction and Safety Standards concerning the transportation of manufactured homes. The FHWA and HUD propose to adopt mutually consistent and readily enforceable regulations and interpretations that promote the safe and effective transportation of manufactured homes. The FHWA and HUD are proposing to permit the overloading of manufactured home tires by not more than 18 percent for a period of two years from the effective date of the final rule. During that two year period, both agencies would review test and other technical data concerning the relative performance of tires which are overloaded by 18 percent versus no tire overloading. Unless both agencies are persuaded that the 18 percent overloading does not pose a risk to the traveling public or have an adverse impact on the safety or transportability of manufactured homes, any overloading of tires beyond their design capacity would be prohibited after two years from the effective date of the final rule. These proposed changes are intended to clarify the regulations of the FHWA and the interpretation of its regulations by HUD and to resolve differences between Federal regulations for the overloading of tires used in the transportation of manufactured homes.

DATES: Comment Due Date: Comments must be received on or before June 24, 1996.

ADDRESSES: To file responses on this proposed rule submit written, signed comments to FHWA Docket No. MC-95-1, Room 4232, HCC-10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., Eastern Time, Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: For FHWA: Mr. Larry W. Minor, Office of Motor Carrier Research and Standards, HCS-10, (202) 366-4009; or Mr. Charles E. Medalen, Office of the Chief Counsel, HCC-20, (202) 366-1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., (eastern standard time), Monday through Friday, except Federal holidays.

For HUD: Mr. Philip W. Schulte, Acting Director, Manufactured Home and Construction Standards Division, Office of Manufactured Housing and Regulatory Functions, Department of Housing and Urban Development, L'Enfant Plaza North, Suite 3214, Washington, D.C. (mailing address: Room B-133, HUD Building, Washington, D.C. 20410-8000). Telephones: (voice) (202) 755-7420; (TDD) (202) 708-4594. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:**Background**

The Department of Housing and Urban Development (HUD) and the Federal Highway Administration (FHWA) have regulations applicable to the transportation of manufactured housing which are mutually inconsistent. In this joint NPRM, the two agencies are proposing to adopt identical rules to correct the inconsistency.

On March 4, 1995, President Clinton directed all agencies to remove obsolete and unnecessary regulations, and revise and improve necessary regulations. As part of HUD's and FHWA's review of their respective regulations, each agency identified its regulations applicable to the transportation of manufactured housing as inconsistent with one another. In accordance with the President's directive to improve regulations, and in accordance with the principles of Executive Order 12866, which directs agencies to avoid

regulations that are inconsistent with regulations of other agencies, this rule proposes to make HUD's and FHWA's regulations consistent on this subject. Additionally, at the final rule stage the format of this rule may be revised to conform to the President's regulatory reinvention principles.

I. Department of Housing and Urban Development**A. Manufactured Home Construction and Safety Standards**

The National Manufactured Housing Construction and Safety Standards Act of 1974 (Act), 42 U.S.C. 5401 *et seq.*, authorizes the Secretary of Housing and Urban Development (HUD) to establish and amend the Federal Manufactured Home Construction and Safety Standards (FMHCSS), 24 CFR Part 3280 (Standards). The stated purposes of the Act are to reduce the number of personal injuries and deaths and the amount of insurance costs and property damage resulting from manufactured home accidents and to improve the quality and durability of manufactured homes.

B. Transportation Systems for Manufactured Homes

Subpart J of the Standards covers the general requirement for designing the manufactured home to fully withstand the adverse effects of transportation shock and vibration without damaging the integrated structure or its component parts. One of its components is the running gear assembly which is defined in 24 CFR 3280.902 to include the subsystem consisting of suspension springs, axles, bearings, wheels, hubs, tires, and brakes, with their related hardware.

Under 24 CFR 3280.904(a), the entire transportation "system (frame, drawbar and coupling mechanism, running gear assembly, and lights) shall be designed and constructed as an integrated, balanced and durable unit which is safe and suitable for its specified use during the intended life of the manufactured home." The running gear assembly, including the tires, must be able to sustain the designed loads set forth in 24 CFR 3280.904(b)(3) and "to provide for *durable dependable safe mobility of the manufactured home*" (emphasis added) (24 CFR 3280.904(b)(4)(i)).

The design load consists of the dead load plus a minimum of 3 pounds per square foot floor load (for example, free-standing range, refrigerator, and loose furniture), and the superimposed dynamic load resulting from highway movement but shall not be required to exceed twice the dead load. The

integrated design shall be capable of insuring rigidity and structural integrity of the complete manufactured home structure and to insure against deformation of structural or finish members during the intended life of the home.

C. Interpretative Bulletin J-1-76

HUD interpreted the transportation requirements for subpart J in the Standards by an Interpretative Bulletin published on December 7, 1976 (41 FR 53626). Sections C and D of the Interpretative Bulletin provide as follows:

Section C—Axles

Unless substantiated in the design to the satisfaction of the approval agency [Design Approval Primary Inspection Agency] (DAPIA) by either engineering analysis, load tests or documented evidence of actual transportation experience, there shall be no less than the following minimum number of 6,000 lb. rated axles with not less than the mobile (manufactured) home rated tires indicated in Table 1 or Table 2 on each mobile home or floor section of the multiple unit mobile home:

TABLE 1

Length of the mobile (manufactured) home	Number of 6,000 lb. axles equipped with 7-14.5, mobile home 8 ply tires
1. 12 foot wide:	
A. To 60 ft. maximum	2
B. Greater than 60 ft.—80 ft. max	3
2. 14 foot wide:	
A. To 52 ft. maximum	2
B. To 76 ft. maximum	3
C. To 80 ft. maximum	4

TABLE 2

Length of the mobile (manufactured) home	Number of 6,000 lb. axles equipped with 8-14.5, mobile home 8 and 10 ply tires
1. 12 foot wide:	
A. To 65 ft. maximum	2
B. Greater than 65 ft.—80 ft. max	3
2. 14 foot wide:	
A. To 56 ft. maximum	2
B. Greater than 56 ft.—80 ft. max	3

Length of a mobile home is the length as defined in § 3280.902(b).

Determination of the number of axles required by use of the above tables does not

eliminate the requirement for each axle to be capable of withstanding the actual imposed dead load without exceeding the maximum allowable stresses for design axle life as recommended by the axle manufacturer, or the maximum tire load rating in § 280.904(b)(8) [now § 3280.904(b)(8)]. If a manufacturer has submitted documented evidence of transportation experience to meet the requirements of § 280.903(c)(2) [now § 3280.903(c)(2)], the minimum number of axles required by the experience record may not be reduced by use of the above tables. (The number of axles must be consistent with and no less than the number and rating of the axles indicated in the experience record.)

Section D—Tires, Wheels and Rims

Tires shall be sized and fitted to axles in accordance with the gross axle weight rating determined by the mobile home manufacturer. The permissible tire loading may be increased by utilizing a service load factor not to exceed 50 percent of the mobile home tire load limits specified in MH-1 of the Tire and Rim Association Handbook (1975 edition), but the individual permissible tire loading may not exceed 3,000 pounds. For example, the maximum tire loading for a 7×14.5 mobile home 8 ply tire at 70 PSI cold inflation pressure would be 2805 lbs. (1,870 lbs. (MH-1 rating)×1.5(service load factor)=2,805 lbs.). The tire load limit specified in MH-1 shall be determined by the tire manufacturer in accordance with procedures described in 49 CFR 571.119.

Used tires may also be sized in accordance with the above criteria whenever the tread depth is at least 2/32 of an inch as determined by a tread wear indicator. The determination as to whether a particular used tire is acceptable shall also include a visual inspection of thermal and structural defects (e.g., dry rotting, excessive tire sidewall splitting, etc.).

Wheels and rims shall be sized in accordance with the tire manufacturer's recommendations as suitable for use with the tires selected.

II. Department of Transportation

A. Federal Motor Carrier Safety Regulations

The FHWA's Federal Motor Carrier Safety Regulations (FMCSRs) are based on a series of statutes starting with the Motor Carrier Act of 1935. The FMCSRs are codified at Subchapter B of Chapter III, Title 49 of the Code of Federal Regulations. The FMCSRs provide requirements for the operation of commercial motor vehicles in interstate commerce. The FMCSRs define a commercial motor vehicle as any self-propelled or towed vehicle used on public highways in interstate commerce to transport passengers or property when: the vehicle has a gross vehicle weight rating or gross combination weight of 10,001 or more pounds; or the vehicle is designed to transport more than 15 passengers, including the driver; or, the vehicle is used in the

transportation of hazardous materials in a quantity requiring a placard. Under this definition, a manufactured home transported in interstate commerce is considered a commercial motor vehicle and is subject to the FMCSRs.

Part 393 of the FMCSRs covers parts and accessories necessary for safe operation. Among the safety regulations applicable to manufactured homes are the requirements for lamps and reflective devices, brake systems, coupling devices, tires, and suspension systems.

Under the Motor Carrier Safety Assistance Program (MCSAP), the FHWA provides financial assistance to States to enforce the FMCSRs or compatible State regulations pertaining to commercial motor vehicle safety (see 49 CFR part 350). State enforcement officials have expressed concerns about the safety of certain practices of carriers transporting manufactured homes. Their principal concern is the movement of manufactured homes on overloaded tires. In certain cases, vehicles with tires loaded to 150 percent of their capacity are operated at highway speeds. These practices are inconsistent with the FMCSRs.

B. FHWA Requirements for Tires

Section 393.75(f) prohibits the operation of commercial motor vehicles on tires that carry a greater weight than that specified in publications of certain standard-setting organizations listed by the National Highway Traffic Safety Administration in 49 CFR 571.119 (S5.1(b)) unless (1) the vehicle is being operated under the terms of a special permit issued by the State, and (2) the vehicle is being operated at a reduced speed that is appropriate to compensate for tire loading in excess of the manufacturer's normal rated capacity. The FHWA first proposed restrictions on the use of overloaded tires on April 17, 1974 (39 FR 13785). The proposal was in response to two petitions from the Professional Drivers Council (PROD), a non-profit association of professional interstate truck and bus drivers, and investigations of front tire failures by the FHWA. The PROD petitions addressed front tire overloading in general, and specifically front tire overloading resulting from the fifth wheel position on the towing vehicle.

The investigations performed by the FHWA revealed that a significant number of vehicles operate with overloaded or under-inflated tires. A tire was considered under-inflated if it carried a load greater than it was designed to carry at the pressure to which it was inflated, and overloaded if

it carried a load greater than it could safely carry at any pressure. The agency cited a growing body of evidence that both under-inflation and overloading create identifiable dangers. Among these were the impairment of vehicle handling and the loss of control from sudden tire failures. On July 11, 1975, the FHWA published the final rule prohibiting the operation of motor vehicles on overloaded tires (40 FR 29292). Several industry groups and numerous tire manufacturers immediately petitioned for reconsideration. The FHWA amended the final rule a few months later (September 29, 1975, 40 FR 44555). The petitioners asked the FHWA to allow tire pressures greater than those labeled on the tire's sidewalls; and to allow increased loading for reduced speed operations.

The available information from tire manufacturers supported allowing increased tire loadings if vehicles were operated at reduced speeds. Accordingly, the FHWA amended the final rule to that effect, provided the vehicle was operated in compliance with a special permit which specified a speed limitation.

The Heavy Specialized Carriers Conference (now the Specialized Carriers and Rigging Association) of the American Trucking Associations (ATA) subsequently submitted a petition for rulemaking. According to the petitioner, only a few States specified speed limits for vehicles operating under special permits. The wording of the September 29, 1975, final rule therefore had the effect of limiting the exemption for overloaded tires to motor carriers operating in those States. The petitioner requested that the FHWA rescind the requirement that the State-issued permit must include a specific reduced speed.

On June 17, 1976 (41 FR 24608), the FHWA proposed to modify the conditions under which tires on axles other than the front axle could be overloaded. Based upon user experience and information obtained from commercial vehicle tire manufacturers, the agency acknowledged that tires may be safely overloaded if vehicle speed is reduced sufficiently to prevent heat buildup. The FHWA concluded that if the reference to reduced speed specified on State-issued permits were deleted, the agency should impose its own speed restriction on motor vehicles which operate on overloaded tires. An upper speed limit of 72 kilometers per hour (km/hr) (45 miles per hour (mph)) was proposed for inclusion in the exemption. This value was selected to prevent conflicts between § 393.75(f) and the posted minimum speeds on

many Primary and Interstate highways. Since the minimum speed limits help to ensure safety by regulating the maximum allowable speed differential between motor vehicles, the agency's proposal addressed both the need for reduced speed to compensate for overloading and the need for limiting speed differentials between the affected commercial motor vehicles and other traffic.

On August 31, 1976 (41 FR 36656), the FHWA published a final rule amending § 393.75(f) to permit the overloading of tires if (1) the vehicle is being operated under the terms of a special overweight permit issued by the State and (2) the vehicle is being operated at a reduced speed which is appropriate to compensate for tire loading in excess of the manufacturer's normal rated capacity. The exemption only applied to tires on axles other than the front axle and included a maximum speed limit of 72 km/hr (45 mph). The effective date for the final rule was October 1, 1976.

HUD requested that the FHWA postpone the effective date of the August 1976 final rule with regard to the interstate transportation of manufactured homes. The FHWA issued Notice N 7510.1 on September 27, 1976, which instructed motor carrier safety personnel to refrain from citing mobile home transporters for operating on overloaded tires until further notice. This temporary relief was conditioned upon observing a speed limitation of 72 km/hr (45 mph). States which had adopted the FMCSRs were encouraged to adopt this policy. The notice indicated that HUD's request was based on statistical data relating to accidents resulting from tire failures on new mobile homes. The data indicated an "insignificant accident incident ratio related to tire failure and an adverse economic impact on the mobile home industry and on consumers." A copy of the September 1976 notice is included in the FHWA and HUD docket files.

On October 10, 1978, in response to a petition from the ATA concerning tire marking and the HUD request, the FHWA published another notice of proposed rulemaking (43 FR 46555). The notice discussed HUD's tire overloading standards for manufactured homes: 150 percent of rated capacity provided the total tire load does not exceed 3,000 pounds. HUD had the National Highway Traffic Safety Administration (NHTSA) conduct two series of tests on mobile home tires. The first results were summarized in a September 1976 report entitled "A Safety Performance Test for Mobile Home Tires, Phase I: New Tires." The

second report (April 1978) was entitled "A Safety Performance Test for Mobile Home Tires, Phase II: Used Tires." A copy of both reports is included in the FHWA and HUD docket files. The tests indicated that new tires on mobile homes were capable of operating satisfactorily under 150 percent loading, although used tires did not perform as well. In view of this research, the FHWA proposed replacing the term "special overweight permit" with "special permit." The FHWA believed the proposal would address HUD's concerns. Because manufactured homes generally did not exceed the normal axle or gross weight limits, they rarely qualified for overweight permits. The FHWA therefore proposed to allow the use of overloaded tires if the transporter was operating under any "special permit," typically a permit for over-width vehicles.

