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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 235

[Amdt. No. 15]

Child Nutrition Programs; Revision of State Administrative Expense (SAE) Funds Sanction Authority and Withdrawal of Proposal to Allocate SAE for State Commodity Processing Activities

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This rule finalizes the proposal to amend the regulations governing the use of State Administrative Expense (SAE) funds which was published in the Federal Register on September 17, 1985, (50 FR 37667). The Food and Nutrition Service (FNS) proposed to change the manner in which SAE funds are allocated to State agencies by providing some of these funds to distributing agencies for commodity processing activities. The proposal was intended to assist distributing agencies in establishing or expanding State commodity processing efforts in order to encompass processing currently being conducted under the FNS administered National Commodity Processing (NCP) System. However, in view of negative commenter reaction to these provisions and the 2 year legislative extension of the NCP System, FNS has decided to withdraw this portion of the proposed rule. The rule also proposed to amend the sanction provisions of the SAE regulations to include failure to comply with the Food Distribution Program regulations (7 CFR Part 250) as a basis for a sanction. This proposed sanction provision is being finalized in this rule.

EFFECTIVE DATE: October 24, 1986.

FOR FURTHER INFORMATION CONTACT: Lou Pastura, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, USDA, Alexandria, Virginia 22302; telephone (703) 756–3620.

SUPPLEMENTARY INFORMATION:

Classification

This final rule has been reviewed under Executive Order 12291 and has been classified as not major because it does not meet any of the three criteria identified under the Executive Order. This action will not have an annual effect on the economy of $100 million or more, nor will it result in major increases in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions. Furthermore, it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S. based enterprises to compete with foreign-based enterprises in domestic or export markets.

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Administrator of the Food and Nutrition Service has certified that this rule will not have a significant adverse economic impact on a substantial number of small entities.

This rule imposes no new reporting or recordkeeping provisions that are subject to Office of Management and Budget review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520).

This activity (SAE) is listed in the Catalog of Federal Domestic Assistance under No. 10.560 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V and Final Rule Related Notice 48 FR 29114, June 24, 1983.)

Background

Under authority contained in section 203 of the Temporary Emergency Food Assistance Act of 1983 and in the Second Supplemental Appropriations Act for Fiscal Year 1985 (Pub. L. 99–88), FNS established and has been operating a National Commodity Processing (NCP) System. Under this system, FNS entered into agreements with commercial food processors for the processing and distribution of designated "bonus" donated foods to eligible recipient agencies. After over two years of operation, however, FNS felt that the NCP System should not be continued since it has not been as effective in utilizing "bonus" commodities as planned and the system lacked adequate accountability. FNS felt that State commodity processing would be a more effective way to increase the utilization of excess commodities than a central Federal system.

Under the proposal published on September 17, 1985, a portion of SAE funds available from recoveries and reserves, would have been provided to distributing agencies for commodity processing during a start-up year. The start-up year was to be considered a transition period from NCP to State processing and, FNS proposed to designate approximately two million dollars for this purpose. For subsequent years, it was proposed that commodity processing compete with other discretionary SAE provisions, including the Assessment, Improvement and Monitoring System (AIMS), for funds. The proposed rule set forth a two-part formula for allocating these funds to those distributing agencies that distribute USDA donated commodities to public and private schools and discussed the intended use of these funds. Finally, it was proposed that the SAE sanction provisions be amended to authorize FNS to recover, withhold or cancel payment of SAE funds to a distributing agency for that agency's failure to comply with the requirements of the Food Distribution Program regulations.

Comments Received—During the open public comment period (September 17 to November 18, 1985), FNS received forty comments—35 from State agencies or distributing agencies, 2 from professional associations and 3 from local school food authorities. Of these, 29 were clearly opposed to the proposed provisions regarding the allocation of SAE funds for State commodity processing, 3 were clearly supportive, 4 supported the concept of State processing but opposed the proposed funding method, and 4 expressed neither opposition to nor support for these provisions but did offer specific comments. Only three of the forty commenters addressed the sanction

provision with all three expressing some opposition to it.

Commenters who addressed the proposed allocation of SAE funds for State commodity processing generally felt that NCP should remain an integral part of FNS' overall bonus commodity effort. The overwhelming majority opposed the use of discretionary SAE funds to fund State commodity processing. They pointed out that these funds are now committed primarily to AIMS and that no reduction in AIMS requirements had been proposed.

Two of the commenters who addressed the proposed SAE sanction provision were not opposed to the concept of SAE sanctions for Food Distribution Program failures but, rather, the application of such sanctions. One commenter was concerned that SAE sanctions could be applied for failure to comply with FNS-imposed State commodity processing requirements which were considered to be excessive and inappropriate. A second commenter was opposed because the provision could subject all or much of a State's SAE allocation to a sanction action for failure to comply with Food Distribution Program regulations. This would be the case in those States where the State educational agency administers the Food Distribution Program to schools and child care institutions as well as some or all of the various Child Nutrition Programs. If the State agency administering the Food Distribution Program is different than the State agency which administers the Child Nutrition Programs, a failure to comply with the Food Distribution Program regulations would result in a sanction of only those SAE funds which are payable to the State agency administering the Food Distribution Program. The third commenter who addressed the sanction provision provided no reason for opposition.

Final Rule—In view of the fundamental opposition by commenters to the proposed allocation of SAE funds for State commodity processing and the fact that the NCP System was extended through School Year 1987 by the Food Security Act of 1985 (Pub. L. 99-198), FNS has determined that no further action should be taken on this portion of the proposed rule at this time. Accordingly, this part of the proposed rule is hereby withdrawn. However, FNS believes that the proposed sanction provision is necessary for the prudent Federal management of SAE funds and should be finalized. Currently, the Food Distribution Program is the only SAE-assisted program that is not covered by SAE sanction authority. Commenter concerns about the potential application of any such sanction should be alleviated by the withdrawal of the proposed provisions to allocate SAE funds for State commodity processing and the fact that the regulatory procedures for implementing SAE sanctions contain appeal provisions that would mitigate against the imposition of excessively severe sanctions for food distribution administrative failures. Furthermore, this final rule makes it clear that the expanded SAE sanction authority would only apply to a State agency's administration of the Food Distribution Program in schools and child care institutions, since SAE funds are only made available for that aspect of food distribution.

Finally, this rule makes several nonsubstantive revisions in § 235.4, paragraphs (a), (b), (b)(1), (b)(2), (b)(3) and (b)(4), and in § 235.11(b)(5)(vi) for the sake of consistency and clarity.

List of Subjects in 7 CFR Part 235

Food assistance programs, National School Lunch Program, School Breakfast Program, Special Milk Program, Grants administration, Intergovernmental relations, Reporting and recordkeeping requirements, Administrative practice and procedure.

Accordingly, Part 235 is amended as follows:

PART 235—STATE ADMINISTRATIVE EXPENSE FUNDS

1. The authority citation for Part 235 continues to read as follows:

Authority: Secs. 7 and 10, Pub. L. 89-642, 80 Stat. 888, 889 (42 U.S.C. 1776, 1779), unless otherwise noted.

§ 235.4 [Amended]

2. In § 235.4:

a. Paragraph (a) is revised.

b. The first sentence of introductory paragraph (b) and paragraphs (b)(1) and (b)(2) are amended by removing the word "For the fiscal year ending September 30, 1979, and for each succeeding fiscal year," and adding, in their place, the words "For each fiscal year,".

c. Paragraph (b)(2) is amended further by removing the words "and any Food Distribution Program allocation provided for in paragraph (b)(4) of this section";

d. Introductory paragraph (b)(3) is revised;

e. The first sentence of paragraph (b)(4) is amended by removing the words "For the fiscal year ending September 30, 1980, and for each succeeding fiscal year," and adding, in their place, the words "For each fiscal year,".

The revisions specified above read as follows:

§ 235.4 Allocation of funds to States.

(a) For each fiscal year, FNS shall allocate to each State agency which administers the National School Lunch, School Breakfast or Special Milk Programs an amount equal to one (1) percent of the funds expended by such agency during the second preceding fiscal year under sections 4 and 11 of the National School Lunch Act, as amended, and sections 3 and 4 of the Child Nutrition Act of 1966, as amended. However, the total amount allocated to any State under this paragraph shall not be less than $100,000 or the amount allocated to the State in the fiscal year ending September 30, 1981, whichever is greater.

(b) * * *

(3) For each fiscal year, FNS shall allocate to each State agency which is allocated funds under paragraph (a) of this section amounts derived by application of the following four-part formula:

* * * * *

§ 235.11 [Amended]

3. In §235.11:

a. Paragraph (b)(1) is amended by adding the words "and in Part 250 of this title as it applies to the operation of the Food Distribution Program in schools and child care institutions." Before the period at the end of the paragraph.

b. Paragraph (b)(5)(vi) is amended by changing the words "school nutrition programs" to "programs for which SAE funds were made available."

Dated: September 18, 1986.

Robert E. Leard,

Administrator.

[FR Doc. 86-21634 Filed 9-23-86; 8:45 am]

BILLING CODE 3410-30-M

Animal and Plant Health Inspection Service

[Docket No. 86-354]

7 CFR Part 301

Oriental Fruit Fly

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: This document amends the "Domestic Quarantine Notices" by adding "Oriental Fruit Fly" regulations. These regulations quarantine portions of Riverside and San Bernardino Counties

in California because of the Oriental fruit fly, and restrict the interstate movement of regulated articles from the quarantined portions of Riverside and San Bernardino Counties. This document is necessary on an emergency basis to prevent the artificial spread of the Oriental fruit fly into noninfested areas of the United States.

DATES: Effective date of this interim rule September 19, 1986. Written comments concerning this interim rule must be received on or before November 24, 1986.

ADDRESSES: Written comments should be submitted to Steven Poore, Acting Assistant Director, Regulatory Coordination, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, Room 728, 6505 Belcrest Road, Hyattsville, Maryland 20782. Comments should state that they are in response to Docket Number 86–354. Written comments received may be inspected at Room 728, Federal Building, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Ron Johnson, Acting Assistant Director, Survey and Emergency Response Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 611 Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782 (301) 436–6365.

SUPPLEMENTARY INFORMATION:

Background

This document amends the "Domestic Quarantine Notices" in 7 CFR Part 301 by adding "Oriental Fruit Fly" regulations (referred to below as the regulations). These regulations quarantine a portion of Riverside and San Bernardino Counties in California because of the Oriental fruit fly, and restrict the interstate movement of regulated articles from the quarantined portions of Riverside and San Bernardino Counties.

The Oriental fruit fly, *Dacus dorsalis* (Hendel), is a very destructive pest of numerous fruits (especially citrus fruits), nuts, vegetables, and berries. This pest can cause serious economic losses. Heavy infestations can result in complete loss of such crops. Its short life cycle permits the rapid development of serious outbreaks.

Recent trapping surveys near Grand Terrace, California have established that portions of Riverside and San Bernardino Counties in California are infested with the Oriental fruit fly.

Officials of the United States Department of Agriculture (USDA) and officials of State and county agencies in California have begun an intensive Oriental fruit fly survey and eradication program in the infested areas in California. Also, as explained below, California has taken action to impose restrictions on the intrastate movement of certain articles from the quarantined areas in order to prevent the artificial spread of the Oriental fruit fly within California. However, it is also necessary to impose restrictions on the interstate movement of certain articles from the quarantined areas in order to prevent the artificial spread of the Oriental fruit fly to noninfested areas in other States. Accordingly, this document establishes Federal regulations for the purpose of preventing the artificial spread of the Oriental fruit fly. These regulations are described below by section.

Section 301.93

Section 301.93 prohibits any common carrier or other person from moving any regulated article interstate from any quarantined area except in accordance with conditions prescribed in the regulations. For informational purposes, a footnote (footnote 1) has been added to reference the authority of an inspector to stop and inspect persons and means of conveyance, and to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated articles as provided in section 10 of the Plant Quarantine Act (7 U.S.C. 164a) and sections 105 and 107 of the Federal Plant Pest Act (7 U.S.C. 150dd, 150ff).

Definitions (Section 301.93–1)

Section 301.93–1 contains definitions of the following terms: "Certificate," "Compliance Agreement," "Deputy Administrator," "Infestation," "Inspector," "Interstate," "Limited permit," "Moved," "Movement or move," "Oriental fruit fly," "Person," "Plant Protection and Quarantine," "Quarantined area," "Regulated article," and "State." These terms are defined in accordance with definitions and authority set forth in the Plant Quarantine Act (7 U.S.C. 151 *et seq.*) and the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*).

Regulated Articles (Section 301.93–2)

The regulations impose conditions on the interstate movement of those articles which present a significant risk of spreading the Oriental fruit fly if moved without restrictions from quarantined areas into or through noninfested areas. Such articles are designated as regulated articles. Regulated articles are prohibited from moving interstate from quarantined areas except in accordance with conditions specified in §§ 301.93–4 through 301.93–10.

Section 301.93–2 designates the following articles as regulated articles:

(a) The following fruits, nuts, vegetables and berries:

Akia (*Wikstromeia phyllyraefolia*)
Alexander laurel (*Calophyllum inophyllum*)
Apple (*Malus sylvestris*)
Apricot (*Prunus armeniaca*)
Avocado (*Persea americana*)
Banana (*Musa paradisiaca* var. *sapientum*)
(*Musa x paradisiaca*)
Banana, dwarf (*Musa nana*)
Barbados cherry (*Malpighia glabra*)
Bell pepper (*Capsicum annum*)
Brazil cherry (*Eugenia dombeyi*)
Breadfruit (*Artocarpus altilis*)
Caimitillo (*Chrysophyllum oliviforme*)
Cashew (*Anacardium occidentale*)
Cactus (*Cereus coerulescens*)
Cherimoya (*Anonna cherimola*)
Cherry, Catalina (*Prunus ilicifolia*)
Cherry, Portuguese (*P. lusitanica*)
Chili (*Capsicum annum*)
Coffee, Arabian (*Coffea arabica*)
Country gooseberry (*Averrhoa carambola*)
Cucumber (*Cucumis sativas*)
Custard apple (*Annona reticulata*)
Date palm (*Phoenix dactylifera*)
Dragon tree (*Dracena draco*)
Eggfruit tree (*Pouteria campechiana*)
Elengi tree (*Mimusops elengi*)
Fig (*Ficus carica*)
Gourka (*Garinia celebica*)
Granadilla, sweet (*Passiflora ligularis*)
Grape (*Vitis* spp.)
Grapefruit (*Citrus paradisi*)
Guava (*Psidium guajava*)
(*P. Littorale*)
(*P. cattleianum*)
Imbu (*Spondias tuberosa*)
Jackfruit (*Artocarpus heterophyllus*)
Jerusalem cherry (*Solanum pseudocapsicum*)
Kitembilla (*Dovyalis hebecarpa*)
Kumquat (*Fortunella japonica*)
Laurel (*Calophyllum inophyllum*)
Lemon (*Citrus limon*)
Lime, key or Mexican (*Citrus aurantifolia*)
Lime, Persian (*Citrus latifolia*)
Lime, sweet (*Citrus limetioides*)
Longan (*Euphoria longan*)
Loquat (*Eriobotrya japonica*)
Lychee nut (*Lychee chinensis*)
Malay apple (*Eugenia malaccensis*)
Mammee apple (*Mammea americana*)
Mandarin orange (*Citrus reticulata*)
(tangerine)
Mango (*Mangifera indica*)
Mangosteen (*Garcinia mangostana*)
Mock orange (*Murraya exotica*)
Mulberry (*Morus nigra*)
Myrtle, downy rose (*Rhodomyrtus tomentosa*)
Natal plum (*Carissa grandiflora*)
Nectarine (*Prunus persica* var. *nectarina*)
Oleander, yellow (*Thevetia peruviana*)
Orange, calamondin (*Citrus riticulata* x. *Fortunella*)
Orange, Chinese (*Fortunella japonica*)
Orange, king (*Citrus reticulata* x. *C. sinensis*)
Orange, sweet (*Citrus sinensis*)
Orange, Unshu (*Citrus reticulata* var. *Unshu*)

Oriental bush red pepper (*Capsicum frutescens abbreviatum*)
Otaheite apple (*Spondias dulcis*)
Palm, syrup (*Jubaea spectabilis*)
Papaya (*Carica papaya*)
Passionflower (*Passiflora edulis*)
Passionflower, softleaf (*Passiflora mollissima*)
Passionfruit (*Passiflora edulis*) (yellow lilikoi)
Peach (*Prunus persica*)
Pear (*Pyrus communis*)
Pepino (*Solanum muricatum*)
Pepper, sweet (*Capsicum frutescens* var. *grossum*)
Persimmon, Japanese (*Diospyros kaki*)
Pineapple guava (*Feijoa sellowiana*)
Plum (*Prunus americana*)
Pomegranate (*Punica granatum*)
Prickly pear (*Opuntia megacantha*) (*Opuntia ficus indica*)
Prune (*Prunus domestica*)
Pummelo (*Citrus grandis*)
Quince (*Cydonia oblonga*)
Rose apple (*Eugenia jambos*)
Sandalwood (*Santalum paniculatum*)
Sandalwood, white (*Santalum album*)
Santol (*Sandericum koetjape*)
Sapodilla (*Manilkara zapota*)
Sapodilla, chiku (*Manilkara zapota*)
Sapota, white (*Casimiroa edulis*)
Seagrape (*Coccoloba uvifera*)
Sour orange (*Citrus aurantium*)
Soursop (*Annona muricata*)
Star apple (*Chrysophyllum cainito*)
Surinam cherry (*Eugenia uniflora*)
Tomato (*Lycopersicon esculentum*)
Tropical almond (*Terminalia catappa*) (*Terminalia chebula*)
Velvet apple (*Diospyros discolor*)
Walnut (*Juglans hindsii*)
Walnut, English (*Juglans regia*)
Wampi (*Citrus lansium*)
West Indian cherry (*Malpighia punicifolia*)
Ylang-Ylang (*Cananga odorata*).

Except that the list does not include any fruits, nuts, vegetables, or berries which are canned or dried or that have been frozen below −17.8 °C. (0 °F.);

(b) Soil within the drip area of plants which produce the fruits, nuts, vegetables, or berries listed in paragraph (a); and

(c) Any other product, article, or means of conveyance, of any character whatsoever, not covered by paragraphs (a) or (b) of this section, when it is determined by an inspector that it presents a risk of spread of the Oriental fruit fly and the person in possession thereof has actual notice that the product, article, or means of conveyance is subject to the restrictions of this subpart.