The final rule amending § 393.75(f) was published on May 1, 1979 (44 FR 25455). The preamble included reference to the mobile home tire research studies and HUD's request that the FHWA amend § 393.75. With this amendment, tires on axles other than the front axle could be overloaded if (1) the vehicle was operated under the terms of a special permit (as opposed to a special overweight permit) issued by the state and (2) the vehicle was operated at a reduced speed not to exceed 72 km/hr (45 mph).

On October 29, 1980, the FHWA issued FHWA Notice N 7510.2 which rescinded Notice N 7510.1. Since the 1979 final rule allowed all vehicles subject to the FMCSRs to be operated on overloaded tires provided the vehicles adhered to the terms of a special permit and did not exceed speeds of 72 km/hr (45 mph), Notice N 7510.1 was no longer necessary. A copy of the 1980 notice is included in the FHWA and HUD docket files.

The current wording of § 393.75(f) is the outcome of a 1988 final rule on parts and accessories necessary for safe operation (53 FR 49380, December 7, 1988). Under the final rule, the 72 km/hr (45 mph) maximum speed for vehicles operating on overloaded tires was removed, and any speed below the posted speed limit is thus considered a reduced speed. The effective date of the amendment was March 7, 1989.

The removal of the 72 km/hr (45 mph) maximum speed limit combined with the fact that the FMCSRs do not include restrictions on the extent to which a tire may be overloaded have created problems for State officials responsible for enforcing motor carrier safety laws.

III. Differences Between the HUD and the FHWA Regulations

Under 42 U.S.C. 5401 *et seq.*, HUD was required to issue construction and safety standards for manufactured homes. Congress provided that whenever a Federal Manufactured Home Construction and Safety Standard is in effect, no State or political subdivision of a State shall have the authority to establish or permit to continue in effect with respect to any manufactured home covered, any standard "regarding construction or safety applicable to the same aspect of performance of such manufactured home which is not identical to the Federal manufactured home construction and safety standard" (42 U.S.C. 5403(d)). HUD issued 24 CFR 3280, subpart J and Interpretative Bulletin J-1-76 which establish standards for the running gear and which permit the overloading of the tires.

Furthermore, HUD has indicated in 24 CFR 3282.11(c) that the Federal system establishes the exclusive system for enforcement of the Federal manufactured housing standards. No State may establish or keep in effect through a building code enforcement system or otherwise, "procedures or requirements which constitute systems for enforcement of the Federal standards or of identical State standards which are outside the system established in these regulations or which go beyond this system to require remedial actions which are not required by the Act and these regulations."

In contrast, the Motor Carrier Safety Act of 1984 (49 U.S.C. 31131 *et seq.*, formerly 49 U.S.C. app. 2501 *et seq.*) has

a different purpose and scope than the Manufactured Housing Construction and Safety Standards Act. It ratified the regulations adopted on the authority of the Motor Carrier Act of 1935, and directed the Department of Transportation to establish minimum Federal standards to ensure that commercial motor vehicles (CMVs) are safely equipped, maintained, loaded, and operated; that the duties imposed on CMV drivers do not impair their ability to drive safely; that the physical condition of CMV drivers does not have an adverse impact on safety; and that driving CMVs does not harm the drivers' physical condition [49 U.S.C. 31136]. The FHWA's regulation of vehicle components and systems, including tires, axles, brakes, etc., is consistent with this purpose and necessary for the protection of motorists who share the roads with CMVs, including manufactured homes.

Most State motor carrier safety laws in effect today are essentially required by Federal law. Congress directed the Department of Transportation to preempt State safety regulations that are not compatible with the FMCSRs [49 U.S.C. 31141 (formerly 49 U.S.C. App. 2507), 49 CFR 355]. The MCSAP has also induced States to model their safety laws on the FMCSRs. The FMCSRs as adopted by the States are State laws. The Federal Courts have not had occasion to consider the relationship between the Manufactured Home Construction and Safety Standards and the FMCSRs (or compatible State regulations) with regard to manufactured home tire overloading.

Both the FHWA and HUD recognize that the current inconsistency between their regulations and interpretations

requires clarification through the issuance of joint rulemaking to establish uniform requirements for motor carriers who are transporting manufactured homes. The proposed changes to the FHWA's and HUD's respective requirements for motor carriers transporting manufactured homes are covered under Sections X, XI, and XII of this notice.

IV. Analysis of Tire Loading and the Tires Used in the Transporting of Manufactured Homes

A. Typical Tires Used in Manufactured Housing

To consider whether there should be changes in its interpretation of the standards for transporting manufactured homes (Interpretative Bulletin J-1-76), HUD has gathered information from various sources about the types of tires and axles used by the manufactured housing industry. Some of this information was submitted to HUD by the Manufactured Housing Institute (MHI) which had established a Transportation Task Force. Information was also obtained from suppliers, and from materials provided by the Department of Transportation.

The MHI wrote HUD on August 5, 1994, and supplied certain information concerning the types of tires typically used in manufactured homes, the typical transport distance and the number of tire failures noted by major transporters. The average transport distance was reported to be approximately 225 miles; the data concerning the types of tires, the relative usage of 7-14.5 vis-a-vis 8-14.5 tires, etc., is shown in Table A.

TABLE A

Tire size and type	Percent use in manufactured houses	Tire capacity	Tire capacity at max. overload/percent overload
7-14.5, 8 PLY, SERIES D	80%	1,870 lbs	2,805 lbs., >50% Over.
8-14.5, 8 PLY, SERIES D	20% are 8 and 10 ply	2,270 lbs	3,000 lbs., 32% Over.
8-14.5, 10 PLY, SERIES E	See above	2,540 lbs	3,000 lbs., 18% Over.
8-14.5, 12 PLY, SERIES F	Not Available	2,790 lbs	3,000 lbs., 8% Over.
9-14.5, 8 PLY, SERIES D	Not Available	2,620 lbs	3,000 lbs., 15% Over.
9-14.5, 10 PLY, SERIES E	Not Available	2,940 lbs	3,000 lbs., 2% Over.
9-14.5, 12 PLY, SERIES F	Not Available	3,240	NO OVER-LOADING.

The maximum load ratings for the 9-14.5 tires are obtained from the 1994 Tire and Rim Association Yearbook.

It is apparent from a review of several DAPIA-approved designs and information received from the MHI that most manufacturers are using 7-14.5, 8 ply (Series D) tires. Under the provisions of Section D of Interpretative Bulletin (IB) J-1-76, the tire capacity at maximum overload is limited to 2,805

lbs. (1.5 x 1870 lbs.). However, the above-mentioned review of designs indicated that manufacturers and DAPIAs have misinterpreted another provision of the IB to permit 7-14.5, 8 ply (Series D) tires to be loaded up to 3,000 lbs. or 160 percent of their rated capacity.

Anecdotal accounts from some manufacturers indicated that the larger 8-14.5 tires are used for longer transport distances or where the road surfaces are less smooth than those on the Interstate highways. Presumably, manufacturers have discovered by experience that the use of 8-14.5 Series D or E tires may

reduce the possibility of tire failure under these circumstances.

B. The Number of Reported Failures of New and Used Tires During Transport

HUD has obtained information from three companies which transport large numbers of manufactured homes. These three companies collectively transport more than 30 percent of the manufactured homes produced in the United States and in the case of the largest transporter, nearly 50,000 manufactured homes per year.

The three companies differed in the reported overall rate of tire failure for shipment of manufactured homes. The failure rate for new tires ranged from 4 percent to 7 percent. The used tire failure rate was 9 percent. According to the MHI, roughly 55 percent of the tires sold to manufactured housing producers in 1994 were used tires.

Since the data from one company represented a large share of the market and transportation experience in a large number of States, HUD believes that the company's failure rate of 7 percent is the most representative of actual conditions. Therefore, HUD has used a failure rate of 7 percent for new tires and 9 percent for used tires with an overall average failure rate of 8 percent. Since each section of a manufactured home usually contains 6 tires, a tire will fail on about 40 percent of the sections shipped each year. Multiple failures of tires are less common but are known to occur.

There was also substantial variability among these three companies concerning the causes of tire failure. One company indicated that foreign

objects were the cause of 99 percent of tire failures, while the other companies indicated that substandard tires and tire overloading were the chief causes of tire failure. The other companies also noted that operating at excessive speed and other causes were less significant factors in tire failure.

There are no separate data as to the rate of failure due to tire overloading in relation to other factors, such as substandard tires, improper inflation, excessive heat, etc. The risk of tire failure due to overloading can be increased by operating the tire at reduced inflation, by the heat of the pavement, high speeds, mounting procedures and other practices which, if combined, may virtually assure tire failure. Hence, determining the percentage of failures attributable solely to tire overloading is difficult.

Data from one tire recycler, however, indicated that up to 70 percent of tires which are damaged can be recycled and reused after repair. This would suggest that foreign objects may have been the principal cause of tire failure rather than blow-outs due to overloading or other causes. The damage associated with blow-outs or causes other than foreign objects is generally too extensive to be repaired.

Based on the available information, HUD's best estimate is that 25 percent of reported failures can be attributed partly to tire overloading. HUD has reduced this estimate by half to account for failures due in part to aggravating factors, such as improper inflation or mounting. Therefore, assuming that 450,000 sections of manufactured

homes are shipped this year (450,000 shipments \times 0.40 (factor for shipments with at least one tire failure) \times 0.125 (percentage attributable to tire overloading), tire overloading would be responsible for at least 22,500 tire blowouts.

C. The Average Number of Times That the Tire Is Used

There is no reporting mechanism or authoritative data on the number of times a tire is used. However, incomplete data from transporters indicate that tires are used an average of ten times before they are unable to pass the tread depth requirement.

V. Cost Estimates of Possible Options for the Protection of the Public and To Ensure the Safe Transport of Manufactured Homes

Based on the available information, there are four approaches which would substantially alleviate or eliminate the problem of overloading of tires. These four options are discussed below:

A. Option No. 1: Reduction of the Permissible Tire Overloading to 18 Percent

HUD has obtained data from suppliers on the cost to upgrade from the 7-14.5 tires to tires with a rated capacity of 2,540 lbs. Assuming that the design calls for 3,000 lbs. per tire, the degree of tire overloading would be reduced from 50 to 60 percent to 18 percent. The wholesale incremental cost estimates were determined by assuming that each transportable section uses six tires. The results are shown in Table B:

TABLE B

Type of tire	Wholesale cost of 8-14.5 10 ply (series E)	Wholesale cost of 7-14.5 8 ply (series D)	Increase in wholesale cost	Total incremental cost per section
NEW	\$40	\$30	\$10	\$60
USED	30	26	4	24
AVERAGE COST FOR UPGRADED TIRES MAN. HOME				59

As shown in Table B, the cost for upgraded tires is relatively modest and this results in an average wholesale cost increase of nearly \$60 per home. The average cost per home is based on the usage patterns of new versus used tires and the relative percentage of single (53 percent) and multi-section (47 percent) homes.

B. Option No. 2: Reduction of the Permissible Tire Overloading to 8 Percent

HUD has obtained data from suppliers on the cost to upgrade from the 7-14.5 tires to tires with a rated capacity of 2,790 lbs. Assuming that the design calls for 3,000 lbs. per tire, the degree of tire overloading would be reduced from 50 to 60 percent to 8 percent. The same assumptions concerning the number of tires per section, new and used tires, etc. have been made to permit comparison of the various options. The results are shown in Table C:

TABLE C

Type of tire	Wholesale cost of 8-14.5 12 ply (series F)	Wholesale cost of 7-14.5 8 ply (series D)	Increase in wholesale cost	Total incremental cost per section
NEW	\$44	\$30	\$14	\$84
USED	Not available in sufficient quantities.	26
AVERAGE COST PER MAN. HOME	123.5

C. Elimination of Tire Overloading

1. Option No. 3: Addition of Another Axle and the Use of 8-14.5, 10 Ply Tires (Series E)

Another option is to require that the tires' rated capacity meet or exceed the live and dead load which will be applied to them. The manufacturer would probably have to use an additional axle to carry some of this load. The cost of this increased axle along with the upgraded tires is shown in Table D as follows:

TABLE D

Average cost of tires	Wholesale cost of new non-braking axles	Wholesale cost of used non-braking axles	
\$59	\$174	\$139
Total wholesale cost of tires and axles	\$287

According to one source, the cost of the additional wheels and axles would be greater because half of the axles would be braking axles which are 25 percent more expensive than non-braking axles. However, discussions with suppliers and analysis of manufactured home designs indicated that the changes in the degree of tire overloading have no impact on the number of braking versus non-braking axles as this is a function of the vehicle's weight, not the strength of the tires. Therefore, HUD believes that the additional cost of nearly \$287 is closer to the expected cost of the axle and tires.

2. Option No. 4: The Use of 9-14.5 12 Ply Series E and F Tires

Another alternative would be to upgrade the tires to 9-14.5, Series E and F tires which would involve little or no overloading with the use of a 6,000 lb. axle. Suppliers reported that because the 9-14.5 tires are being made only in small quantities, current prices would not be reliable indicators of unit costs at higher production levels. Therefore, it will be assumed that the cost of the 9-14.5 tires are double the cost of the 7-14.5 tires for these cost comparisons. The cost of these tires is shown in Table E:

TABLE E

Type of tire	Est. wholesale cost of 9-14.5 12 ply tires (series F)	Wholesale cost of 7-14.5 8 ply tires (series D)	Increase in wholesale cost	Total average cost per section
New	\$60	\$30	\$30	\$180
Used	Not available	26
Average cost per man. home	265

D. Adjustment to Cost Increases Due to Multiple Usages

In estimating the useful life of the 8-14.5 and 9-14.5 tires, it is conservative to assume that these tires would be able to be used for at least the same number of trips as the current 7-14.5 tires. Therefore, the FHWA and HUD have assumed that the upgraded tires can also be used a total of ten times. Based on ten trips per tire and shipments of 450,000 transportable sections of manufactured homes each year, the estimated wholesale cost per transportation unit and the annual wholesale cost of each option is shown in Table F.