Articles that are canned or dried or that have been frozen below −17.8 °C. (0 °F.) are not included as regulated articles since the Oriental fruit fly could not survive under such conditions.

Based on research and experience, the articles listed in § 301.93–2 (a) and (b) as regulated articles are those articles that are known to present a significant risk of causing the artificial spread of the Oriental fruit fly. Paragraph (c) sets forth criteria for designating other products, articles, or means of conveyance as regulated articles on an emergency basis if found to present a risk of spreading the Oriental fruit fly. These articles would have to be determined by an inspector on a case-by-case basis since it cannot be anticipated specifically which other products, articles, or means of conveyance, if any, would present such a risk. There is authority to regulate such products, articles, or means of conveyance on an emergency basis under sections 105 and 106 of the Federal Plant Pest Act. If it is determined that these additional products, articles, or means of conveyance generally present a risk of spreading Oriental fruit fly, an amendment to this rule to include such items in the list of regulated articles will be made.

Quarantined Areas (Section 301.93–3)

As stated in § 301.93–3(a), it is necessary to designate as quarantined areas, areas in which the Oriental fruit fly has been found, areas in which the Deputy Administrator has reason to believe the Oriental fruit fly is present, and areas deemed necessary to regulate because of their proximity to the Oriental fruit fly or their inseparability for quarantine enforcement purposes from localities where Oriental fruit flies have been found.

Also, § 301.93–3(a) further provides that less than an entire State will be designated as a quarantined area only if the Deputy Administrator determines that (1) the State has adopted and is enforcing a quarantine or regulation which imposes restrictions on the intrastate movement of the regulated articles which are substantially the same as those which are imposed with respect to the interstate movement of such articles under the regulations; and (2) the designation of less than the entire State as a quarantined area will otherwise be adequate to prevent the artificial interstate spread of the Oriental fruit fly. This would not appear to lessen protection against the spread of the Oriental fruit fly compared to the designation of the entire State as a quarantined area. It appears that such State activities would help confine infestations to the quarantined areas and eliminate the need for designating larger protions of a State as quarantined areas.

In accordance with the criteria discussed above, it is necessary to designate as a quarantined area an area in Riverside and San Bernardino Counties in California. This area is as follows:

(1) That portion of Riverside and San Bernardino Counties beginning at a point where Cedar Avenue intersects Merrill Avenue, then east on Merrill Avenue, which becomes Mill Street, and continuing east on Mill Street to its intersection with Tippecanoe Avenue, the south on said avenue to its intersection with San Bernardino Avenue, then east on said avenue to its intersection with Bryn Mawr Avenue, then south on said avenue to its intersection with Redlands Boulevard, then south from said intersection along an imaginary line which re-connects with Bryn Mawr Avenue, then south on Bryn Mawr Avenue to its intersection with Beaumont Avenue, then south along an imaginary line to the intersection of Manzanita Avenue and Indian Avenue, then south on Indian Avenue to its intersection with Highway 60, then northwesterly on said highway to its intersection with Central Avenue, then westerly on said avenue to its intersection with Cage Canal, then westerly on said canal to its intersection with Central Avenue, then westerly on said avenue to its intersection with Palm Avenue, then north on said avenue to its intersection with Jurupa Avenue, then north along an imaginary line from the intersection of Palm Avenue and Jurupa Avenue to the intersection of Highway 60 and Rubidoux Boulevard, then northerly on said boulevard, which becomes Cedar Avenue, and continuing northerly on Cedar Avenue to the point of beginning.

California has adopted and is enforcing regulations imposing restrictions on the intrastate movement of the regulated articles which are substantially the same as those which are imposed with respect to the interstate movement of such articles under this subpart, and there does not appear to be any reason for designation of any areas in California as quarantined areas other than those areas specified above.

Section 301.93–3(b) provides for the temporary designation of an area as a quarantined area without publication in the **Federal Register** for a short period of time if there is a basis for listing the area as a quarantined area under § 301.93–3(a) and if the owner or person in possession thereof is given written notice of such action. This is necessary in order to prevent further artificial spread of the Oriental fruit fly until a document imposing such requirements could be published in the **Federal Register.**

Section 301.93–4

Section 301.93–4(a) allows regulated articles to be moved interstate from a quarantined area if accompanied by a certificate or limited permit issued and attached in accordance with §§ 301.93–5 and 301.93–8. The criteria for the

issuance of certificates and limited permits are set forth in § 301.93–5 and are discussed below.

Section 301.93–4(b) allows a regulated article to be moved interstate from a quarantined area without a certificate or limited permit, if:

(1) The article originated outside of any quarantined area and is moved directly through (without stopping except for brief refueling, or for normal traffic conditions, such as traffic lights or stop signs) the quarantined area in an enclosed vehicle or is completely enclosed by a covering adequate to prevent access by Oriental fruit flies (such as canvas, plastic, or closely woven cloth) while moving through the quarantined area, or

(2) The article is part of a shipment originating outside of any quarantined area which is moved into the quarantined area for packing or processing at a facility which an inspector has determined will not expose the article to Oriental fruit flies, and the article is moved to and from the facility under the conditions of paragraph (1), and

(3) The point of origin of the article is clearly indicated by shipping documents and its identity has been maintained.

These requirements would be adequate to ensure that the regulated articles would not become infested with the Oriental fruit fly while moving through a quarantined area. These requirements would also be adequate to ensure that the identity of such articles is maintained while moving through a quarantined area.

Section 301.93–4(c) provides that a regulated article may be moved interstate from a quarantined area without a certificate or limited permit, if:

(1) Moved by the United States Department of Agriculture for experimental or scientific purposes;

(2) Moved pursuant to a permit issued by the Deputy Administrator;

(3) Moved in accordance with conditions specified on the permit and found by the Deputy Administrator to be adequate to prevent the dissemination of the Oriental fruit fly, i.e., conditions of treatment, processing, shipment, disposal; and

(4) Moved with a tag or label securely attached to the outside of the container containing the article or securely attached to the article itself if not in a container, and with such tag or label bearing a permit number corresponding to the number of the permit issued for such article.

These requirements are in accord with the intent of the Plant Quarantine Act and the Federal Plant Pest Act to allow provisions for movement of articles by the Department for experimental or scientific purposes pursuant to a permit. The conditions for movement are required to be specified on the permit in order to assure that they will be understood and followed.

In § 301.93–4, a footnote (footnote 2) is added to remind persons that all other applicable Federal domestic plant quarantines and regulations must also be met.

Section 301.93–5

Section 301.93–5 explains the conditions for issuing a certificate or limited permit. Regulated articles accompanied by a certificate can be moved interstate to any destination. Limited permits are issued for regulated articles when the Department has determined that, because of a possible pest risk, such articles may be safely moved interstate only subject to further restrictions, e.g., movement to limited areas, movement for limited purposes.

Section 301.93–5(a) provides that a certificate shall be issued by an inspector for the interstate movement of a regulated article if the inspector:

(1) (i) Determines that it has been treated under the direction of an inspector in accordance with § 301.93–10; or

(ii) Determines, based on inspection of the premises of origin, that the premises are free from Oriental fruit fly and the article has not been exposed to Oriental fruit fly; or

(iii) Determines, based on inspection of the article, that it is free of Oriental fruit fly; and

(2) Determines that it is to be moved in compliance with any additional emergency conditions necessary to prevent the spread of the Oriental fruit fly pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd);[3] and

(3) Determines that it is eligible for unrestricted movement under all other Federal domestic plant quarantines and regulations applicable to such articles.

These provisions would be adequate to ensure that the articles are free of Oriental fruit fly.

A footnote (footnote 3) is added which explains that USDA can, pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd), take emergency actions against any article moving into or through the United States or interstate, or which has been moved into the United States or interstate, and which is believed to be infested or infected by plant pests.

Section 301.93–5(b) provides that a limited permit shall be issued by an inspector for the interstate movement of a regulated article if the inspector:

(1) Determines, in consultation with the Deputy Administrator, that it is to be moved to a specified destination for specified handling, utilization, or processing (such destination and other conditions to be specified in the limited permit), and when, upon evaluation of all of the circumstances involved in each case, it is determined that such movement will not result in the spread of the Oriental fruit fly because life stages of the pest will be destroyed by such specified handling, utilization or processing;

(2) Determines that it is to be moved in compliance with any additional emergency conditions necessary to prevent the spread of the Oriental fruit fly pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd); and

(3) Determines that it is eligible for such movement under all other Federal domestic plant quarantines and regulations applicable to such articles.

Section 301.93–5(c) allows any person who has entered into and is operating under a compliance agreement to execute and issue a certificate or limited permit for the interstate movement of a regulated article once an inspector has made an initial determination that such article is eligible for a certificate or limited permit in accordance with § 301.93–5 (a) or (b). These initial determinations concerning the eligibility of regulated articles for issuance of a certificate or limited permit are limited to inspectors because of their nature and complexity.

A footnote (footnote 4) is added for informational purposes to indicate how to contact inspectors for obtaining inspection services.

Also, § 301.93–5(d) contains provisions for the withdrawal of a certificate or limited permit by an inspector upon a determination that the holder thereof has not complied with conditions for the use of the document. This section also contains provisions for notifying the holder of the reasons for the withdrawal and provisions for holding a hearing if there is any conflict concerning any material fact.

Section 301.93–6

Section 301.93–6 provides for the issuance and cancellation of compliance agreements. Compliance agreements can be entered into by any person engaged in the business of growing, handling, or moving regulated articles who agrees in writing to comply with the regulations and any conditions imposed pursuant thereto. Compliance agreements are provided for the convenience of persons who, because of their business, are involved in frequent shipments of regulated articles from quarantined areas and are designed to insure that persons issuing certificates and limited permits are knowledgeable with respect to the requirements of the regulations and have agreed to comply with them.

Section 301.93–6 also provides that a compliance agreement may be cancelled by an inspector supervising its enforcement whenever the inspector finds that a person who has entered into such an agreement has failed to comply with any of the provisions of the regulations or any conditions imposed

pursuant thereto. This section also contains provisions for notifying the holder of the compliance agreement of the reasons for cancellation and for holding a hearing to resolve any conflict concerning any material fact. A footnote (footnote 5) is added to explain where compliance agreement forms can be obtained.

Sections 301.93–7, 301.93–8 and 301.93–9

Section 301.93–7 provides that any person who desires a certificte or limited permit to move regulated articles should request inspection by an inspector as far in advance as possible (no less than 48 hours before the desired movement).

Section 301.93–8 requires the certificate or limited permit issued for the movement of the regulated article to be attached to the regulated article, or to a container carrying the regulated article, or to the accompanying waybill or other shipping document during the interstate movement.

These provisions of § 301.93–7 and § 301.93–8 are necessary for enforcement purposes and to ensure that persons desiring inspection services can arrange for them before the intended movement date.

Section 301.93–9 explains the Department's policy that services of an inspector needed in order for a person to comply with the provisions of the regulations are provided without cost during normal business hours, but that any other incidental costs or charges shall not be the responsibility of the Department.

Section 301.93–10

Section 301.93–10 sets forth treatment schedules for certain regulated articles that must be met if such articles are to be certified prior to movement as provided in § 301.93–4. Based on research it has been determined that these treatments would be adequate to destroy the Oriental fruit fly. Section 301.93–10 states that some varieties of fruit fly may be injured by methyl bromide and that shippers should test treat before making commercial treatments.

The treatment schedules for regulated articles in § 301.93–10 are as follows:

(a) Avocado:

Fumigation with methyl bromide at normal atmospheric pressure with 32 g/m ^{3} for 2½ hours at 21 °C. (70 °F.) or above followed by refrigeration for 7 days at 7.22 °C. (45 °F.) or below. The 7 day period may include up to 24 hours precooling time. Time between fumigation and start of cooling shall not exceed 24 hours, but must include at least 30 minutes aeration.

(b) Tomato:

Fumigation with methyl bromide at normal atmospheric pressure with 32 g/m ^{3} for 3½ hours at 21 °C. (70 °F.) or above.

(c) Papaya, pepper and tomato:

Heat the article by saturated water vapor at 44.44 °C. (112 °F.) until approximate center of article reaches 44.44 °C. (112 °F.), and maintain at 44.44 °C. (112 °F.) for 8¾ hours, then immediately cool.

Note.—Commodities should be tested by the shipper at the 44.44 °C. (112 °F.) temperature to determine each commodity's tolerance to the treatment before commercial treatments are attempted. Pretreatment conditioning is optional. Such conditioning is the responsibility of the shipper and would be conducted in accordance with procedures the shipper believes necessary. It is common to perform pretreatment conditioning. For example, it is the practice to condition eggplant at 43.30 °C. (110 °F.) at 40 percent relative humidity for 6 to 8 hours.

(d) Apple, apricot, cherry, fig, grape, grapefruit, lemon, nectarine, orange, peach, pear, plum, pomegranate and prickly pear:

Fumigation with 32 g/m ^{3} methyl bromide at 21 °C. (70 °F.) or above (chamber load not to exceed 80 percent of volume), and at normal atmospheric pressure, followed by refrigeration, as set forth below.

Fumigation exposure time	Refrigeration
2 hours	4 days at 0.55°–2.7 °C. (33°–37 °F.); or 11 days at 3.33°–8.3 °C. (38°–47 °F.)
2½ hours	4 days at 3.33°–4.44 °C. (38°–40 °F.); or 6 days at 5.0°–8.33 °C. (41°–47 °F.); or 10 days at 8.88°–13.33 °C. (48°–56 °F.)
3 hours	3 days at 6.11°–8.33 °C. (43°–47 °F.); or 6 days at 8.88°–13.33 °C. (48°–56 °F.)

Minimum concentrations for above fumigations.

(25 g minimum gas concentration at ½ hr.)
(18 g minimum gas concentration at 2 or 2½ hrs.)
(17 g minimum gas concentration at 3 hrs.)

Aerate all fruit at least 2 hours following fumigation. Time lapse between fumigation and start of cooling shall not exceed 24 hours.

Note.—Some varieties of fruit may be injured by methyl bromide. Shippers should test treat before making commercial shipments.

(e) Soil:

Soil within the drip area of plants which are producing or have produced the fruits, nuts, vegetables and berries listed in § 301.93–2(a): Apply diazinon at the rate of 5 pounds actual ingredient per acre to the soil within the drip area with sufficient water to wet the soil to at least a depth of ½ inch. Both immersion and pour-on treatment procedures are acceptable.

Emergency Action

The Deputy Administrator of the Animal and Plant Health Inspection Service for Plant Protection and Quarantine has determined that an emergency situation exists which warrants publication of this interim rule without prior opportunity for a public comment period. Due to the possibility that the Oriental fruit fly could be spread artificially to noninfested areas of the United States, a situation exists requiring immediate action to help control the spread of this pest.

Further, pursuant to the administrative procedure provisions of 5 U.S.C. 553, it is found upon good cause that prior notice and other public procedure with respect to this interim rule are impracticable and contrary to the public interest; and good cause is found for making this interim rule effective upon signature. Comments will be solicited for 60 days after publication of this document, and a final document discussing comments received and any amendments required will be published in the **Federal Register** as soon as possible.

Executive Order 12291 and Regulatory Flexibility Act.

This rule is issued in conformance with Executive Order 12291 and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that this rule will have an effect on the economy of less than 100 million dollars; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this rulemaking action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

Within the quarantined area there are fewer than 100 small entities which may be affected, including no more than 5 packers, 5 outdoor fruit stands, 9 nurseries and a number of groceries and retail stores. Except for the packers and nurseries, most of the sales of these entities are local intrastate and would not be affected by the quarantine. Effects on the packers and nurseries will be minimized by treatments and conditions in the regulations which will allow continued movement of most of their products. Based on the circumstances described above, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have

a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V).

Paperwork Reduction Act

The regulations in this subpart contain no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases, Plant pests, Plants (Agriculture), Quarantine, Transportation, Oriental fruit fly.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, 7 CFR Part 301 is amended as follows:

1. The authority citation for Part 301 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff; 161, 162, and 164–167; 7 CFR 2.17, 2.51, and 371.2(c).

2. Part 301 is amended by adding a new "Subpart—Oriental Fruit Fly" to read as follows:

Subpart—Oriental Fruit Fly

Sec.

* * * * *

Subpart—Oriental Fruit Fly

§ 301.93 Restrictions on interstate movement of regulated articles.[1]

No common carrier or other person shall move interstate from any quarantined area any regulated article except in accordance with the conditions prescribed in this subpart.

§ 301.93–1 Definitions.

Terms used in the singular form in this subpart shall be construed as the plural and vice versa, as the case may demand. The following terms, when used in this subpart, shall be construed, respectively, to mean:

Certificate. A document which is issued for a regulated article by an inspector or by a person operating under a compliance agreement, and which represents that such article is eligible for interstate movement to any destination.

Compliance agreement. A written agreement between Plant Protection and Quarantine and a person engaged in the business of growing, handling, or moving regulated articles, wherein the person agrees to comply with the provisions of this subpart and any conditions imposed pursuant thereto.

Deputy Administrator. The Deputy Administrator of the Animal and Plant Health Inspection Service for Plant Protection and Quarantine, or any officer or employee of the Department to whom authority to act in his or her stead has been or may hereafter be delegated.

Infestation. The presence of the oriental fruit Fly or the existence of circumstances that make it reasonable to believe that the Oriental fruit fly is present.

Inspector. Any employee of Plant Protection and Quarantine, Animal and Plant Health Inspection Service U.S. Department of Agriculture, or other person authorized by the Deputy Administrator in accordance with law to enforce the provisions of this subpart.

Interstate. From any State into or through any other State.

Limited permit. A document which is issued for a regulated article by an inspector or by a person operating under a compliance agreement, and which represents that such regulated article is eligible for interstate movement in accordance with § 301.93–5(b).

Moved. Shipped, offered for shipment to a common carrier, received for transportation or transported by a common carrier, or carried, transported, moved, or allowed to be moved by any means.

Movement or move. The act of shipping, offering for shipment to a common carrier, receiving for transportation or transporting by a common carrier, or carrying, transporting, moving, or allowing to be moved by any means.

Oriental fruit fly. The insect known as Oriental fruit fly *(Dacus dorsalis* (Hendel)) in any stage of development.