TABLE F.—COST PER TRANSPORTATION UNIT AND ANNUAL COSTS

OPTION NO. 1 (UPGRADE TO 8-14.5 SERIES E TIRES)	\$6
TOTAL ANNUAL COST (WHOLESALE) FOR ALL HOMES	\$2,700,000
OPTION NO. 2 (UPGRADE TO 8-14.5 SERIES F TIRES)	\$12
TOTAL ANNUAL COST (WHOLESALE) FOR ALL HOMES	\$5,400,000
OPTION NO. 3 (ADDITIONAL AXLE AND UPGRADED TIRES)	\$29
TOTAL ANNUAL COST (WHOLESALE) FOR ALL HOMES	\$13,050,000
OPTION NO. 4 (UPGRADE TO 9-14.5 SERIES F TIRES)	\$27
TOTAL ANNUAL COST (WHOLESALE) FOR ALL HOMES	\$12,150,000

VI. Discussion Concerning the Overloading of Tires and the Other Requirements of the Interpretative Bulletin

In addition to an examination of the various options, HUD has reviewed the basis of the 1976 decision to permit the overloading of manufactured home tires. The overloading of manufactured home tires was based on certain assumptions and conditions existing at the time the rule was promulgated. These assumptions are discussed below:

A. Single or Very Limited Use of Tires; Short Travel Distances

In 1976, it was a common practice to limit the use of the tires to one, or perhaps a few more trips so that the total distance traveled would be only about 500 miles. Based on such limited usage, it may be permissible to exceed the normal supplier recommendations.

However, the markets for manufactured homes have broadened beyond the 2- to 3-hour driving distance so that some companies are shipping units for distances in excess of 500 miles. This long distance shipping is substantially greater than the limited range which the original Interpretative Bulletin was based on.

In order to determine common travel distances for homes, HUD has analyzed data to determine the total distance traveled from factories in several Southern States to the retailers who received the homes. The data is summarized in Table G:

TABLE G

Number of shipments analyzed	Percent shipped 1-250 miles	Percent shipped 251-500 miles	Percent shipped more than 500 miles
30,000	50	40	10

In 50 percent of the cases, the home was shipped more than 250 miles and in 10 percent of the cases, the distance shipped was more than 500 miles. Therefore, the typical transportation patterns at the time the Interpretative Bulletin was issued have changed significantly. Secondly, these data understate the total travel distance since they are calculated on the distance from the factory to the retailer, not to the homeowner's site. More significantly, the data supplied by the transporters indicate that the average tire is used ten times before it is unable to be used further.

B. Increased Weight of Manufactured Homes

At the time the Interpretative Bulletin was issued, the typical weight of manufactured homes per square foot was in the range of 16 to 17 lbs. Over the years, the average weight of the homes has increased due to the use of heavier exterior roofing materials, heavier exterior and interior wall coverings, and the addition of roof and wall sheathing materials. According to information provided by the National Conference of States on Building Codes and Standards, Inc. (NCSBCS), the average weight of these homes is now 19 to 23 lbs. per square foot, or an average increase of over 25 percent.

Furthermore, the increase in the design standards for homes shipped into high wind areas (Federal Register Vol. 59, No. 10, published January 14, 1994) will further increase the weight of homes due to the strengthening of the roof and wall construction. In this new wind standard, the wind design pressure for homes placed in High Wind Zone 2 has been increased to 39 psf with a 47 psf design pressure in High Wind Zone 3. Therefore, in high wind areas, the increase in weight from 1976 to the present could be as much as 30 percent.

C. Increased Speed on the Highways

Tire research undertaken by HUD indicated that tire overloading would not degrade tire life and performance when homes were transported at 50 mph. During the mid-1970's, the speed of travel in the United States was limited to 55 mph. Accordingly, HUD concluded that the likely travel speeds would be consistent with the research results and that the overloading of tires would not result in a high percentage of tire failure.

In large areas of the southern and western United States, the speed limit has been increased to 65 mph. The 1994 Tire and Rim Association Yearbook has indicated that tires can be overloaded by 9 percent if the tires are operated at speeds less than 50 mph. Speeds of 65 mph impose substantially greater loads on tires and industry standards would not permit the overloading of the tires at high speeds.

VII. The Use of Products in Excess of the Manufacturer's Recommendations Is Contrary to Accepted Practice in Other Sections of the Standards

In many sections of the Manufactured Home Construction and Safety Standards, HUD has indicated that products included in manufactured homes should be used in accordance

with the requirements of their listing and the supplier's installation instructions. While Subpart J does not specifically include requirements that the components be listed and certified, there are a number of other sections of the Standards (e.g. § 3280.304 etc.) where HUD has indicated that the component should be used in accordance with the manufacturer's design limitations for safe and effective operation.

HUD believes that the transportation system should be modeled after these other sections of the Standards that acknowledge the limitations established for listed products or the limitations determined by the supplier of the product. For this reason, HUD believes that significant overloading of the tires is a practice which is contrary to the collective judgement of the producers of these products and sound engineering practices because it permits the use of a product well beyond its design capacity. Such a direct violation of the listing or the supplier's usage instructions is not permitted in other sections of the Standards. Also, suppliers indicated that tire overloading of this magnitude is not permitted for any other commercial tire.

VIII. Conclusions and the Proposed Schedule for Modifying the Current Interpretative Bulletin

Based on the high rate of tire failure, the impact of tire failure on the structural integrity of the home and concerns about the safety of the travelling public on increasingly crowded public highways, HUD has concluded that the current overloading of manufactured home tires is no longer defensible. Secondly, HUD believes that the reasons for previously permitting the overloading do not reflect the current weights of manufactured homes, the multiple reuse of running gear equipment, and the experience of the transporters.

In addition, HUD is persuaded that the use of products substantially in excess of their design capacity is unsound and that the current degree of tire overloading and failure rates associated with increased travel speeds, less-than-ideal highway conditions, and heavier manufactured homes is not acceptable. Given today's conditions, the Interpretative Bulletin may be permitting practices which do not assure "that the running gear assembly, as part of the chassis, shall be designed to perform, as a balanced system, in order to effectively sustain the designed loads set forth in § 3280.904(b)(3) and to provide for *durable dependable safe*

mobility of the manufactured home" (emphasis added).

Therefore, HUD has concluded that elimination or substantial mitigation of tire overloading is needed. While the use of 9-14.5 Series F tires would be a possible option, these tires are not currently being produced. Therefore, a proposed rule which imposes such a requirement would require a long phase-in period. Also, the use of 9-14.5 Series F tires would be the most expensive option.

The 8-14.5 Series F tires can be produced with the same molds as 8-14.5 Series E tires which would shorten the necessary lead time. Series F tires, though, have not been produced in any quantity over the last several years and therefore, there are relatively few used tires that are available. Since most of the tires used to transport homes are used, this would further exacerbate a potential tire shortage and delay the implementation of a proposed rule. Hence, the available options have been narrowed to the acceptance of 18 percent overloading versus the elimination of tire overloading through the use of 8-14.5 Series E tires and an additional axle.

Absence of Authoritative Information Concerning This Subject

Definitive data on the effect of reducing the number of tire failures through the use of 8-14.5 Series E tires is not available. Evaluating the risk of allowing tire overloading by 18 percent versus no tire overloading is complicated by inadequate information on the causes of tire failure, the safety margins built into various tires, and the relative performance of new and used tires.

The Administration's policy in Executive Order 12866, Regulatory Planning and Review, requires that "Agencies should assess costs and benefits, both quantifiable and non-quantifiable and choose the approach with the maximum net benefits." Based on the information included in Table F, 18 percent tire overloading would impose one-half of the cost of the elimination of tire overloading and might therefore be the best alternative at this time, since it provides the greatest benefits for the least added cost.

While Options 1 and 3 will entail some additional cost to home manufacturers, the use of slightly overloaded and properly inflated 8-14.5 Series E tires should substantially reduce the number of tire failures. The cost avoided by eliminating tire failures will be considerable since there are service calls, lost productivity due to the time it takes to change the tire, and

even in some cases damage to the home. Knowledgeable sources indicated that the added cost for upgraded tires may be substantially or wholly offset by reduced service calls, longer tire life, and other benefits.

Therefore, FHWA and HUD are proposing to permit the overloading of manufactured home tires by not more than 18 percent for a period of two years from the effective date of the final rule and amended interpretative bulletin. During that two year period, both agencies would review any test and other technical data submitted by the manufactured housing industry and tire manufacturers concerning the relative performance of tires which are overloaded by 18 percent versus no tire overloading.

Unless both agencies are persuaded that the 18 percent overloading does not pose a risk to the traveling public and to the stability of the manufactured home, any overloading of tires beyond their design capacity would be prohibited after two years from the effective date of the final rule. FHWA and HUD encourage tire manufacturers and suppliers to submit all test and relevant information concerning the use of 8-14.5 Series E tires with an effective overloading of 18 percent.

Implementation Schedule for Changes in the Standards

Manufactured home production is likely to exceed 450,000 sections this year which will be a 20-year high for the industry. Since there are insufficient 8-14.5, Series E tires being produced, a sudden change in the tire requirements could result in shortages and disruption of manufactured housing shipments.

In a letter to Mr. Frank Williams, Director of the Florida Manufactured Housing Association, dated February 7, 1994, Goodyear Tire and Rubber indicated that the tire demand for 1994 would be 2,400,000 tires. Goodyear also indicated that should HUD eliminate the overloading of tires, thus prohibiting the use of the 7-14.5 tires, Goodyear could meet only 20 percent of the demand for 8-14.5 Series E tires.

Discussions with other tire industry officials indicated that producers would require a number of months to increase production to 90 percent of the expected 8-14.5 Series E tire demand. Other sources believed that adequate supplies of 8-14.5 Series E tires could be made available within 9 months. HUD has concluded that it is in the public interest to modify Interpretative Bulletin J-1-76 as soon as an adequate supply of 8-14.5 Series E tires is available. Therefore, these changes are proposed to be made effective nine months after

the publication of the amended interpretative bulletin.

Upon the effective date, tire overloading would be reduced to a level not greater than 18 percent and the number of axles necessary to support the transportation of the home would be based on engineering analysis or testing as required by 24 CFR 3280.904. HUD would welcome comments from tire suppliers and producers as to the feasibility of this implementation schedule.

IX. Proposed Changes to Interpretative Bulletin J-1-76 of the Manufactured Housing Standards

HUD has determined that the following changes should be made to Interpretative Bulletin J-1-76:

1. Section C—"Axles" would be deleted in its entirety because the Tables in that Section were based on higher service load factors of up to 50% for tires. In addition, there has been an increase of approximately 25% in design weights for currently produced manufactured homes than was originally assumed to develop the Tables.

Axles would be required to withstand the actual imposed dead load including all of the design loads outlined in § 3280.904(b)(3) without exceeding maximum allowable stresses for design axle life as recommended by the axle manufacturer. The manufacturer would determine the number of axles by engineering analysis or by testing as permitted in Section 3280.903(c).

Alternatively, if the manufacturer has submitted documented evidence of transportation experience, the minimum number of axles permitted by the experience record (weight slips, etc.) may not be less than the number of axles required to meet the above criteria. Also, the transportation experience must reflect the number of axles and tires that would be required under Subpart D of the Interpretative Bulletin as amended by this proposed rule.

2. Section D—"Tires, Wheels, and Rims" would be revised as follows:

Tires shall be sized and fitted to axles in accordance with the gross axle weight rating determined by the manufactured home manufacturer. The permissible tire loading may be increased up to a maximum of 18 percent over the rated load capacity of the manufactured home tire as determined by the manufacturer of the tire. Used tires may also be sized in accordance with the above criteria whenever the tread depth is at least $\frac{2}{32}$ of an inch as determined by a tread wear indicator. The determination as to whether a particular used tire is acceptable shall also include a visual

inspection for thermal and structural defects (e.g., dry rotting, excessive tire sidewall splitting, etc.). Wheels and rims shall be sized in accordance with the tire manufacturer's recommendations as suitable for use with the tires selected.

X. Proposed Amendments to the FMCSRs

The FHWA is proposing to amend 49 CFR 393.75 to make the FMCSRs consistent with the HUD's proposed amendments to Interpretative Bulletin J-1-76. Section 393.75(f)(1)(i) and (ii) would be redesignated as § 393.75(f)(1) and (2). The redesignated paragraphs would address all CMVs with the exception of manufactured homes. Section 393.75(f)(2) would also reinstate speed restrictions on CMVs operated on overloaded tires. The FHWA is proposing that vehicles with overloaded tires be prohibited from operating at speeds above 80 km/hr (50 mph). This speed ensures the safe operation of the vehicle while preventing conflicts with minimum speed limits in certain States. The 80 km/hr (50 mph) speed is consistent with the previous speed restriction which was rescinded in 1988.

The FHWA is not proposing limitations on the amount of tire overloading allowed for vehicles other than manufactured homes. The FHWA will examine that issue separately from this rulemaking and, if necessary, propose amendments in a future proceeding.

To address the issue of overloaded tires on manufactured homes, the FHWA is proposing a new paragraph. Section 393.75(g) would allow 18 percent overloading of manufactured home tires for a period of two years after the effective date of the final rule. Manufactured homes operating on tires overloaded by more than 9 percent would be restricted to a maximum speed of 80 km/hr (50 mph). This speed restriction is consistent with information contained in the 1994 Tire and Rim Association Handbook.

The FHWA notes that HUD is not proposing to include a speed restriction in the Interpretative Bulletin. While this would result in a difference between the revised Interpretative Bulletin and the amended FMCSRs, the FHWA and HUD do not believe this minor difference will create enforcement problems for the States. Since speed limits are not related to the HUD standards for components or elements of the manufactured housing units, the reinstatement of a speed restriction under § 393.75, and subsequent adoption by the States,

would not be in conflict with the revised Interpretative Bulletin.

With regard to the tire pressure and inflation requirements currently found at § 393.75(f)(2) and (3), the FHWA proposes to include these provisions in a new paragraph, § 393.75(h). The FHWA is not proposing substantive changes to the requirements concerning tire pressure and inflation at this time.

XI. Proposed Effective Date for FHWA and HUD Amendments

The FHWA and HUD propose that these revisions to the Regulations and the Interpretative bulletin be made effective nine months after the publication of the final rule.

XII. Rulemaking Analysis and Notices

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the dockets at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable, but the FHWA and HUD may issue a final rule at any time after the close of the comment period. In addition to late comments, the FHWA will also continue to file in the docket FHWA MC-95-1 relevant information that becomes available after the comment closing date, and interested persons should continue to examine the docket for new material.

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

The FHWA and HUD have determined that this action is not a significant regulatory action within the meaning of Executive Order 12866. In addition, the FHWA has determined that this action is not significant within the meaning of Department of Transportation regulatory policies and procedures. This rule would, if adopted, establish tire loading limitations for manufactured homes transported in interstate commerce. This action would eliminate inconsistency between the FHWA and HUD requirements for manufactured homes. The FHWA and HUD have evaluated the economic impact of potential changes to the regulatory requirements concerning the safe transportation of manufactured homes and determined that the proposed standard is reasonable, appropriate, and the least costly and intrusive approach for the resolution of this issue.

Nevertheless, based on the information received in response to this notice, the FHWA and HUD intend to

carefully consider the costs and benefits associated with various alternative requirements. Comments, information, and data are solicited on the economic impact of the potential changes.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601-612), the FHWA and HUD have evaluated the potential effects of this rulemaking proposal on small entities and determined that the proposed standard is reasonable, appropriate, and the least costly and intrusive approach for the resolution of this issue. The FHWA and HUD certify that this rulemaking does not have a significant economic impact on a substantial number of small entities. The FHWA and HUD solicit comments, information, and data on these impacts.

Executive Order 12612 (Federalism Assessment)

The FHWA has analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 12612, *Federalism*, and determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The General Counsel of HUD, as the Designated Official under Section 6(a) of Executive Order 12612, has determined that the policies contained in this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, the rule is not subject to review under the Order.

Specifically, the requirements of this rule are directed to manufacturers and do not impinge upon the relationship between the Federal government and State and local governments.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

The proposal in this document does not contain information collection requirements [44 U.S.C. 3501 *et seq.*].

National Environmental Policy Act

The FHWA has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined that this action would not have any effect on the quality of the environment.

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR Part 50, which implement section 102(2)(c) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk at the above address.

Regulation Identification Numbers

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RINs contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

Executive Order 12606, The Family

The General Counsel of HUD, as the Designated Official under Executive Order 12606, The Family, has determined that this rule does not have potential for significant impact on formation, maintenance, and general well-being of families, and thus, is not subject to review under the Order. The rule involves requirements for transportation safety standards for manufactured homes. Any effect on the family would likely be indirect and insignificant.

List of Subjects in 24 CFR Part 3280

Fire prevention, Housing standards, Manufactured homes.

List of Subjects in 49 CFR Part 393

Highway safety, Highways and roads, Motor carriers, and Motor vehicle safety.

In consideration of the foregoing, the Department of Housing and Urban Development proposes to amend 24 CFR part 3280 and Interpretative Bulletin J-1-76, and the Department of Transportation, Federal Highway Administration proposes to amend 49 CFR part 393 as set forth below.

24 CFR Chapter XX

PART 3280—MANUFACTURED HOME CONSTRUCTION AND SAFETY STANDARDS

1. The authority citation for Part 3280 is revised to read as follows:

Authority: 42 U.S.C. 3535(d), 5301, and 5401.

2. Interpretative Bulletin J-1-76 published at 41 FR 53627 (December 7, 1976) would be amended as follows. (The Interpretative Bulletin is available from the Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 7th St. SW., Washington, DC 20410).

Section C. of the interpretative bulletin would be removed. Section D. would be redesignated as Section C. and would be revised to read as set forth below. Sections E. and F. would be redesignated as Sections D. and E.

* * * * *

C. Tires shall be sized and fitted to axles in accordance with the gross axle weight rating determined by the mobile home manufacturer. The permissible tire loading may be increased up to a maximum of 18 percent beyond the rated load capacity of the manufactured home tire as determined by the manufacturer of the tire. Used tires may also be sized in accordance with the above criteria whenever the tread depth is at least $\frac{2}{32}$ of an inch as determined by a tread wear indicator. The determination as to whether a particular used tire is acceptable shall also include a visual inspection of thermal and structural defects (e.g., dry rotting, excessive tire sidewall splitting, etc.). Wheels and rims shall be sized in accordance with the tire manufacturer's recommendations as suitable for use with the tires selected. This provision will become effective nine months after the publication date of the final rule (insert publication date). This provision will expire (INSERT DATE TWO YEARS AFTER THE EFFECTIVE DATE OF THE AMENDED INTERPRETATIVE BULLETIN) unless extended by mutual consent of FHWA and HUD.

* * * * *

49 CFR Chapter III

PART 393—PARTS AND ACCESSORIES NECESSARY FOR SAFE OPERATION

4. The authority citation at the end of § 393.75 would be removed and the authority citation for 49 CFR part 393 would be revised to read as follows:

Authority: Section 1041(b) of Pub. L. 102-240, 105 Stat. 1914, 1993; 49 U.S.C. 31136 and 31502; 49 CFR 1.48.

5. Section 393.5 would be amended by adding the definitions of *manufactured home*, *length of a manufactured home*, and *width of a manufactured home*, placing them in alphabetical order, as follows:

* * * * *

Length of a manufactured home. The largest exterior length in the traveling mode, including any projections which contain interior space. Length does not include bay windows, roof projections,

overhangs, or eaves under which there is no interior space, nor does it include drawbars, couplings or hitches.

* * * * *

Manufactured home. A structure, transportable in one or more sections, which in the traveling mode, is eight feet or more in width or forty feet or more in length or, when erected on site, is three hundred and twenty or more square feet, and which is built on a permanent chassis and designed to be used as a dwelling with or without a permanent foundation when connected to the required utilities, and includes the plumbing, heating, air-conditioning, and electrical systems contained therein. Calculations used to determine the number of square feet in a structure will be based on the structure's exterior dimensions measured at the largest horizontal projections when erected on site. These dimensions will include all expandable rooms, cabinets, and other projections containing interior space, but do not include bay windows. This term includes all structures which meet the above requirements except the size requirements and with respect to which the manufacturer files a certification pursuant to 24 CFR 3282.13 and complies with the standards set forth in part 24 CFR 3280.

* * * * *

Width of a manufactured home. The largest exterior width in the traveling mode, including any projections which contain interior space. Width does not include bay windows, roof projections, overhangs, or eaves under which there is no interior space.

6. Section 393.75 would be amended by revising paragraph (f), and by adding paragraphs (g) and (h) to read as follows:

§ 393.75 Tires.

* * * * *

(f) *Tire loading restrictions.* With the exception of manufactured homes, no motor vehicle shall be operated with tires that carry a weight greater than that marked on the sidewall of the tire or, in the absence of a marking on the sidewall of the tire, a weight greater than that specified for the tires in any of the publications of any of the organizations listed in FMVSS No. 119 (49 CFR 571.119, S5.1(b)) unless:

(1) The vehicle is being operated under the terms of a special permit issued by the State; and

(2) The vehicle is being operated at a reduced speed to compensate for the tire loading in excess of the manufacturer's rated capacity for the tire. In no case shall the speed exceed 80 km/hr (50 mph).

(g) *Tire loading restrictions for manufactured homes.* Effective (INSERT

DATE NINE MONTHS AFTER THE PUBLICATION DATE OF THE FINAL RULE), tires used for the transportation of manufactured homes (i.e., tires marked or labeled 7-14.5MH and 8-14.5MH) may be loaded up to 18 percent over the load rating marked on the sidewall of the tire or, in the absence of a marking on the sidewall of the tire, 18 percent over the load rating specified in any of the publications of any of the

organizations listed in FMVSS No. 119 (49 CFR 571.119, S5.1(b)). Manufactured homes transported on tires overloaded by 9 percent or more must not be operated at speeds exceeding 80 km/hr (50 mph). This provision will expire (INSERT DATE TWO YEARS AFTER THE EFFECTIVE DATE OF THE FINAL RULE) unless extended by mutual consent of FHWA and HUD.
(h) *Tire inflation pressure.*

(1) No motor vehicle shall be operated on a tire which has a cold inflation pressure less than that specified for the load being carried.
(2) If the inflation pressure of the tire has been increased by heat because of the recent operation of the vehicle, the cold inflation pressure shall be estimated by subtracting the inflation buildup factor shown in Table 1 from the measured inflation pressure.

TABLE 1.—INFLATION PRESSURE MEASUREMENT CORRECTION FOR HEAT

Average speed of vehicle in the previous hour	Minimum inflation pressure buildup	
	Tires with 1,814 kg (4,000 lbs.) maximum load rating or less	Tires with over 1,814 kg (4,000 lbs.) load rating
66–88.5 km/hr (41–55 mph)	34.5 kPa (5 psi)	103.4 kpa (15 psi).

Issued on: March 15, 1996.
 Nicolas P. Retsinas,
Assistant Secretary for Housing-Federal Housing Commissioner.
 Rodney E. Slater,
Federal Highway Administrator.
 [FR Doc. 96-9717 Filed 4-22-96; 8:45 am]
 BILLING CODE 4210-27-P

Federal Register

Tuesday
April 23, 1996

Part IV

**Department of
Housing and Urban
Development**

Office of the Secretary

24 CFR Parts 26, 28, 30, et al.
Streamlining Hearing Procedures;
Proposed Rule

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

Office of the Secretary

**24 CFR Parts 26, 28, 30, 81, 200, 950,
965, and 3500**

[Docket No. FR-4022-P-01]

RIN 2501-AC19

**Streamlining Hearing Procedures;
Proposed Rule**

AGENCY: Office of the Secretary, HUD.
ACTION: Proposed rule.

SUMMARY: In response to the President's regulatory reform initiatives, this proposed rule would streamline and consolidate many of HUD's regulations containing hearing procedures. This rule also proposes several substantive changes to these regulations in order to improve the hearing process and to make the regulations more closely follow applicable statutes. This proposed rule would make the regulations easier for the public to use and understand.

DATES: *Comments due:* June 24, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Emmett N. Roden, Assistant General Counsel for Administrative Proceedings, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street, S.W., Room 10251, Washington, D.C. 20410, telephone (202) 708-2350. (This is not a toll-free number.) Hearing- and speech-impaired persons may access this number via TTY by calling the Federal Information Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION:

I. Regulatory Reinvention

On March 4, 1995, President Clinton issued a memorandum to all Federal departments and agencies regarding regulatory reinvention. In response to this memorandum, the Department of Housing and Urban Development conducted a page-by-page review of its regulations to determine which can be

eliminated, consolidated, or otherwise improved. HUD has determined that this proposed rule is necessary to consolidate and streamline HUD's various sets of regulations containing hearing procedures. Therefore, this proposed rule would consolidate several sets of hearing procedures into one part, thereby eliminating approximately 20 pages of unnecessary regulations from the Code of Federal Regulations (CFR).

II. Background

**A. Hearings According to the
Administrative Procedure Act**

In this rule, HUD proposes to use 24 CFR part 26 to contain two sets of hearing regulations. The first set of regulations would contain all the procedures that currently appear in part 26. These procedures apply in HUD proceedings before a hearing officer, including administrative sanction hearings under part 24 and hearings with respect to actions by the Mortgagee Review Board under part 25. This proposed rule would not change the substance of any of these provisions, but it would set them apart so that they all appear within a new subpart A of part 26.

This proposed rule would add the second set of regulations to form a new subpart B. The regulations in subpart B would contain a relatively uniform set of hearing procedures for formal hearings according to the Administrative Procedure Act (5 U.S.C. 551 et seq.) (APA). By adding these uniform procedures to subpart B of part 26, HUD intends to consolidate as many of its hearing procedures as possible into one part. This should make HUD's hearing procedures easier to use and understand.

The hearing procedures in subpart B would apply to hearings under the Program Fraud Civil Remedies Act of 1986, the procedures for which currently appear in part 28. Subpart B would also apply to hearings in which HUD seeks civil money penalties, the procedures for which currently appear in part 30, and to hearings pursuant to the Interstate Land Sales Full Disclosure Act, the procedures for which currently appear in part 1720. HUD intends that subpart B will be used in hearings conducted pursuant to the APA, unless other statutory or regulatory provisions apply.

In addition to consolidating these hearing procedures into one part and making them uniform, this proposed rule would also make a number of changes in order to streamline pleadings and reduce administrative overhead. This proposed rule contains specific

time limits to ensure rapid disposition of cases (see, e.g., §§ 26.39, 26.42, 26.44, 26.50). The proposed rule also would clarify that parties must seek Secretarial review in order to exhaust their administrative remedies before seeking judicial review, thereby addressing the Supreme Court's decision in *Darby v. Cisneros*, 113 S.Ct. 2539 (1993). This proposed rule also incorporates the Federal Rules of Civil Procedure for certain aspects of discovery (see §§ 26.41(a), (c); § 26.43(b)).

HUD specifically invites the public to comment on these procedural changes that would be incorporated into part 26 subpart B, as well as ways in which HUD could further streamline its hearing procedures.

**B. Program Fraud Civil Remedies Act of
1986**

Part 28 of HUD's regulations contains the procedures for imposing civil penalties and assessments, pursuant to the Program Fraud Civil Remedies Act of 1986 (PFCRA), upon persons who make false or fraudulent claims or statements to Federal authorities. HUD established the regulations in part 28 on June 24, 1988 (53 FR 24000). The Department of Health and Human Services led a task force to draft a model regulation to implement PFCRA, and part 28 follows the model closely with only minor variations to accommodate HUD's organizational and program structure.

This proposed rule would streamline the provisions in part 28 by removing the hearing procedures, and by retaining in their place a cross-reference to the uniform hearing procedures in part 26 subpart B (see, e.g., § 28.40 of this proposed rule). This proposed rule would also streamline the substantive provisions of the PFCRA regulations by eliminating unnecessary language and by clarifying the remaining language, making these regulations easier to use and understand. In addition to these streamlining changes, HUD also proposes to shorten the decision process by removing the reconsideration of initial determinations.

C. Civil Money Penalties

HUD established the civil money penalties regulations in part 30 on May 22, 1991 (56 FR 23622). These regulations implemented several sections of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235; approved December 15, 1989), which authorized HUD to impose civil money penalties for unlawful conduct in connection with a broad array of programs.

In this rule, HUD proposes to streamline the regulations in part 30. As with the regulations in part 28 for PFCRA, this proposed rule would remove the hearing procedures from part 30, maintaining a cross-reference to the uniform hearing procedures in part 26 subpart B. In addition, this proposed rule would eliminate three of the civil money penalty panels that exist in the current regulations: the Housing Civil Penalties Panel (HCPP), the Government National Mortgage Association Civil Penalties Panel (GCPP), and the Departmental Civil Penalties Panel (DCPP) (see § 30.205 of the current regulations). HUD created these panels to review recommendations for and to propose civil money penalties. However, this proposed rule would provide that certain appropriate HUD officials would replace the panels in their authority to initiate actions for civil money penalties. For instance, in § 30.20 of this proposed rule, the General Counsel or his or her designee, rather than the DCP, may initiate a civil money penalty action against HUD employees who improperly disclose information. See also §§ 30.25 through 30.60 of this proposed rule.

In addition to the streamlining changes contained in this proposed rule, HUD proposes to revise and clarify the list of violations for Government National Mortgage Association (GNMA) issuers and custodians (§ 30.45 of this proposed rule). HUD also proposes to revise the list of violations applicable to mortgagees and lenders to include the misuse of loan proceeds and the failure to comply with settlement agreements with HUD (§ 30.35(a)(11) and (a)(15) of this proposed rule), and to expand the violation for failure to service Section 235 mortgages to include other housing programs (§ 30.35(a)(10) of this proposed rule).