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant Protection and Quarantine. The organizational unit within the Animal and Plant Health Inspection Service, United States Department of Agriculture, delegated responsibility for enforcing provisions of the Plant Quarantine Act, the Federal Plant Pest Act, and related legislation, and quarantines and regulations promulgated thereunder.

Quarantined area. Any State, or any portion thereof, listed in § 301.93–3(c) or otherwise designated as a quarantined area in accordance with § 301.93–3(b).

Regulated article. Any article listed in § 301.93–2 or otherwise designated as a regulated article in accordance with § 301.93–2(c).

State. Each of the several States of the United States, the District of Columbia, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and all other Territories and Possessions of the United States.

§ 301.93–2 Regulated articles.

(a) The following fruits, nuts, vegetables and berries:

Akia (*Wikstromeia phyllyraefolia*)
Alexander laurel (*Calophyllum inophyllum*)
Apple (*Malus sylvestris*)
Apricot (*Prunus armeniaca*)
Avocado (*Persea americana*)
Banana (*Musa paradisiaca* var. *sapientum*) (*Musa x paradisiaca*)
Banana, dwarf (*Musa nana*)
Barbados cherry (*Malpighia glabra*)
Bell pepper (*Capsicum annum*)
Brazil cherry (*Eugenia dombeyi*)
Breadfruit (*Artocarpus altilis*)
Caimitillo (*Chrysophyllum oliviforme*)
Cashew (*Anacardium occidentale*)
Cactus (*Cereus coerulescens*)
Cherimoya (*Anonna cherimola*)
Cherry, Catalina (*Prunus ilicifolia*)
Cherry, Portuguese (*P. lusitanica*)
Chili (*Capsicum annum*)
Coffee, Arabian (*Coffea arabica*)
Country gooseberry (*Averrhoa carambola*)
Cucumber (*Cucumis sativas*)
Custard apple (*Annona reticulata*)
Date palm (*Phoenix dactylifera*)
Dragon tree (*Dracena draco*)
Eggfruit tree (*Pouteria campechiana*)
Elengi tree (*Mimusops elengi*)
Fig (*Ficus carica*)
Gourka (*Garcinia celebica*)
Granadilla, sweet (*Passiflora ligularis*)
Grape (*Vitis spp.*)
Grapefruit (*Citrus paradisi*)
Guava (*Psidium guajava*), (*P. Littorale*), (*P. cattleianum*)

[1] Any properly identified inspector is authorized to stop and inspect persons and means of conveyance, and to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated articles as provided in section 10 of the Plant Quarantine Act (7 U.S.C. 164a) and section 105 and 107 of the Federal Pest Act (7 U.S.C. 150dd, 150ff).

Imbu (*Spondias tuberosa*)
Jackfruit (*Artocarpus heterophyllus*)
Jerusalem cherry (*Solanum pseudocapsicum*)
Kitembilla (*Dovyalis hebecarpa*)
Kumquat (*Fortunella japonica*)
Laurel (*Calophyllum inophyllum*)
Lemon (*Citrus limon*)
Lime, key or Mexican (*Citrus aurantifolia*)
Lime, Persian (*Citrus latifolia*)
Lime, sweet (*Citrus limetioides*)
Longan (*Euphoria longan*)
Loquat (*Eriobotrya japonica*)
Lychee nut (*Lychee chinensis*)
Malay apple (*Eugenia malaccensis*)
Mammee apple (*Mammea americana*)
Mandarin orange (*Citrus reticulata*) (tangerine)
Mango (*Mangifera indica*)
Mangosteen (*Garcinia mangostana*)
Mock orange (*Murraya exotica*)
Mulberry (*Morus nigra*)
Myrtle, downy rose (*Rhodomyrtus tomentosa*)
Natal plum (*Carissa grandiflora*)
Nectarine (*Prunus persica* var. *nectarina*)
Oleander, yellow (*Thevetia peruviana*)
Orange, calamondin (*Citrus riticulata* x. *Forrtunella*)
Orange, Chinese (*Fortunella japonica*)
Orange, king (*Citrus reticulata* x. *C. sinensis*)
Orange, sweet (*Citrus sinensis*)
Orange, Unshu (*Citrus reticulata* var. *Unshu*)
Oriental bush red pepper (*Capsicum frutescens abbreviatum*)
Otaheite apple (*Spondias dulcis*)
Palm, syrup (*Jubaea spectabilis*)
Papaya (*Carica papaya*)
Passionflower (*Passiflora edulis*)
Passionflower, softleaf (*Passiflora mollissima*)
Passionfruit (*Passiflora edulis*) (yellow lilikoi)
Peach (*Prunus persica*)
Pear (*Pyrus communis*)
Pepino (*Solanum muricatum*)
Pepper, sweet (*Capsicum frutescens* var. *grossum*)
Persimmon, Japanese (*Diospyros kaki*)
Pineapple guava (*Feijoa sellowiana*)
Plum (*Prunus americana*)
Pomegranate (*Punica granatum*)
Prickly pear (*Opuntia megacantha*) (*Opuntia ficus indica*)
Prune (*Prunus domestica*)
Pummelo (*Citrus grandis*)
Quince (*Cydonia oblonga*)
Rose apple (*Eugenia jambos*)
Sandalwood (*Santalum paniculatum*)
Sandalwood, white (*Santalum album*)
Santol (*Sandericum koetjape*)
Sapodilla (*Manilkara zapota*)
Sapodilla, chiku (*Manilkara zapota*)
Sapota, white (*Casimiroa edulis*)
Seagrape (*Coccoloba uvifera*)
Sour orange (*Citrus aurantium*)
Soursop (*Annona muricata*)
Star apple (*Chrysophyllum cainito*)
Surinam cherry (*Eugenia uniflora*)
Tomato (*Lycopersicon esculentum*)
Tropical almond (*Terminalia catappa*) (*Terminalia chebula*)
Velvet apple (*Diospyros discolor*)
Walnut (*Juglans hindsii*)
Walnut, English (*Juglans regia*)
Wampi (*Citrus lansium*)
West Indian cherry (*Malpighia punicifolia*)
Ylang-Ylang (*Cananga odorata*).

Except that the list does not include any fruits, nuts, vegetables, or berries which are canned or dried or have been frozen below −17.8 °C. (0 °F.);

(b) Soil within the drip area of plants which produce the fruits, nuts, vegetables, or berries listed in paragraph (a); and

(c) Any other product, article, or means of conveyance, of any character whatsoever, not covered by paragraphs (a) or (b) of this section, when it is determined by an inspector that it presents a risk of spread of the Oriental fruit fly and the person in possession thereof has actual notice that the product, article, or means of conveyance is subject to the restrictions of this subpart.

§ 301.93–3 Quarantined areas.

(a) Except as otherwise provided in paragraph (b) of this section, the Deputy Administrator shall list as a quarantined area in paragraph (c) of this section, each State, or each portion thereof, in which the Oriental fruit fly has been found by an inspector, or in which the Deputy Administrator has reason to believe that the Oriental fruit fly is present, or each portion of a State which the Deputy Administrator deems necessary to regulate because of its proximity to the Oriental fruit fly or its inseparability for quarantine enforcement purposes from localities in which the Oriental fruit fly occurs. Less than an entire State will be designated as a quarantined area only if the Deputy Administrator determines that:

(1) The State has adopted and is enforcing a quarantine or regulation which imposes restrictions on the intrastate movement of the regulated articles which are substantially the same as those which are imposed with respect to the interstate movement of such articles under this subpart; and

(2) The designation of less than the entire State as a quarantined area will otherwise be adequate to prevent the artifical interstate spread of the Oriental fruit fly.

(b) The Deputy Administrator or an inspector may temporarily designate any nonquarantined area in a State as a quarantined area in accordance with the criteria specified in paragraph (a) of this section for listing such area. Written notice of such designation shall be given to the owner or person in possession of such nonquarantined area, and, thereafter, the interstate movement of any regulated article from such area shall be subject to the applicable provisions of this subpart. As soon as practicable, such area shall be added to the list in paragraph (c) of this section or such designation shall be terminated by the Deputy Administrator or an inspector, and notice thereof shall be given to the owner or person in possession of the area.

(c) The areas described below are designated as quarantined areas:

California

(1) That portion of Riverside and San Bernardino Counties beginning at a point where Cedar Avenue intersects Merrill Avenue, then east on Merrill Avenue, which becomes Mill Street, and continuing east on Mill Street to its intersection with Tippecanoe Avenue, then south on said avenue to its intersection with San Bernardino Avenue, then east on said avenue to its intersection with Bryn Mawr Avenue, then south on said avenue to its intersection with Redlands Boulevard, then south from said intersection along an imaginary line which re-connects with Bryn Mawr, then south on Bryn Mawr Avenue to its intersection with Beaumont Avenue, then south along an imaginary line to the intersection of Manzanita Avenue and Indian Avenue, then south on Indian Avenue to its intersection with Highway 60, then northwesterly on said highway to its intersection with Central Avenue, then westerly on said avenue to its intersection with Cage Canal, then westerly on said canal to its intersection with Central Avenue, then westerly on said avenue to its intersection with Palm Avenue, then north on said avenue to its intersection with Jurupa Avenue, then north along an imaginary line from the intersection of Palm Avenue and Jurupa Avenue to the intersection on Highway 60 and Rubidoux Boulevard, then northerly on said boulevard, which becomes Cedar Avenue, and continuing northerly on Cedar Avenue to the point of beginning.