This proposed rule would also revise part 30 to include the civil money penalties that were enacted as part of the Housing and Community Development Act of 1992 (Pub. L. 102-550; approved October 28, 1992). Specifically, the proposed rule would add provisions concerning failure to disclose lead-based paint (§ 30.60 of this proposed rule) and violations by mortgagees and lenders concerning loan guarantees for Indian Housing (§ 30.35(a)(14) of this proposed rule).

D. Conforming Changes

This proposed rule would also make necessary conforming changes, which are merely technical and nonsubstantive, to the following HUD regulations:

1. Government Sponsored Enterprises, 24 CFR part 81;

2. Participation and Compliance Requirements for Federal Housing Administration programs, 24 CFR 200.243;

3. Insurance Entities under the Indian Housing Programs, 24 CFR 950.190, and the Public Housing Programs, 24 CFR 965.205;

4. The Real Estate Settlement Procedures Act, 24 CFR part 3500.

III. Other Matters

National Environmental Policy Act

In accordance with 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.20(k) of HUD regulations, the policies and procedures contained in this proposed rule relate only to hearing procedures and administrative decisions, which do not constitute development decisions and do not affect the physical condition of a project area or building site. Therefore, this proposed rule is categorically excluded from the requirements of the National Environmental Policy Act.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule implements statutory authority intended to protect HUD's programs from abusive practices, but it will have no adverse or disproportionate economic impact on small businesses.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this proposed rule does not have potential for significant impact on family formation, maintenance, and general well-being. No significant change in existing HUD policies or programs will result from promulgation of this proposed rule, as those policies and programs relate to family concerns. Therefore, the proposed rule is not subject to review under the Order.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under Section 6(a) of Executive Order 12612, *Federalism*, has determined that the policies contained in this proposed rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal Government and the States, or on the

distribution of power and responsibilities among the various levels of government. As a result, the proposed rule is not subject to review under the Order.

List of Subjects

24 CFR Part 26

Administrative practice and procedure, Claims, Fraud, Grant programs—housing and community development, Loan programs—housing and community development, Mortgages, Penalties.

24 CFR Part 28

Administrative practice and procedure, Claims, Fraud, Penalties.

24 CFR Part 30

Administrative practice and procedure, Grant programs—housing and community development, Loan programs—housing and community development, Mortgages, Penalties.

24 CFR Part 81

Accounting, Federal Reserve System, Mortgagees, Reporting and recordkeeping requirements, Securities.

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Incorporation by reference, Lead poisoning, Loan programs—housing and community development, Minimum property standards, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 950

Aged, Grant programs—housing and community development, Grant programs—Indians, Indians, Individuals with disabilities, Low and moderate income housing, Public housing, Reporting and recordkeeping requirements.

24 CFR Part 965

Energy conservation, Government procurement, Grant programs—housing and community development, Lead poisoning, Loan programs—housing and community development, Public housing, Reporting and recordkeeping requirements, Utilities.

24 CFR Part 3500

Consumer protection, Condominiums, Housing, Mortgages, Mortgage servicing, Reporting and recordkeeping requirements.

Accordingly, parts 26, 28, 30, 81, 200, 950, 965, and 3500 of title 24 of the Code of Federal Regulations are proposed to be amended as follows:

PART 26—HEARING PROCEDURES

1. The part heading for part 26 is revised to read as set forth above.

2. The authority citation for 24 CFR part 26 continues to read as follows:

Authority: 42 U.S.C. 3535(d).

3. The heading of subpart A is revised to read, "Subpart A—Hearings Before Hearing Officers".

Subparts B, C, D, E, F, and G [Redesignated]

4. The headings for subparts B, C, D, E, F, and G are redesignated as undesignated center headings; and §§ 26.2 through 26.26 of subparts B, C, D, E, F, and G are redesignated as §§ 26.2 through 26.26 of subpart A.

5. A new subpart B is added to read as follows:

Subpart B—Hearings Pursuant to the Administrative Procedure Act

General

Sec.

- 26.27 Purpose and scope.
- 26.28 Definitions.
- 26.29 Powers and duties of the Administrative Law Judge (ALJ).
- 26.30 Ex parte contacts.
- 26.31 Disqualification of ALJ.
- 26.32 Parties to the hearing.
- 26.33 Separation of functions.
- 26.34 Time computations.
- 26.35 Service and filing.
- 26.36 Sanctions.

Prehearing Procedures

- 26.37 Commencement of action.
- 26.38 Motions.
- 26.39 Default.
- 26.40 Prehearing conferences.
- 26.41 Discovery.
- 26.42 Subpoenas.
- 26.43 Protective order.

Hearings

- 26.44 General.
- 26.45 Witnesses.
- 26.46 Evidence.
- 26.47 The record.
- 26.48 Posthearing briefs.
- 26.49 Initial decision.
- 26.50 Appeal to the Secretary.
- 26.51 Exhaustion of administrative remedies.
- 26.52 Judicial review.
- 26.53 Collection of civil penalties and assessments.
- 26.54 Right to administrative offset.

Subpart B—Hearings Pursuant to the Administrative Procedure Act

General

§ 26.27 Purpose and scope.

Unless otherwise specified in this part, the rules in this subpart B apply to hearings that HUD is required by statute to conduct pursuant to the Administrative Procedure Act (5 U.S.C. 554 *et seq.*).

§ 26.28 Definitions.

The following definitions apply to subpart B of this part:

Chief Docket Clerk means the Chief Docket Clerk of the Office of Administrative Law Judges at the following address: 409 3rd Street, S.W., Suite 320, Washington, D.C. 20024.

Complaint means the notice from HUD alleging violations of a HUD statute and/or regulation, citing the legal authority upon which it is issued, stating the relief HUD seeks, and informing a respondent of his or her right to file a response and to request an opportunity for a hearing before an Administrative Law Judge.

Response means the written response to a complaint, admitting or denying the allegations in the complaint and setting forth any affirmative defense and/or any mitigating factors or extenuating circumstances. A response is deemed a request for a hearing.

§ 26.29 Powers and duties of the Administrative Law Judge (ALJ).

Authority of the Administrative Law Judge (ALJ). The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made. The ALJ is authorized to:

- (a) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;
- (b) Continue or recess the hearing in whole or in part for a reasonable period of time;
- (c) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;
- (d) Administer oaths and affirmations;
- (e) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;
- (f) Rule on motions and other procedural matters;
- (g) Regulate the scope and timing of discovery;
- (h) Regulate the course of the hearing and the conduct of representatives and parties;
- (i) Examine witnesses;
- (j) Receive, rule on, exclude, or limit evidence;

(k) Upon motion of a party, take official notice of facts;

(l) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(m) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(n) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

§ 26.30 Ex parte contacts.

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 26.31 Disqualification of ALJ.

(a) An ALJ in a particular case may disqualify himself or herself.

(b) A party may file with the ALJ a motion for the ALJ's disqualification. The motion shall be accompanied by an affidavit alleging the grounds for disqualification.

(c) Upon the filing of a motion and affidavit, the ALJ shall proceed no further in the case until the matter of disqualification is resolved.

§ 26.32 Parties to the hearing.

(a) *General*. The parties to the hearing shall be the respondent and HUD.

(b) *Rights of parties*. Except as otherwise limited by subpart B of this part, all parties may:

- (1) Be accompanied, represented, and advised by a representative;
- (2) Participate in any conference held by the ALJ;
- (3) Conduct discovery;
- (4) Agree to stipulations of fact or law, which shall be made part of the record;
- (5) Present evidence relevant to the issues at the hearing;
- (6) Present and cross-examine witnesses;
- (7) Present oral arguments at the hearing as permitted by the ALJ; and
- (8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 26.33 Separation of functions.

No officer, employee, or agent of the Federal Government engaged in the performance of investigative, conciliatory, or prosecutorial functions in connection with the proceeding shall, in that proceeding or any factually

related proceeding under subpart B of this part, participate or advise in the decision of the administrative law judge, except as a witness or counsel during the proceeding, or in its appellate review.

§ 26.34 Time computations.

(a) In computing any period of time under subpart B of this part, the time period begins the day following the act, event, or default and includes the last day of the period, unless the last day is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which case the time period includes the next business day. When the prescribed time period is seven days or less, intermediate Saturdays, Sundays, and legal holidays shall be excluded from the computation.

(b) *Entry of orders.* In computing any time period involving the date of the issuance of an order or decision by an administrative law judge, the date of issuance is the date the order or decision is served by the Chief Docket Clerk.

(c) *Service by mail.* If a document is served by mail, five days shall be added to the time permitted for a response.

§ 26.35 Service and filing.

(a) *Filing.* All documents shall be filed with the Chief Docket Clerk, at the address listed in § 26.28. Filing may be by first class mail, delivery, facsimile transmission, or electronic means; however, the ALJ may place appropriate limits on filing by facsimile transmission or electronic means. All documents shall clearly designate the docket number and title of the proceeding.

(b) *Service.* One copy of all documents filed with the Chief Docket Clerk shall be served upon each party by the persons filing them and shall be accompanied by a certificate of service stating how and when such service has been made. Service may be made by delivery, first class mail, facsimile transmission, or electronic means; however, the ALJ may place appropriate limits on service by facsimile transmission or electronic means. Documents shall be served upon a party's address of residence or principal place of business, or, if the party is represented by counsel, upon counsel of record at the address of counsel. Service is complete when handed to the person or delivered to the person's office or residence and deposited in a conspicuous place. If service is by first-class mail, facsimile transmission or electronic means, service is complete upon deposit in the mail or upon electronic transmission.

§ 26.36 Sanctions.

(a) The ALJ may sanction a person, including any party or representative, for failing to comply with an order, rule, or procedure governing the proceeding; failing to prosecute or defend an action; or engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) *Failure to comply with an order.* When a party fails to comply with an order, including an order compelling discovery, the ALJ may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, regard each matter about which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with the order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; or

(4) Strike any part of the pleadings or other submissions of the party failing to comply with the order.

(d) If a party fails to prosecute or defend an action under this part, the ALJ may dismiss the action or may issue an initial decision against the respondent.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document that is not filed in a timely fashion.

Prehearing Procedures

§ 26.37 Commencement of action.

An action under subpart B of this part shall commence with the Government's filing of a complaint, and a response thereto, as those terms are defined in § 26.28, with the Chief Docket Clerk. If the respondent fails to file a response, then the Government may file a motion for a default judgment, together with a copy of the complaint, in accordance with § 26.39.

§ 26.38 Motions.

(a) *General.* All motions shall state the specific relief requested and the basis therefor and, except during a conference or the hearing, shall be in writing. Written motions shall be filed and served in accordance with § 26.35.

(b) *Response to motions.* Unless otherwise ordered by the ALJ, a response to a written motion may be filed within 7 days after service of the motion. A party failing timely to

respond to a motion shall be deemed to have waived any objection to the granting of the motion.

§ 26.39 Default.

(a) *General.* The respondent may be found in default, upon motion, for failure to file a timely response to the Government's complaint. The motion shall include a copy of the complaint and a proposed default order, and shall be served upon all parties. The respondent shall have 7 days from such service to respond to the motion.

(b) *Default order.* The ALJ shall issue a decision on the motion within 15 days after the expiration of the time for filing a response to the default motion. If a default order is issued, it shall constitute the final agency action.

(c) *Effect of default.* A default shall constitute an admission of all facts alleged in the Government's complaint and a waiver of respondent's right to a hearing on such allegations. The penalty proposed in the complaint shall be set forth in the default order and shall be immediately due and payable by respondent without further proceedings.

§ 26.40 Prehearing conferences.

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) Prehearing conferences may consider the following:

(1) Simplification of the issues;

(2) Stipulations of fact and of the authenticity, accuracy, and admissibility of documents;

(3) Submission of the case on briefs in lieu of an oral hearing;

(4) Limitation of the number of witnesses;

(5) The exchange of witness lists and of proposed exhibits;

(6) Discovery;

(7) The time and place for the hearing; and

(8) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

§ 26.41 Discovery.

(a) Unless otherwise stated in subpart B of this part, discovery shall be conducted in accordance with the Federal Rules of Civil Procedure, except for Rule 26(a), (d) and (f).

(b) Discovery in Program Fraud Civil Remedies actions (24 CFR part 28), unless agreed to by the parties, shall be available only as ordered by the ALJ. The party opposing discovery shall have 10 days to respond to a motion for discovery. The ALJ shall grant a motion

for discovery only if he or she finds that discovery is necessary for the expeditious, fair, and reasonable consideration of the issues, is not unduly costly or burdensome, will not unduly delay the proceeding, and does not seek privileged information. The ALJ may grant discovery subject to a protective order under § 26.43. The request for approval sent to the Attorney General from the General Counsel or designee, as described in § 28.20 of this title, is not discoverable under any circumstances.

(c) The following types of discovery are authorized:

(1) Requests for production of documents for inspection and copying. Nothing contained herein shall be interpreted to require the creation of a document.

(2) Requests for admissions.

(3) *Written interrogatories*. Such interrogatories shall be limited in number in accordance with Rule 33 of the Federal Rules of Civil Procedure.

(4) Depositions.

(d) *Motions to compel*. A party may file a motion to compel discovery. The motion shall describe the information sought, cite the opposing party's objection, and provide arguments supporting the motion. The opposing party may file a response to the motion, including a request for a protective order. The ALJ may issue an order compelling a response, issue sanctions pursuant to § 26.36, or issue a protective order. For purposes of paragraph (d) of this section, an evasive or incomplete answer to a request for discovery is treated as a failure to answer.

(e) Each party shall bear its own costs of discovery.

§ 26.42 Subpoenas.

(a) *General*. Upon written request of a party, the ALJ may issue a subpoena requiring the attendance of a witness at a deposition or hearing, and/or the production of documents. The request shall specify any documents to be produced and shall list the names and addresses of the witnesses.

(b) *Time of request*. A request for a subpoena in aid of discovery shall be filed in time to permit the conclusion of discovery 15 days before the date fixed for the hearing. A request for a subpoena to testify at the hearing shall be filed at least three days prior to the hearing, unless otherwise allowed by the ALJ for good cause shown.

(c) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(d) *Service and fees*. Subpoenas shall be served, and fees and costs paid to

subpoenaed witnesses, in accordance with Rule 45(b)(1) of the Federal Rules of Civil Procedure.

(e) *Motion to quash*. The individual to whom the subpoena is directed or a party may file a motion to quash the subpoena within 10 days after service, or on or before the time specified in the subpoena for compliance if it is less than 10 days after service.

§ 26.43 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may issue any order that justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, as provided for in Rule 26(c) of the Federal Rules of Civil Procedure.

Hearings

§ 26.44 General.

(a) *Time of hearing*. The hearing shall commence not later than 60 days following the filing of the complaint and response under § 26.37, unless the time is extended for good cause. The ALJ shall provide written notice to all parties of the reasons for any extension of time.