§ 301.93–4 Conditions governing the interstate movement of regulated articles from quarantined areas.[2]

Any regulated article may be moved interstate from a quarantined area only if moved under the following conditions:

(a) With a certificate or limited permit issued and attached in accordance with §§ 301.93–5 and 301.93–8;

(b) Without a certificate or limited permit, if:

(1) The article originated outside of any quarantined area and is moved directly through (without stopping

[2] Requirements under all other applicable Federal domestic plant quarantines and regulations must also be met.

except for brief refueling, or for normal traffic conditions, such as traffic lights or stop signs) the quarantined area in an enclosed vehicle or is completely enclosed by a covering adequate to prevent access by Oriental fruit flies (such as canvas, plastic, or closely woven cloth) while moving through the quarantined area, or

(2) The article is part of a shipment originating outside of any quarantined area which is moved into the quarantined area for packing or processing at a facility which an inspector has determined will not expose the article to Oriental fruit flies, and the article is moved to and from the facility under the conditions of paragraph (b)(1), and

(3) The point or origin of the article is clearly indicated by shipping documents and its identity has been maintained.

(c) Without a certificate or limited permit, if:

(1) Moved by the United States Department of Agriculture for experimental or scientific purposes;

(2) Moved pursuant to a permit issued by the Deputy Administrator;

(3) Moved in accordance with conditions specified on the permit and found by the Deputy Administrator to be adequate to prevent the dissemination of the Oriental fruit fly, i.e., conditions of treatment, processing, shipment, disposal; and

(4) Moved with a tag or label securely attached to the outside of the container containing the article or securely attached to the article itself if not in a container, and with such tag or label bearing a permit number corresponding to the number of the permit issued for such article.

§ 301.93-5 Issuance and cancellation of certificates and limited permits.

(a) A certificate shall be issued by an inspector for the interstate movement of a regulated article if such inspector:

(1) (i) Determines that it has been treated under the direction of an inspector in accordance with § 301.93-10; or

(ii) Determines, based on inspection of the premises of origin, that the premises are free from Oriental fruit fly and the article has not been exposed to Oriental fruit fly; or

(iii) Determines, based on inspection of the article, that it is free of Oriental friut fly; and

(2) Determines that it is to be moved in compliance with any additional emergency conditions necessary to prevent the spread of the Oriental fruit fly pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd);[3] and

(3) Determines that it is eligible for unrestricted movement under all other Federal domestic plant quarantines and regulations applicable to such articles.

(b) A limited permit shall be issued by an inspector [4] for the movement of a regulated article if such inspector:

(1) Determines, in consultation with the Deputy Administrator, that it is to be moved to a specified destination for specified handling, utilization, or processing (such destination and other conditions to be specified in the limited permit), and when upon evaluation of all of the circumstances involved in each case, it is determined that such movement will not result in the spread of the Oriental fruit fly because life stages of the pest will be destroyed by such specified handling, utilization, or processing;

(2) Determines that it is to be moved in compliance with any additional emergency conditions necessary to prevent the spread of the Oriental fruit fly pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd); and

(3) Determines that it is eligible for such movement under all other Federal domestic plant quarantines and regulations applicable to such articles.

(c) Certificates and limited permits for use for movement of regulated articles may be issued by an inspector [4] or person engaged in the business of growing, handling, or moving regulated articles provided such person is operating under a compliance agreement. Any such person may execute and issue a certificate for the interstate movement of a regulated article if the inspector has made the determination that such article is otherwise eligible for a certificate in accordance with paragraph (a) of this section. Any such person may execute and issue a limited permit for interstate movement of a regulated article when the inspector has made the determination that such article is eligible for a limited permit in accordance with paragraph (b) of this section.

(d) Any certificate or limited permit which has been issued or authorized may be withdrawn by an inspector orally or in writing, if such inspector determines that the holder thereof has not complied with all conditions under the regulations for the use of such document. If the cancellation is oral, the decision and the reasons for the withdrawal shall be confirmed in writing as promptly as circumstances allow. Any person whose certificate or limited permit has been withdrawn may appeal the decision in writing to the Deputy Administrator within ten (10) days after receiving the written notification of the withdrawal. The appeal shall state all of the facts and reasons upon which the person relies to show that the certificate or limited permit was wrongfully withdrawn. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Deputy Administrator.

§ 301.93-6 Compliance agreement and cancellation thereof.

(a) Any person engaged in the business of growing, handling, or moving regulated articles may enter into a compliance agreement to facilitate the movement of regulated articles under this subpart.[5] The compliance agreement shall be a written agreement between a person engaged in such a business and Plant Protection and Quarantine, wherein the person agrees to comply with the provisions of this subpart and any conditions imposed thereto.

(b) Any compliance agreement may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that such person has failed to comply with the provisions of this subpart or any conditions imposed

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[3] Section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd) provides, among other things, that the Secretary of Agriculture may, whenever he deems it necessary as an emergency measure in order to prevent the dissemination of any plant pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of, in such manner as he deems appropriate, any product or article of any character whatsoever, or means of conveyance, which is moving into or through the United States or interstate, and which he has reason to believe is infested or infected by or contains any such plant pest; or which has moved into the United States or interstate, and which he has reason to believe was infested or infected by or contained any such plant pest at the time of such movement.

[4] Inspectors are assigned to local offices of Plant Protection and Quarantine which are listed in telephone directories. Information concerning such local offices may also be obtained from the Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, Federal Building, Hyattsville, Maryland, 20782.

[5] Compliance agreement forms are available without charge from the Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, Federal Building, Hyattsville, MD 20782, and from local offices of the Plant Protection and Quarantine (Local offices are listed in telephone directories).

pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose compliance agreement has been cancelled may appeal the decision, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully cancelled. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Deputy Administrator.

§ 301.93–7 Assembly and inspection of regulated articles.

(a) Any person (other than a person authorized to issue certificates or limited permits under § 301.93–5(c)), who desires to move interstate a regulated article accompanied by a certificate or limited permit shall, as far in advance as possible (should be no less than 48 hours before the desired movement), request an inspector [4] to take necessary action under this subpart prior to movement of the regulated article.

(b) Such article shall be assembled at such point and in such manner as the inspector designates as necessary to comply with the requirements of this subpart.

§ 301.93–8 Attachment and disposition of certificates and limited permits.

(a) A certificate or limited permit required for the interstate movement of a regulated article, at all times during such movement, shall be securely attached to the outside of the container containing the regulated article, securely attached to the article itself if not in a container, or securely attached to the consignee's copy of the accompanying waybill or other shipping document: *Provided however*, that the requirements of this section may be met by attaching the certificate or limited permit to the consignee's copy of the waybill or other shipping documents only if the regulated article is sufficiently described on the certificate, limited permit, or shipping document to identify such article.

(b) The certificate or limited permit for the movement of a regulated article shall be furnished by the carrier to the consignee at the destination of the shipment.

§ 301.93–9 Costs and charges.

The services of the inspector shall be furnished without cost. The United States Department of Agriculture will not be responsible for any costs or charges incident to inspections or compliance with the provisions of the regulations in this subpart, other than for the services of the inspector.

§ 301.93–10 Treatments.

The treatment schedules for regulated articles are as follows:

(a) Avocado: Fumigation with methyl bromide at normal atmospheric pressure with 32 g/m ^{3} for 2½ hours at 21 °C. (70 °F.) or above followed by refrigeration for 7 days at 7.22 °C. (45 °F.) or below. The 7 day period may include up to 24 hours precooling time. Time between fumigation and start of cooling shall not exceed 24 hours, but must include at least 30 minutes aeration.

(b) Tomato: Fumigation with methyl bromide at normal atmospheric pressure with 32 g/m ^{3} for 3½ hours at 21 °C. (70 °F.) or above.

(c) Papaya, pepper and tomato: Heat the article by saturated water vapor at 44.44 °C. (112 °F.) until approximate center of article reaches 44.44 °C. (112 °F.), and maintain at 44.44 °C. (112 °F.) for 8¾ hours, then immediately cool.

Note.—Commodities should be tested by the shipper at the 44.44 °C. (112 °F.) temperature to determine each commodity's tolerance to the treatment before commercial treatments are attempted. Pretreatment conditioning is optional. Such conditioning is the responsibility of the shipper and would be conducted in accordance with procedures the shipper believes necessary. It is common to perform pretreatment conditioning. For example, it is the practice to condition eggplant at 43.30 °C. (110 °F.) at 40 percent relative humidity for 6 to 8 hours.

(d) Apple, apricot, cherry, fig, grape, grapefruit, lemon, nectarine, orange, peach, pear, plum, pomegranate and prickly pear: Fumigation with 32 g/m ^{3} methyl bromide at 21 °C. (70 °F.) or above (chamber load not to exceed 80 percent of volume), and at normal atmospheric pressure, followed by refrigeration, as set forth below.

Fumigation exposure time	Refrigeration
2 hours	4 days at 0.55°–2.7 °C. (33°–37 °F.); or 11 days at 3.33°–8.3 °C. (38°–47 °F.)
2½ hours	4 days at 3.33°–4.44 °C. (38°–40 °F.); or 6 days at 5.0°–8.33 °C. (41°–47 °F.); or 10 days at 8.88°–13.33 °C. (48°–56 °F.)
3 hours	3 days at 6.11°–8.33 °C. (43°–47 °F.); or 6 days at 8.88°–13.33 °C. (48°–56 °F.)

Minimum concentrations for above fumigations.

(25 g minimum gas concentration at ½ hr.)
(18 g minimum gas concentration at 2 or 2½ hrs.)
(17 g minimum gas concentration at 3 hrs.)

Aerate all fruit at least 2 hours following fumigation. Time lapse between fumigation and start of cooling shall not exceed 24 hours.

Note.—Some varieties of fruit may be injured by methyl bromide. Shippers should test treat before making commercial shipments.

(e) Soil: Soil within the drip area of plants which are producing or have produced the fruits, nuts, vegetables and berries listed in § 301.93–2(a): Apply diazinon at the rate of 5 pounds actual ingredient per acre to the soil within the drip area with sufficient water to wet the soil to at least a depth of ½ inch. Both immersion and pour-on treatment procedures are acceptable.

Done at Washington, DC, this 19th day of September 1986.

Richard R. Backus,

Acting Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service.

[FR Doc. 86–21602 Filed 9–23–86; 8:45 am]

BILLING CODE 3410–34–M

Agricultural Marketing Service

7 CFR Part 967

Celery Grown in Florida; Handling Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action will help Florida celery producers compete for a share of the U.S. celery market by establishing an upper limit on the quantity of Florida celery that may be marketed fresh during the 1986–87 season. The establishment of a marketable quantity is expected to encourage growers to assume the risks of planting celery and thus provide consumers with an adequate supply. The rule was recommended by the Florida Celery Committee which works with the U.S. Department of Agriculture in administering the order.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Ronald L. Cioffi, Chief, Marketing Order Administration Branch, F&V, AMS, USDA, Washington, DC 20250, telephone: 202/477–5697.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512–1 and has been

determined to be a "nonmajor" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Agricultural Marketing Agreement Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities on their own behalf. Thus, both statutes have small entity orientation and compatibility.

This action will establish an upper limit on the quantity of Florida celery that may be marketed fresh during the 1986–87 season in order to encourage growers to assume the risks of planting and thus provide consumers with an adequate supply. As in past seasons, the limitation on the quantity of Florida celery handled for fresh shipment is not expected to restrict the quantity of Florida celery sold.

It is estimated that seven handlers of celery under the marketing order for celery grown in Florida will be subject to regulation during the course of the current season and that the majority of these firms may be classified as small entities. The regulations issued under this rulemaking have been in effect in prior seasons and have resulted in shipments into fresh markets of ample supplies of celery, and the promotion of buyer confidence and consumer satisfaction with purchases of fresh Florida celery, with attendant benefits to producers, handlers, and the industry.

This rule is issued under Marketing Agreement No. 149 and Marketing Order No. 967, both as amended, regulating the handling of celery grown in Florida. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This action is based upon the recommendation and information submitted by the Florida Celery Committee and upon other available information.

The committee met on June 4, 1986, and recommended a marketability quantity of 6,789,738 crates of fresh celery for the 1986–87 season. This recommendation was based on an appraisal of the expected supply and prospective market demand. The recommended marketable quantity is about 15 percent more than the approximately 5.9 million crates marketed fresh during the 1985–86 season, and the 1986–87 season allotment is also expected to be above actual shipments for that season. Additionally, the uniform percentage of 100 percent was recommended which would allow each producer registered pursuant to § 967.37(f) of the order to market 100 percent of their base quantities.

As required by § 967.37(d)(1) of the order, a reserve of 6 percent of the 1985–86 total base quantities is authorized for new producers and for increases by existing producers for the 1986–87 season. However, there were no applications for new or additional base submitted for the 1986–87 season.

Notice of this rule was published in the **Federal Register** on July 22, 1986, (51 FR 26253) and provided the opportunity for public comment. One comment was received which opposed the issuance of the proposed handling regulation for Florida celery and marketing orders in general. The commenter questioned the "justification for starting another marketing order." The commenter's opposition centered on the restrictions that the Florida Celery Marketing Order utilizes as a producer allotment program. The establishment of the handling regulation is, however, favored by all producers and handlers of Florida celery, since it was recommended by the committee, which is comprised of all the producers and handlers of Florida celery. The regulation has benefited the industry in the past, and thus, was recommended for the current season. The Florida Celery Marketing Order has been in effect since 1965 and similar regulations have been recommended by the committee and issued by the Department for more than ten years. The regulations set forth in this final rule for the 1986–87 season are consistent with the recommendations made by the committee, the marketing order, Departmental guidelines, and the Agricultural Marketing Agreement Act of 1937, as amended.

It is further found that it is impracticable and contrary to the public interest to postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because: (1) Adequate notice has been given of the requirements of this regulation through publicity in the production area and by publication in the July 22, 1986, issue of the **Federal Register** (51 FR 26253); (2) the regulation should become effective as early as possible in the marketing year which began August 1, 1986, so producers and handlers will be afforded maximum time in which to plan their operations; and (3) this regulation is similar to those issued in previous seasons.

List of Subjects in 7 CFR Part 967

Marketing agreements and orders, Celery.

PART 967—FLORIDA CELERY

Subpart—Rules and Regulations

1. The authority citation for 7 CFR Part 967 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. New § 967.322 under Subpart—Rules and Regulations, is added to read as follows: (The following provisions will not be published in the Code of Federal Regulations).

§ 967.322 Handling regulation; marketable quantity; and uniform percentage for the 1986–87 season beginning August 1, 1986.

(a) The marketable quantity established under § 967.36(a) is 6,789,738 crates of celery.

(b) As provided in § 967.38(a), the uniform percentage shall be 100 percent.

(c) Pursuant to § 967.36(b), no handler shall handle any harvested celery unless it is within the marketable allotment of a producer who has a base quantity and such producer authorizes the first handler thereof to handle it.

(d) As required by § 967.37(d)(1) a reserve of 6 percent of the total base quantities is hereby authorized for: (1) New producers; and (2) increases for existing base quantity holders.

(e) Terms used herein shall have the same meaning as when used in the said marketing agreement and order.

Dated: September 18, 1986.

Joseph A. Gribbin,

Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 86–21644 Filed 9–23–86; 8:45 am]

BILLING CODE 3410–02–M

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7 CFR Part 1079

Milk in The Iowa Marketing Area; Order Suspending Certain Provisions

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Suspension of rules.

SUMMARY: This action increases for the months of September, October and November 1986 the limits on the quantity of milk not needed for fluid (bottling) use that may be moved directly from farms to nonpool manufacturing plants and still be priced under the Iowa order. The suspension

was requested by a cooperative association in order to pool the milk of its members who have been historically associated with the market.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Richard A. Glandt, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–4829.

SUPPLEMENTARY INFORMATION: Prior document in this proceeding:

Notice of Proposed Suspension: Issued July 29, 1986; published August 1, 1986 (51 FR 27554).

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires the Agency to examine the impact of a proposed rule on small entities. Pursuant to 5 U.S.C. 605(b), the Administrator of the Agricultural Marketing Service has certified that this action will not have a significant economic impact on a substantial number of small entities. Such action lessens the regulatory impact of the order on certain milk handlers and tends to ensure that dairy farmers will continue to have their milk priced under the order and thereby receive the benefits that accrue from such pricing.

This order of suspension is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*) and of the order regulating the handling of milk in the Iowa marketing area (7 CFR Part 1079).

Notice of proposed rulemaking was published in the **Federal Register** on August 1, 1986 (51 FR 27554) concerning a proposed suspension of certain provisions of the order. Interested parties were afforded an opportunity to file data, views, and arguments thereon. Four comments were received.

After consideration of all relevant information, including the proposal in the notice and other available information, it is hereby found and determined that for the months of September through November 1986 the following provisions of the order (7 CFR Part 1079) do not tend to effectuate the declared policy of the Act:

In § 1079.13(d)(2) and (3) the words "50 percent in the months of September through November and", and the words "in other months," as they appear in each paragraph.

Statement of Consideration

This action makes inoperative for September through November 1986 the seasonal reduction (from 70-percent to 50-percent) of the limit on the proportion of a handler's producer milk that may be moved directly from the farm to a nonpool manufacturing plant and still be pooled. Through a separate action, the supply plant shipping percentage has been lowered from 35 percent to 25 percent for the same months.

Under the current order, without these two actions, a supply plant would have to ship 35 percent of its milk supply to fluid milk plants in order to be a pool supply plant. The remaining 65 percent of the supply plant's milk may be disposed of at manufacturing plants. However, only 50 percent can be moved directly from the farms to nonpool plants during the months of September throught November.

As the result of both actions, handlers should be aware that the diversion limit for these three months is 70 percent. However, because of the distributing plant pooling standards, distributing plant operators would be able to divert no more than 60 percent of their producer milk.

Associated Milk Producers, Inc. (AMPI), an association of producers, operates a supply plant regulated by the Iowa milk order. The cooperative had requested that the supply plant shipping requirements be suspended for September through November 1986 so that a supply plant operator would not have to ship a percentage of its receipts of Grade A milk to distributing plants. Also, the cooperative asked that the 50-percent diversion limitation be suspended for this same period.