(b) *Location of hearing*. The hearing shall be held where the respondent resides or transacts business, or in such other place as may be agreed upon by the parties and the ALJ. Hearings for Program Fraud Civil Remedies Act cases shall be located in accordance with 31 U.S.C. 3803(g)(4).

(c) *Notice of hearing*. The ALJ shall issue a notice of hearing to all parties specifying the time and location of the hearing, the matters of fact and law to be heard, the legal authority under which the hearing is to be held, a description of the procedures for the conduct of the hearing, and such other matters as the ALJ determines to be appropriate.

(d) *Limitations for Program Fraud Civil Remedies Act cases*. The notice of hearing must be served upon the respondent within 6 years after the date on which the claim or statement is made. If the respondent fails to file a timely response to the Government's complaint, service of a default judgment under § 26.39 shall be regarded as a notice of hearing for purposes of this section. The statute of limitations may be extended by agreement of the parties.

(e) *Burden and standard of proof*. HUD shall prove the respondent's

liability and any aggravating factors by a preponderance of the evidence. Respondent shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(f) *Public hearings*. Unless otherwise ordered by the ALJ for good cause shown, the hearing shall be open to the public.

§ 26.45 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. In order to be admissible, any written statement must be provided to all other parties along with the last known address of the witness, in a manner that allows sufficient time for other parties to subpoena the witness for cross-examination at the hearing.

§ 26.46 Evidence.

(a) The ALJ shall admit any relevant oral or documentary evidence that is not privileged. The ALJ may, however, exclude evidence if its probative value is substantially outweighed by the danger of unfair prejudice, by confusion of the issues, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

(b) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(c) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ in accordance with § 26.43.

§ 26.47 The record.

(a) The hearing will be recorded and transcribed. The transcript of testimony, exhibits, and other evidence admitted at the hearing and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary or designee.

(b) The record may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ in accordance with § 26.43.

§ 26.48 Posthearing briefs.

Posthearing briefs shall be filed only upon order by the ALJ.

§ 26.49 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the relief

granted. The ALJ shall consider such factors as may be set forth in applicable statutes and regulations.

(b) The ALJ shall serve the initial decision on all parties within 45 days after either the close of the record, or the expiration of time permitted for submission of posthearing briefs, whichever is later. The initial decision shall include a statement of each party's right to file a request for Secretarial review. The ALJ may extend the 45-day period for serving the initial decision in writing for good cause.

(c) If no appeal is timely filed with the Secretary or designee, the initial decision shall become the final agency action.

§ 26.50 Appeal to the Secretary.

(a) Except as otherwise set forth in paragraph (b) of this section, either party may file with the Secretary a petition for review within 30 days after the ALJ issues an initial decision. The Secretary or designee may extend the 30-day period for good cause. If the Secretary or designee does not act upon the petition for review within 90 days of its service, then the initial decision shall become final.

(b) *Appeals of Program Fraud Civil Remedies Act decisions (24 CFR part 28).* Only the respondent may file a petition for Secretarial review. The petition must be filed within 30 days after the ALJ issues the initial decision. The Secretary or designee may extend the 30-day period for good cause. If the Secretary or designee does not act upon the petition for review within 30 days of its service, then the initial decision shall become final.

(c) *Brief in support of petition.* The petition for review shall be accompanied by a written brief, not to exceed 10 pages, specifying exceptions to the initial decision and reasons supporting the exceptions.

(d) *Service.* The party submitting the petition for review shall serve a copy of the petition and brief in support on the other parties and on the Chief Docket Clerk.

(e) *Forwarding of the record.* Upon the filing of a petition for review, the ALJ shall forward the record of the proceeding to the Secretary or designee.

(f) *Brief in opposition.* Any opposing party may file a brief opposing review, not to exceed 10 pages, within 20 days of receiving the petition for review and accompanying brief. The brief in opposition shall be served on all parties.

(g) *Additional briefs.* If the petition is granted, then the Secretary or designee may order the filing of additional briefs.

(h) There is no right to appear personally before the Secretary or designee.

(i) There is no right to appeal any interlocutory ruling by the ALJ.

(j) In reviewing the initial decision, the Secretary or designee shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(k) The Secretary or designee shall consider only evidence contained in the record forwarded by the ALJ. However, if any party demonstrates to the satisfaction of the Secretary or designee that additional evidence not presented at the hearing is material and that there were reasonable grounds for the failure to present such evidence at such hearing, the Secretary or designee shall remand the matter to the ALJ for consideration of such additional evidence.

(l) The prohibitions of ex parte contacts in § 26.30 shall apply to contacts with the Secretary or designee.

(m) The Secretary or designee may affirm, reduce, reverse, compromise, remand, or settle any relief granted in the initial decision. The Secretary or designee shall consider, and include in any final determination, such factors as may be set forth in applicable statutes or regulations.

(n) The Secretary or designee shall promptly serve each party to the appeal with a copy of his or her decision and a statement describing the right to seek judicial review.

(o) *Judicial review.* Generally, a party must file a petition for judicial review within 20 days of service of the Secretary's determination, or the Secretary's determination shall become final and not subject to judicial review. In Program Fraud Civil Remedies Act matters (24 CFR part 28), the respondent shall have 60 days from the date that the determination is sent to the respondent in which to file a petition.

§ 26.51 Exhaustion of administrative remedies.

In order to fulfill the requirement of exhausting administrative remedies, a party must seek Secretarial review under § 26.50 prior to seeking judicial review of any initial decision issued under subpart B of this part.

§ 26.52 Judicial review.

Judicial review shall be in accordance with applicable statutory procedures and the procedures of the appropriate Federal court. The Government may not seek judicial review of an adverse determination of a Program Fraud Civil Remedies Act matter.

§ 26.53 Collection of civil penalties and assessments.

Collection of civil penalties and assessments shall be in accordance with applicable statutory provisions.

§ 26.54 Right to administrative offset.

The amount of any penalty or assessment that has become final, or for which a judgment has been entered under §§ 26.52 or 26.53, or agreed upon in a compromise or settlement among the parties, may be collected by administrative offset under 31 U.S.C. 3716 or other applicable law. In Program Fraud Civil Remedies Act matters, an administrative offset may not be collected against a refund of an overpayment of Federal taxes then or later owing by the United States to the respondent.

6–8. Part 28 is revised to read as follows:

PART 28—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL REMEDIES ACT OF 1986

Sec.

28.1 Purpose.

28.5 Definitions.

28.10 Basis for civil penalties and assessments.

28.15 Investigation.

28.20 Request for approval by the Justice Department.

28.25 Notice of civil penalty (and assessment).

28.30 Response.

28.35 Disclosure of documents.

28.40 Hearings.

28.45 Settlements.

Authority: 31 U.S.C. 3801; 42 U.S.C. 3535(d).

§ 28.1 Purpose.

This part:

(a) Establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to Federal authorities or to their agents; and

(b) Specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments. Hearings under this part shall be conducted pursuant to 24 CFR part 26, subpart B.

§ 28.5 Definitions.

The terms *ALJ* and *HUD* are defined in 24 CFR part 5.

Benefit means anything of value, including, but not limited to, any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan insurance or guarantee.

Claim means any request, demand, or submission:

(1) Made to HUD for property, services, or money (including money representing grants, loans, insurance, or benefits);

(2) Made to a recipient of property, services, or money from HUD or to a party to a contract with HUD; or

(3) Made to HUD which has the effect of decreasing an obligation to pay or account for property, services, or money.

Knows or has reason to know means that a person has actual knowledge that a claim or statement is false, fictitious, or fraudulent; acts in deliberate ignorance of the truth or falsity of the claim or statement; or acts in reckless disregard of the truth or falsity of the claim or statement.

Person means any individual, partnership, corporation, association, private organization or entity.

Respondent means any person alleged to be liable for a civil penalty or assessment under § 28.25.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made:

(1) With respect to a claim, to obtain approval or payment of a claim, or relating to eligibility to make a claim; or

(2) With respect to or relating to eligibility for a contract, bid, or proposal for a contract with; or a grant or cooperative agreement, loan, or benefit from; HUD, any State, any political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under the contract or the grant or cooperative agreement, loan, or benefit, or if the Government will reimburse the State, political subdivision, or party for any portion of the money or property under the contract or for the grant or cooperative agreement, loan, or benefit.

§ 28.10 Basis for civil penalties and assessments.

(a) *Claims.* (1) A civil penalty of not more than \$5,000 may be imposed upon a person who makes a claim that the person knows or has reason to know:

(i) Is false, fictitious, or fraudulent;

(ii) Includes or is supported by a written statement that either contains a material fact which is false, fictitious, or fraudulent; or omits a material fact which the person has a duty to include and is false, fictitious, or fraudulent as a result of the omission; or

(iii) Is for payment for the provision of property or services that the person has not provided as claimed.

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to HUD, to a recipient, or to a party when the claim actually is made to an agent, fiscal intermediary, or other entity, including any State or political subdivision of a State, acting for or on behalf of HUD, the recipient, or the party.

(4) Each claim for property, services, or money is subject to a civil penalty without regard to whether the property, services, or money actually is delivered or paid.

(5) *Limit on amount of claim.* Liability under this part shall not lie if the amount of money or value of property or services claimed exceeds \$150,000 as to each claim that a person submits. For purposes of paragraph (a) of this section, a group of claims submitted simultaneously as part of a single transaction shall be considered a single claim.

(6) *Assessment.* If the Government has made any payment, transferred property or provided services on a claim, then the Government may assess a person found liable up to twice the amount of the claim or portion of the claim that is determined to be in violation of paragraph (a)(1) of this section.

(b) *Statements.* (1) A civil penalty of up to \$5,000 may be imposed upon a person who makes a written statement that:

(i) The person knows, or has reason to know, contains a material fact which is false, fictitious, or fraudulent; or omits a material fact that the person has a duty to include and is false, fictitious, or fraudulent because of that omission; and

(ii) Contains or is accompanied by an express certification or affirmation of the truthfulness and accuracy of the contents of the statement.

(2) Each written representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to HUD when the statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision of a State, acting for or on behalf of HUD.

(c) *Limit on liability.* If the claim or statement relates to low-income housing benefits or housing benefits for the elderly or handicapped, then a person may be held liable only if he or she has made the claim or statement in the course of applying for such benefits, with respect to his or her eligibility, or family's eligibility, to receive such benefits. For purposes of paragraph (c) of this section, housing benefits means any instance wherein funds administered by the Secretary directly or indirectly permit low-income families or elderly or handicapped

persons to reside in housing which otherwise would not be available to them.

(d) No proof of specific intent to defraud is required to establish liability under this section.

(e) *Joint and several liability.* A civil penalty or assessment may be imposed jointly and severally where more than one person is determined to be liable.

§ 28.15 Investigation.

(a) *General.* HUD may initiate a Program Fraud Civil Remedies Act (31 U.S.C. 3801) case against a respondent only upon an investigation by the Inspector General or his or her designee.

(b) *Subpoena.* Pursuant to 31 U.S.C. 3804(a), the Inspector General or designee may require by subpoena the production of records and other documents. The subpoena shall state the authority under which it is issued, identify the records sought, and name the person designated to receive the records. The recipient of the subpoena shall provide a certification that the documents sought have been produced, that the documents are not available and the reasons they are not available, or that the documents, suitably identified, have been withheld based upon the assertion of an identified privilege.

(c) *Investigation report.* If the Inspector General or designee concludes that an action under the Program Fraud Civil Remedies Act may be warranted, her or she shall submit a report containing the findings and conclusions of the investigation to the General Counsel or his or her designee.

(d) The Inspector General may refer allegations directly to the Department of Justice for suit under the False Claims Act (31 U.S.C. 3730) or for other civil relief, or may postpone submitting a report to the General Counsel to avoid interference with a criminal investigation or prosecution. The Inspector General shall report violations of criminal law to the Attorney General.

§ 28.20 Request for approval by the Justice Department.

(a) If the General Counsel or designee determines that the investigation report supports an action under this part, he or she must submit a written request to the Department of Justice for approval to issue a notice under § 28.25.

(b) The request shall include a description of the claims or statements at issue; the evidence supporting the notice; an estimate of the amount of money or the value of property, services, or other benefits requested or demanded in violation of § 28.10; any exculpatory or mitigating circumstances that may relate to the claims or

statements; and a statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

§ 28.25 Notice of civil penalty (and assessment).

(a) *General.* Upon obtaining approval from the Department of Justice, the General Counsel or designee may issue a notice of civil penalty (and assessment, if appropriate) to the respondent. The notice shall be sent by certified mail, return receipt requested, or shall be personally served.

(b) *Notice.* The notice shall include:

(1) The allegations of liability against the respondent, including the statutory basis for liability, the claims or statements at issue, and the reasons why liability arises from those claims or statements;

(2) The amount of penalties and assessments for which the respondent may be held liable;

(3) That the respondent may request a hearing by submitting a written response to the notice;

(4) The address to which a response must be sent; and

(5) That failure to submit an answer within 30 days of receipt of the notice may result in the imposition of the maximum amount of penalties and assessments sought without right of appeal.

(c) A copy of this part 28 and of 24 CFR part 26, subpart B shall be included with the notice.

§ 28.30 Response.

(a) The respondent may submit a written response to HUD within 30 days of service of the notice of civil penalty. The response shall be deemed to be a request for hearing. The response should include the admission or denial of each allegation of liability made in the notice; any defense on which the respondent intends to rely; any reasons why the penalties and assessments should be less than the amount set forth in the notice; and the name, address, and telephone number of the person who will act as the respondent's representative, if any.

(b) *Filing with the Administrative Law Judges.* The Department shall file the notice and response with the Chief Docket Clerk, Office of Administrative Law Judges. If no response is submitted, then the Department may file a motion for default judgment, together with a copy of the notice, in accordance with 24 CFR 26.39.

§ 28.35 Disclosure of documents.

Upon receipt of a notice of penalty, the respondent may, upon written

request to the General Counsel or designee, review any relevant and material nonprivileged documents, including any exculpatory documents, that relate to the allegations set out in the notice. Exculpatory information that is contained in a privileged document must be disclosed.

§ 28.40 Hearings.

(a) *General.* Hearings under this part shall be conducted in accordance with the procedures in 24 CFR part 26, subpart B.

(b) *Factors to consider in determining amount of penalties and assessments.* In determining an appropriate amount of civil penalties and assessments, the administrative law judge (ALJ) and, upon appeal, the Secretary shall consider and state in their opinions any mitigating or aggravating circumstances. Because of the intangible costs of fraud, the expense of investigating fraudulent conduct, and the need for deterrence, ordinarily double damages and a significant civil penalty should be imposed. The ALJ and the Secretary shall consider the following factors in determining the amount of penalties and assessments to be imposed:

(1) The number of false, fictitious, or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the respondent's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the cost of investigation;

(6) The relationship of the civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations, including particularly the impact on the intended beneficiaries of such programs;

(8) Whether the respondent has engaged in a pattern of the same or similar misconduct;

(9) Whether the respondent attempted to conceal the misconduct;

(10) The degree to which the respondent has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees or agents is imputed to the respondent, the extent to which the respondent's practices fostered or attempted to preclude the misconduct;

(12) Whether the respondent cooperated in or obstructed an investigation of the misconduct;

(13) Whether the respondent assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the respondent's sophistication with respect to it, including the extent of the respondent's prior participation in the program or in similar transactions;

(15) Whether the respondent has been found, in any criminal, civil, or administrative proceeding, to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly;

(16) The need to deter the respondent and others from engaging in the same or similar misconduct; and

(17) Any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

(c) *Stays ordered by the Department of Justice.* If at any time the Attorney General of the United States or an Assistant Attorney General designated by the Attorney General notifies the Secretary in writing that continuation of the Department's case may adversely affect any pending or potential criminal or civil action related to the claim or statement at issue, the ALJ or the Secretary shall stay the process immediately. The case may be resumed only upon receipt of the written authorization of the Attorney General.

§ 28.45 Settlements.

(a) The Department and the respondent may enter into a settlement agreement at any time prior to the issuing of a notice of final determination under 24 CFR 26.50.

(b) Failure of the respondent to comply with a settlement agreement shall be sufficient cause for resuming an action under this part, or for any other judicial or administrative action.

9-11. Part 30 is revised to read as follows:

PART 30—CIVIL MONEY PENALTIES: CERTAIN PROHIBITED CONDUCT

Subpart A—General

Sec.

30.1 Purpose and scope.

30.5 Effective dates.

30.10 Definitions.

30.15 Application of other remedies.

Subpart B—Violations

30.20 Ethical violations by HUD employees.

30.25 Violations by applicants for assistance.

30.30 Urban Homestead violations.

- 30.35 Mortgagees and lenders.
- 30.40 Multifamily and Section 202 mortgagors.
- 30.45 GNMA issuers and custodians.
- 30.50 Interstate Land Sales violations.
- 30.55 Dealers or loan correspondents.
- 30.60 Failure to disclose lead-based paint hazards.

Subpart C—Procedures

- 30.65 Prepenalty notice.
- 30.70 Response to prepenalty notice.
- 30.75 Factors in determining appropriateness and amount of civil money penalty.
- 30.80 Notice of civil money penalty.
- 30.85 Response to the penalty notice.
- 30.90 Hearings.
- 30.95 Settlements.

Authority: 12 U.S.C. 1701q-1, 1703, 1723i, 1735f-14, 1735f-15; 15 U.S.C. 1717a; 42 U.S.C. 3535(d).

Subpart A—General

§ 30.1 Purpose and scope.

Unless provided for elsewhere in this title or under separate authority, this part implements HUD's civil money penalty provisions. The procedural rules for hearings under this part are set forth in 24 CFR part 26, subpart B.

§ 30.5 Effective dates.

(a) Under § 30.20, a civil money penalty may be imposed for violations occurring on or after May 22, 1991.

(b) Under §§ 30.25, 30.35, 30.40, 30.45, 30.50, and 30.55, but not § 30.35(a)(14), a civil money penalty may be imposed for any violations that occur on or after December 15, 1989.

(c) Under § 30.30, a civil money penalty may be imposed with respect to any property transferred for use under section 810 of the Housing and Community Development Act of 1974, as amended (12 U.S.C. 1706e), after January 1, 1981, to a state, a unit of general local government, or a public agency or qualified community organization designated by a unit of general local government, or a transferee of any such entity.

(d) Under § 30.35(a)(14), concerning loan guarantees for Indian housing, a civil money penalty may be imposed for violations occurring on or after October 28, 1992.

(e) Under § 30.60, a civil money penalty may be imposed for violations occurring on or after the following dates:

- (1) September 6, 1996, for owners of more than four residential dwellings; or
- (2) December 6, 1996, for owners of one to four residential dwellings.

§ 30.10 Definitions.

Since this part is primarily procedural, terms not defined in this section shall have the meanings given

them in relevant program regulations. Comprehensive definitions are in 24 CFR part 4 (Prohibition of Advance Disclosure of Funding Decisions) and 24 CFR part 12 (Accountability in the Provision of HUD Assistance). The terms *ALJ*, *Department*, *HUD*, and *Secretary* are defined in 24 CFR part 5.

Agent. Any person who acts on behalf of another person and includes officers, directors, partners and trustees.

Dealer. A seller, contractor or supplier of goods or services having a direct or indirect financial interest in the transaction between the borrower and the lender, and who assists the borrower in preparing the credit application or otherwise assists the borrower in obtaining the loan from the lender.

Knowing or Knowingly. Having actual knowledge of or acting with deliberate ignorance of or reckless disregard for the prohibitions under subpart B of this part or under 24 CFR parts 4 or 12.

Loan correspondent. A lender or loan correspondent as defined at § 202.2 of this title.

Material or Materially. In some significant respect or to some significant degree.

Person. An individual, corporation, company, association, authority, firm, partnership, society, state, local government or agency thereof, or any other organization or group of people.

Respondent. A person against whom a civil money penalty action is initiated.

§ 30.15 Application of other remedies.

A civil money penalty may be imposed in addition to other administrative sanctions or any other civil remedy or criminal penalty.

Subpart B—Violations

§ 30.20 Ethical violations by HUD employees.

(a) *General*. The General Counsel, or his or her designee, may initiate a civil money penalty action against HUD employees who improperly disclose information pursuant to § 4.110 of this title.

(b) *Maximum penalty*. The maximum penalty is \$10,000 for each violation.

§ 30.25 Violations by applicants for assistance.

(a) *General*. The General Counsel, or his or her designee, may initiate a civil money penalty action against applicants for assistance, as defined in 24 CFR part 12, who knowingly and materially violate the provisions of § 12.32 (a), (b), or (c) of this title.

(b) *Maximum penalty*. The maximum penalty for each violation is \$10,000.

§ 30.30 Urban Homestead violations.

(a) *General*. The Assistant Secretary for Community Planning and Development, or his or her designee, or the Director of the Office of Technical Assistance and Management may initiate a civil money penalty action against persons who knowingly and materially violate section 810 of the Housing and Community Development Act of 1974, as amended (12 U.S.C. 1706e), or the provisions of 24 CFR part 590, in the use or conveyance of property made available under the Urban Homestead Program.

(b) *Maximum penalty*. The maximum penalty is either twice the amount of the gross profit realized from any impermissible use or conveyance of the property, or the amount of section 810 funds used to reimburse HUD, the Department of Veterans Affairs, the Resolution Trust Corporation, or the Farmers Home Administration (or its successor agency under Public Law 103-354) for the property, whichever is greater. If the property is still held by the violator, the gross profit shall include any appreciation between the amount the violator paid for the property and its current value as determined by an independent, HUD-qualified appraiser.

§ 30.35 Mortgagees and lenders.

(a) *General*. The Mortgagee Review Board may initiate a civil money penalty action against any mortgagee or lender who knowingly and materially:

(1) Violates the provisions listed in 12 U.S.C. 1735f-14(b);

(2) Fails to comply with the requirements of § 201.27(a) of this title regarding approval and supervision of dealers;

(3) Approves a dealer that has been suspended, debarred, or otherwise denied participation in HUD's programs;

(4) Makes a payment that is prohibited under § 202.12(p) of this title;

(5) Fails to remit, or timely remit, mortgage insurance premiums, loan insurance charges, or late charges or interest penalties;

(6) Permits loan documents for an FHA insured loan to be signed in blank by its agents or any other party to the loan transaction unless expressly approved by the Secretary;

(7) Fails to follow the mortgage assignment procedures set forth in §§ 203.650 through 203.664 of this title or in §§ 207.255 through 207.258b of this title.

(8) Fails to timely submit documents that are complete and accurate in connection with a conveyance of

property or a claim for insurance benefits, in accordance with §§ 203.365, 203.366, or 203.368 of this title;

(9) Fails to:

(i) Process requests for formal release of liability under an FHA insured mortgage;

(ii) Obtain a credit report, issued not more than 90 days prior to approval of a person as a borrower, as to the person's creditworthiness to assume an FHA insured mortgage;

(iii) Timely submit proper notification of a change in mortgagor or mortgagee as required by § 203.431 of this title;

(iv) Timely submit proper notification of mortgage insurance termination as required by § 203.318 of this title;

(v) Timely submit proper notification of a change in mortgage servicing as required by § 203.502 of this title; or

(vi) Report all delinquent mortgages to HUD, as required by § 203.332 of this title;

(10) Fails to service FHA insured mortgages, in accordance with the requirements of 24 CFR parts 201, 203, and 235;

(11) Fails to fund loans that it originated, or otherwise misuses loan proceeds;

(12) Fails to comply with the conditions relating to the assignment or pledge of mortgages as required by § 207.261 of this title;

(13) Fails to comply with the provisions of the Real Estate Settlement Procedures Act (12 U.S.C. 2601 et seq.), the Equal Credit Opportunity Act (15 U.S.C. 1691 et seq.), or the Fair Housing Act (42 U.S.C. 3601 et seq.);

(14) Violates the provisions of 12 U.S.C. 1715z-13a(g)(2) concerning loan guarantees for Indian housing;

(15) Fails to comply with the terms of a settlement agreement with HUD.

(b) *Continuing violation.* Each day that a violation continues shall constitute a separate violation.

(c) *Amount of penalty.* The maximum penalty is \$5,000 for each violation, up to a limit of \$1,000,000 for all violations committed during any one-year period. Each violation shall constitute a separate violation as to each mortgage or loan application.

§ 30.40 Multifamily and Section 202 mortgagors.

(a) *General.* The Assistant Secretary for Housing-Federal Housing Commissioner, or his or her designee, may initiate a civil money penalty action against any mortgagor of property that includes five or more living units and is subject to a mortgage insured, coinsured, or held by the Secretary, who knowingly and materially commits a violation listed at 12 U.S.C. 1735f-15(b) or (c), or 12 U.S.C. 1701q-1(b) or (c).

(b) *Maximum penalty.* The maximum penalty for each violation of 12 U.S.C. 1735f-15(b) and 12 U.S.C. 1701q-1(b) is the amount of loss that the Secretary incurs at a foreclosure sale, or a sale after foreclosure, with respect to the property involved. The maximum penalty for each violation of 12 U.S.C. 1735f-15(c) and 12 U.S.C. 1701q-1(c) is \$25,000.

§ 30.45 GNMA issuers and custodians.

(a) *General.* The President of GNMA, or his or her designee, may initiate a civil money penalty action against a GNMA issuer or custodian that knowingly and materially violates any provision of 12 U.S.C. 1723i(b), title III of the National Housing Act, or any implementing regulation, handbook, guaranty agreement, or contractual agreement, or participant letter issued by GNMA, or fails to comply with the terms of a settlement agreement with GNMA.

(b) *Continuing violation.* Each day that a violation continues shall constitute a separate violation.

(c) *Amount of penalty.* The maximum penalty is \$5,000 for each violation, up to a limit of \$1 million during any one-year period. Each violation shall constitute a separate violation with respect to each pool of mortgages.

§ 30.50 Interstate Land Sales violations.

(a) *General.* The Assistant Secretary for Housing-Federal Housing Commissioner, or his or her designee, may initiate a civil money penalty action against any person who knowingly and materially violates any provision of the Interstate Land Sales Full Disclosure Act (15 U.S.C. 1701 et seq.); the rules and regulations set forth at 24 CFR parts 1710, 1715, and 1720, or any order issued thereunder.

(b) *Continuing violation.* Each day that a violation continues shall constitute a separate violation.

(c) *Maximum penalty.* The maximum penalty is \$1,000, up to a limit for any particular person of \$1 million during any one-year period. Each violation shall constitute a separate violation as to each sale or lease or offer to sell or lease.

§ 30.55 Dealers or loan correspondents.

(a) *General.* The Assistant Secretary for Housing-Federal Housing Commissioner, or his or her designee, may initiate a civil money penalty action against any dealer or loan correspondent who violates section 2(b)(7) of the National Housing Act (12 U.S.C. 1703). Such violations include, but are not limited to:

(1) Falsifying information on an application for dealer approval or reapproval submitted to a lender;

(2) Falsifying statements on a HUD credit application, improvement contract, note, security instrument, completion certificate or other loan document;

(3) Failing to sign a credit application if the dealer or loan correspondent assisted the borrower in completing the application;

(4) Falsely certifying to a lender that the loan proceeds have been or will be spent on eligible improvements;

(5) Falsely certifying to a lender that the property improvements have been completed;

(6) Falsely certifying that a borrower has not been given or promised any cash payment, rebate, cash bonus, or anything of more than nominal value as an inducement to enter into a loan transaction;

(7) Making a false representation to a lender with respect to the creditworthiness of a borrower or the eligibility of the improvements for which a loan is sought.

(b) *Continuing violation.* Each day that a violation continues shall constitute a separate violation.

(c) *Amount of penalty.* The maximum penalty is \$5,000 for each violation, up to a limit of \$1 million during any one-year period.

§ 30.60 Failure to disclose lead-based paint hazards.

(a) *General.* The Director of the Office of Lead-Based Paint Abatement and Poisoning Prevention, or his or her designee, may initiate a civil money penalty action against any person who knowingly violates 42 U.S.C. 4852d(b)(1) or any provision of 24 CFR part 35, subpart H.

(b) *Amount of penalty.* The maximum penalty is \$10,000 for each violation.

Subpart C—Procedures

§ 30.65 Prepenalty notice.

Whenever HUD intends to seek a civil money penalty, the official designated in subpart B of this part, or his or her designee (or the chairperson of the Mortgagee Review Board, or his or her designee, in actions under § 30.35), shall issue a written notice to the respondent. This prepenalty notice shall include the following:

(a) That HUD is considering seeking a civil money penalty;

(b) The specific violations alleged;

(c) The maximum civil money penalty that may be imposed;

(d) The opportunity to reply in writing to the designated program official within 30 days after receipt of the notice; and

(e) That failure to respond within the 30-day period may result in issuance of

a notice of civil money penalty under § 30.80 without consideration of any information that the respondent may wish to provide.

§ 30.70 Response to prepenalty notice.

The response shall be in a format prescribed in the prepenalty notice. The response shall include any arguments opposing the imposition of a civil money penalty that the respondent may wish to present.

§ 30.75 Factors in determining appropriateness and amount of civil money penalty.

In determining whether to seek a penalty, and the amount of such penalty, the officials designated in subpart B of this part shall consider the following factors:

(a) The gravity of the offense;
 (b) Any history of prior offenses. For violations under §§ 30.25, 30.35, 30.40, 30.45, 30.50, and 30.55, but not violations under § 30.35(a)(14), offenses that occurred prior to December 15, 1989 may be considered;

(1) The ability to pay the penalty;
 (2) The injury to the public;
 (3) Any benefits received by the violator;
 (4) The extent of potential benefit to other persons;
 (5) Deterrence of future violations;
 (6) The degree of the violator's culpability;
 (7) With respect to Urban Homestead violations under § 30.30, the expenditures made by the violator in connection with any gross profit derived; and
 (8) Such other matters as justice may require.

(c) In addition to the above factors, with respect to violations under §§ 30.40, 30.50, and 30.55, the Assistant Secretary for Housing-Federal Housing Commissioner, or his or her designee, shall also consider:

(1) Any injury to tenants; and/or
 (2) Any injury to lot owners.

§ 30.80 Notice of civil money penalty.

(a) *General.* Upon the expiration of the period for the respondent to submit a response to the prepenalty notice, the official designated in subpart B of this part, or his or her designee (or the Mortgagee Review Board in actions under § 30.35) shall determine whether to seek a civil money penalty. Such determination shall be based upon a review of the prepenalty notice, the response, if any, and the factors listed at § 30.75. A determination by the Mortgagee Review Board to seek a civil money penalty shall be by a majority vote of the Board.

(b) *Notice.* If a determination is made to seek a civil money penalty, the official or his or her designee, or the Mortgagee Review Board, shall so notify the respondent, in writing. The notice shall state the following:

(1) The factual basis for the decision to seek a penalty;
 (2) The applicable civil money penalty statute;
 (3) The amount of penalty sought;
 (4) The right to submit a response in writing, within 15 days of receipt of the notice, requesting a hearing on any material fact in the notice, or on the appropriateness of the penalty sought;
 (5) The address to which a response must be sent;
 (6) That the notice shall serve as HUD's complaint if a hearing is requested; and
 (7) That the failure to submit a response may result in the imposition of the penalty in the amount sought.

(c) A copy of this part and of 24 CFR part 26, subpart B shall be included with the notice.

(d) *Service of the notice.* The notice shall be served on the respondent by first class mail, personal delivery, or other means. In cases of violations by mortgagees and lenders of 12 U.S.C. 1735f-14(b)(1)(D) or (1)(F), or by GNMA issuers or custodians of 12 U.S.C. 1723i(b)(1)(G) or (1)(I), a copy of the notice shall be provided to the Attorney General.

§ 30.85 Response to the penalty notice.

(a) *General.* The respondent may submit to HUD a written response to the penalty notice within 15 days of its receipt. The response shall be considered a request for a hearing. The response should include the admission or denial of each allegation of liability made in the notice; any defense on which the respondent intends to rely; any reasons why the civil money penalty is not warranted or should be less than the amount sought in the notice; and the name, address, and telephone number of the person who will act as the respondent's representative, if any.

(b) *Filing with the Administrative Law Judges.* HUD shall file the notice and response with the Chief Docket Clerk, Office of Administrative Law Judges. If no response is submitted, then HUD may file a motion for default judgment, together with a copy of the notice, in accordance with § 26.39 of this title.

§ 30.90 Hearings.

Hearings under this part shall be conducted in accordance with the procedures at 24 CFR part 26, subpart B.

§ 30.95 Settlements.

The officials listed at subpart B of this part, or their designees (or the Mortgagee Review Board for violations under § 30.35), are authorized to enter into settlement agreements of civil money penalty claims. Settlement agreements may be executed at any time prior to the issuing of a notice of final determination under § 26.50 of this title, and may include sanctions for failure to comply with the terms of the agreement.

PART 81—REGULATIONS IMPLEMENTING THE AUTHORITY OF THE SECRETARY OF THE DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT OVER THE CONDUCT OF THE SECONDARY MARKET OPERATIONS OF THE FEDERAL NATIONAL MORTGAGE ASSOCIATION (FNMA)

12. The authority citation for 24 CFR part 81 continues to read as follows:

Authority: 12 U.S.C. 1451 *et seq.*, 1716-1723h, and 4501-4641; 42 U.S.C. 3535(d) and 3601-3619.

13. Section 81.46 is amended by revising the first sentence of paragraph (e)(1) to read as follows:

§ 81.46 Remedial actions.

* * * * *
 (e) * * * (1) Where a lender timely requests a hearing on a remedial action, a hearing shall be conducted before a HUD Administrative Law Judge (ALJ) and a final decision rendered in accordance with the procedures set forth in 24 CFR part 26, subpart B, to the extent such provisions are not inconsistent with subpart C of this part or FHEFSSA. * * *

* * * * *

14. Section 81.82 is amended by revising the second sentence of paragraph (b)(2) to read as follows:

§ 81.82 Cease-and-desist proceedings.

* * * * *
 (b) * * *
 (2) *Administrative Law Judge.* * * *

The hearing shall be conducted in accordance with § 81.84 and, to the extent the provisions are not inconsistent with any of the procedures in this part or FHEFSSA, with 24 CFR part 26, subpart B.

* * * * *

15. Section 81.83 is amended by revising paragraph (d)(3) to read as follows:

§ 81.83 Civil money penalties.

* * * * *
 (d) * * *
 (3) *Administrative Law Judge.* A HUD ALJ shall preside over any hearing

conducted under this section, in accordance with § 81.84 and, to the extent the provisions are not inconsistent with any of the procedures in this part or FHEFSSA, with 24 CFR part 26, subpart B.

* * * * *

16. Section 81.84 is amended by:

a. Revising paragraph (b)(2);

b. Revising paragraph (d);

c. Amending the third sentence of paragraph (h)(1) by removing the reference to “§ 30.515”, and by adding in its place a reference to “§ 26.38”;

d. Amending the first sentence of paragraph (j)(2) by removing the reference to “§ 30.910”, and by adding in its place a reference to “§ 26.51 (c)”;

and amending the second sentence of paragraph (j)(2) by removing the reference to “§ 30.910 (c) and (d)”, and by adding in its place a reference to “§ 26.51(f)”;

to read as follows:

§ 81.84 Hearings.

* * * * *

(b) * * *

(2) Hearings shall be conducted by a HUD ALJ authorized to conduct proceedings under 24 CFR part 26, subpart B.

* * * * *

(d) *Procedure.* Hearings shall be conducted in accordance with the procedures set forth in 24 CFR part 26,

subpart B to the extent that such provisions are not inconsistent with any of the procedures in this part or FHEFSSA.

* * * * *

§ 81.85 [Amended]

17. In section 81.85(c)(1), the third sentence is amended by removing the reference to “§ 30.515”, and by adding in its place a reference to “§ 26.38”.

PART 200—INTRODUCTION

18. The authority citation for 24 CFR part 200 continues to read as follows:

Authority: 12 U.S.C. 1701-1715z-18; 42 U.S.C. 3535(d).

§ 200.243 [Amended]

19. In § 200.243, the second sentence of the introductory text of paragraph (a) is amended by adding the phrase “, subpart A,” after the phrase “24 CFR part 26”.

PART 950—INDIAN HOUSING PROGRAMS

20. The authority citation for 24 CFR part 950 continues to read as follows:

Authority: 25 U.S.C. 450e(b); 42 U.S.C. 1437aa-1437ee, and 3535(d).

§ 950.190 [Amended]

21. In § 950.190, the last sentence of paragraph (e) is amended by adding the

phrase “, subpart A” after the phrase “24 CFR part 26”.

PART 965—PHA-OWNED OR LEASED PROJECTS—MAINTENANCE AND OPERATION

22. The authority citation for 24 CFR part 965 continues to read as follows:

Authority: 42 U.S.C. 1437, 1437a, 1437d, 1437g, and 3535(d). Subpart H is also issued under 42 U.S.C. 4821-4846.

§ 965.205 [Amended]

23. In § 965.205, the last sentence of paragraph (e) is amended by adding the phrase “, subpart A” after the phrase “24 CFR part 26”.

PART 3500—REAL ESTATE SETTLEMENT PROCEDURES ACT

24. The authority citation for 24 CFR part 3500 continues to read as follows:

Authority: 12 U.S.C. 2601 et seq.

§ 3500.17 [Amended]

25. In § 3500.17, paragraphs (n)(1) and (n)(4)(iii) are amended by removing the phrase “, subpart E,”.

Dated: March 12, 1996.

Henry G. Cisneros,

Secretary.

[FR Doc. 96-9877 Filed 4-22-96; 8:45 am]

BILLING CODE 4210-32-P

Executive Order

Tuesday
April 23, 1996

Part V

The President

**Proclamation 6886—National Organ and
Tissue Donor Awareness Week, 1996**

**Proclamation 6887—Jewish Heritage
Week, 1996**

**Proclamation 6888—National Crime
Victims' Rights Week, 1996**

Presidential Documents

Title 3—

Proclamation 6886 of April 19, 1996

The President

National Organ and Tissue Donor Awareness Week, 1996

By the President of the United States of America

A Proclamation

Thousands of lives have been saved by the miracle of organ and tissue transplantation, a medical procedure made possible only by the extraordinary generosity of those who agree to donate and the profound compassion of their loved ones. Recipients are often able to resume normal lives after their transplants, working and caring for their families, and many children are in school today due to a donated liver or bone marrow. Still, the need for organs far exceeds the number donated, and many Americans wait—and some will die waiting—for suitable organs or tissues to become available.

Although our Nation has a potentially adequate supply of organs and tissues, there are more than 45,000 patients on the national transplant waiting list, and some 2,000 new names are added each month. We must educate all Americans about transplantation and its successes and raise public awareness of the urgent need for increased donation. All of our citizens should know that by completing a donor card and carrying it, and particularly by making family members aware of the wish to donate, they may save the health, or even the life, of someone in need.

Americans are a caring people, and our Nation's citizens have always reached out to one another in times of trouble. Organ donation is a unique example of that spirit of giving, and many who have lost loved ones have found comfort in knowing that their loss means the promise of life for others. This week and throughout the year, let us recognize the advances made in organ and tissue transplant techniques, honor those who have already pledged their organs, and encourage people to make the life-giving decision to donate.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 21 through April 27, 1996, as National Organ and Tissue Donor Awareness Week. I call upon health care professionals, educators, the media, public and private organizations concerned with organ donation and transplantation, and all the people of the United States to observe this week with appropriate activities and programs that promote organ donation and invite new donors to get involved.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of April, 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 twentieth.



Presidential Documents

Proclamation 6887 of April 19, 1996

Jewish Heritage Week, 1996

By the President of the United States of America

A Proclamation

The Jewish experience in America has been a mutually rewarding one for this country and for the Jewish people. Jewish Americans have made great contributions in such fields as the arts and sciences, business, government, law and medicine, enriching America's heritage with the resonant tradition of an ancient people. And America, for its part, has been a land of opportunity for its Jewish citizens.

In many ways, the Jewish experience is unique, freighted with the anguish of frequent persecution, but ennobled by an unyielding spirit that has always found a way to turn darkness into light. In the crucible of sorrow, the Jewish people have reaffirmed, time and again, the basic human values of faith, community, justice, and hope.

On the tolerant soil of American democracy, the Jewish people have flourished. We will be forever grateful for the remarkable contributions of our Jewish citizens, and it is fitting that we set aside a week to give thanks for their inestimable gifts and to honor the traditions of their remarkable religion and heritage.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 21 through April 28, 1996, as Jewish Heritage Week. I call upon the people of the United States to observe this week with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of April, 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 twentieth.



Presidential Documents

Proclamation 6888 of April 19, 1996

National Crime Victims' Rights Week, 1996

By the President of the United States of America

A Proclamation

On April 19, 1995, millions of Americans witnessed the chaos and anguish wrought by a single bomb blast in Oklahoma City that took 168 lives and injured scores of others. For days afterwards, our Nation joined the survivors in a grim vigil as somber work crews entered the wreckage again and again to locate victims.

That bomb blast in Oklahoma City was a devastating reminder that too many Americans have become victims of crime. Although violent crime has decreased every year for the last 3 years, 83 percent of our citizens 12 years of age and above will experience violent or attempted violent crime in their lifetimes. And worse, 52 percent will be victimized more than once. Added to these grim statistics is the reality that violent crime is increasingly a problem of our youth. For 12- to 19-year-olds, the chance of being assaulted, robbed, or raped is two to three times higher than for adults, and perpetrators of crime are both younger and more violent. In 1994, for example, about 33 percent of all violent crimes were committed by those under 21 years of age.

There is another, more positive, dimension to the aftermath of crime: the multitude of dedicated professionals and volunteers who support and assist crime victims. They are emergency medical technicians and firefighters, law enforcement officers and rescue teams, victim assistance providers and shelter workers. At the darkest of moments, these selfless men and women renew our Nation's faith in humanity, and their advocacy embodies the time-honored American traditions of compassion and service. They constitute a community of caring whose healing work helps victims to become survivors. As a Nation, we owe these generous individuals our deepest gratitude for making our communities better and safer places in which to live and work.

While 1995 brought tragedy, it also brought the implementation of one of the most comprehensive crime laws ever enacted. The Violent Crime Control and Law Enforcement Act of 1994 furthered the rights of victims in the Federal justice system and targeted resources for criminal justice improvements. The Crime Act's provisions include truth-in-sentencing provisions that ensure longer sentences for violent offenders and allocution rights for victims that give them the right to speak in court before the imposition of a sentence. The Crime Act also provides hundreds of communities around the Nation with increased law enforcement personnel, and its Violence Against Women Act is the first comprehensive Federal effort to combat violence against women.

The Crime Act is just one landmark in a crime victims' movement that has spanned 20 years and brought many hard-won reforms. A victims' bill of rights—once a novel idea—is now a reality in virtually every State. Victim assistance programs, which were few in the 1960s, now number in the thousands. Every State has a compensation program to help reimburse victims for mental health, medical, and other expenses resulting from the crimes committed against them. And in 1995, the Crime Victims Fund

in the U.S. Treasury, which supports many of these programs, surpassed the one-billion-dollar mark in funds collected and distributed to the States.

As we reflect on the events of 1995, let us remember both the horror and the compassion we felt last April. Let us not slip into complacency when we hear or read about another crime victim. Whether we are business owners or teachers, clergy or physicians, neighbors or colleagues, we must join the community of caring and lessen the burdens on our Nation's crime victims. Let us join together to build safe and responsive communities and to promote justice and healing for all who have suffered from violent crime.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim April 21 through April 27, 1996, as National Crime Victims' Rights Week. I urge all Americans to pause and remember crime victims and their families by working to reduce violence, to assist those harmed by crime, and to make our homes and communities safer places in which to live and raise our families.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of April, 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 twentieth.



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Tuesday, April 23, 1996

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