AMPI has withdrawn its request for the suspension of the supply plant shipping requirements. This is because AMPI and Mid-America Dairymen, Inc., have reached an agreement that would continue to pool the AMPI plant through the unit pooling arrangement. Under this arrangement, the total of all shipments to distributing plants by the two cooperatives are used to qualify all the supply plants named in the unit.

AMPI stated that relaxation of the diversion limits under the order is still needed. AMPI pointed out that producer milk on the Iowa market has continued to increase. AMPI noted that producer milk during the first six months of 1986 increased approximately 14 percent over the same period of 1985. During this same period, Class I sales were down about 1.5 percent. AMPI stated that in their opinion, the ratio of producer milk to Class I sales will be higher this fall than last fall, thereby requiring more milk to be moved to nonpool manufacturing plants. However, without the suspension of the diversion provisions, AMPI claims that much of its member milk would have to be pumped into the supply plant and then pumped back out again for transport to a manufacturing plant. AMPI contends that the extra handling involved adversely affects milk quality (more pumping than if diverted) and is an uneconomic means of pooling milk.

Interested parties were given an opportunity to submit written data, views, and arguments concerning the proposed suspension. Three comments were received from other cooperative associations and one comment was received from a proprietary handler. All four comments opposed the suspension of the supply plant shipping requirements. With respect to the suspension of the diversion provisions, one organization supported the suspension, one took no position and two were opposed.

The proprietary handler that supported the request for the suspension, stated that it too would be forced to make some uneconomic shipments of milk this fall or to depool some milk unless the suspension is issued. The handler stated that milk receipts at its supply plant have substantially increased and at the same time the handler expects its Class I sales this fall will decrease.

A cooperative association that was opposed to the suspension of the diversion provisions, stated that the suspension would allow more distant milk supplies to be attached to the pool while being delivered directly to nonpool plants. The cooperative stated that it was concerned because of the insufficient rate of location adjustment in the order and the resulting misalignment of prices in the Wisconsin milkshed. The other opposing comment was by a cooperative association that disagrees with AMPI's contention that the ratio of producer milk to Class I sales will be higher this fall. The cooperative contends that milk production should decline this fall because of the normal seasonal decline and because of the dairy termination program. Also, the cooperative contends that Class I sales will increase and that, with the opening of schools in August and September, the ratio of producer milk to Class I sales should decline.

Market data indicates that producer milk for the first seven months of 1986 was approximately 11.8 percent higher than for the time period of 1985. Class I utilization as a percentage of producer milk for the first seven months of 1986 ranged from a low of 23 percent to a high of 28 percent. For the same period of 1985, this range was from 24 percent to 35 percent.

There is a difference of opinion between the proponent of the suspension and one of the opponents as to the ratio of producer milk to Class I

sales that can be expected this fall. It is uncertain at this point, in part due to the whole herd buyout program, just how the supply-demand situation will change, if it does, during September through November. Nevertheless, with the supply plant shipping requirement reduced from 35 to 25 percent, it is appropriate that the 50-percent diversion limitation provisions be suspended. Without this action, both AMPI and the proprietary supply plant handler likely would be required to uneconomically pump a substantial amount of milk into their supply plants and then pump the milk back out again for transport to manufacturing plants in order to keep the milk pooled. The suspension of the 50-percent diversion limit will not allow more milk to be associated with this market than could be associated under the current provisions.

The 50-percent limit on diversions to nonpool plants is inadequate to permit efficient handling of supply plant milk that is not needed for fluid milk uses in cases where nonpool plants are the only outlet used for disposing of reserve milk. Because of the other action, a supply plant will be required to ship at least 25 percent of its milk supply to other plants to qualify as a pool plant. However, with diversions limited to 50 percent, the other 25 percent of its milk supply would have to be received at the supply plant and then transferred to a nonpool plant. Suspending the 50-percent diversion limit will alleviate these concerns and allow improved handling efficiencies while maintaining the benefits of pool participation.

It is hereby found and determined that thirty days' notice of the effective date hereof is impractical, unnecessary and contrary to the public interest in that:

(a) The suspension is necessary to reflect current marketing conditions and to assure orderly marketing conditions in the marketing area. Otherwise, uneconomic movements of milk would be made solely for the purpose of pooling the milk of producers who have regularly been associated with the Iowa market;

(b) The suspension does not require of persons affected substantial or extensive preparation prior to the effective date; and

(c) Notice of proposed rulemaking was given interested parties and they were afforded opportunity to file written data, views or arguments concerning this suspension.

Therefore, good cause exists for making this order effective upon publication in the **Federal Register.**

List of Subjects in 7 CFR Part 1079

Milk marketing orders, Milk, Dairy products.

It is therefore, ordered that the following language in § 1079.13(d)(2) and (3) is suspended in the months of September through November 1986.

PART 1079—MILK IN THE IOWA MARKETING AREA

1. The authority citation for Part 1079 continues to read as follows:

Authority: (Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674).

§ 1079.13 [Amended]

2. In § 1079.13(d)(2) and (3) the words "50 percent in the months of September through November" and the words "in other months," as they appear in each paragraph, are suspended during the months of September through November 1986.

EFFECTIVE DATE: September 24, 1986.

Signed at Washington, DC, on September 18, 1986.

Karen K. Darling,

Deputy Assistant Secretary, Marketing & Inspection Services.

[FR Doc. 86–21600 Filed 9–23–86; 8:45 am]

BILLING CODE 3410–02–M

Farmers Home Administration

7 CFR Part 1944

Housing; Section 504 Recipients Lists; Retention Period

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulation on Rural Housing Loan and Grants. This action is necessary to include the retention period of section 504 Loan and Grant Recipients Lists previously contained in FmHA Instruction 2033–A. The intended effect is to ensure that these records are retained for the period necessary for FmHA Operations.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Vernola J. Patterson, Management Analyst, Directives and Administrative Services Division, Farmers Home Administration, USDA, 14th and Independence Avenue, SW., Washington, DC 20250, Telephone (202) 382–1585.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291 and has been determined to be exempt from those requirements because it involves only internal Agency management. It is the policy of this Department to publish for comment rules relating to public property, loans, grants, benefits or contracts not withstanding the exemption in 5 U.S.C. 533, with respect to such rules. This final action, however, is not published for proposed rulemaking since it involves only internal Agency management, and publication for comment is unnecessary.

The Catalog of Federal Domestic Assistance program affected by this action is:

10.417 Very Low Income Housing Repair Loans and Grants (Section 504 Rural Housing Loans and Grants)

For the reasons set forth in the final rule related Notice to CFR Part 3015, Subpart V, 48 FR 29115, June 24, 1983, this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, and Environmental Impact Statement is not required.

List of Subjects in 7 CFR Part 1944

Aged, Grant programs-Housing and community development, Home improvement and Loan programs-Housing and community development.

Therefore, Chapter XVIII, Title, Code of Federal Regulations is amended as follows:

PART 1944—HOUSING

1. The authority citation for Part 1944 continues to read as follows:

Authority: 42 U.S.C. 1480; 7 CFR 2.23; and 2.70 Subpart J. Section 504 Rural Housing Loans and Grants.

2. In § 1944.457 the introductory text of paragraph (a)(4) is revised to read as follows:

§ 1944.457 Loan and grant restrictions.

(a) * * *

(4) The amount of assistance provided each borrower/grantee will be documented on the section 504 recipients list, and maintained in the operational file for a period of 25 years.

This list will include the following information recorded at the time a section 504 Loan/grant is made.

* * * * *

Dated: August 28, 1986.

Vance L. Clark,

Administrator, Farmers Home Administrator.

[FR Doc. 86-21601 Filed 9-23-86; 8:45 am]

BILLING CODE 3410-07-M

Office of Transportation

7 CFR Part 3300

Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment To Be Used for Such Carriage (ATP); Inspection, Testing, and Certification of Special Equipment

AGENCY: Office of Transportation, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this rule is to establish procedures for the inspection, testing, and certification of insulated, refrigerated, mechanically refrigerated, and heated transport equipment in accordance with the subject Agreement and the standards specified therein. Under this rule, United States firms which manufacture or own such equipment may obtain certification for their equipment for the international carriage of perishable foodstuffs. This rule has been developed under the authority delegated to the Secretary of Agriculture to implement the Agreement, as set forth in the International Carriage of Perishable Foodstuffs Act, which authority has been further delegated by the Secretary to the Assistant Secretary for Marketing and Inspection Services and the Administrator of the Office of Transportation.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: To obtain further information, including copies of the Agreement, the Senate Committee Report, and the Act (Pub. L. 97-325), contact Robert F. Guilfoy, Jr., Office of Transportation, Department of Agriculture, 1405 Auditors Building, 201-14th Street, SW., Washington, DC 20250. Telephone (202) 447-6235.

SUPPLEMENTARY INFORMATION: The subject Agreement, dated September 1, 1970, was developed by the Economic Commission for Europe (ECE), a regional body of the United Nations. The ECE is made up of 34 member countries, including 32 European countries, the United States, and Canada.

The United States Senate ratified the Agreement on March 20, 1980, followed by enactment by the Congress of the International Carriage of Perishable Foodstuffs Act on October 15, 1982. The U.S. acceded to the Agreement on January 20, 1983.

The basic objectives of this rule derive from the Perishable Foodstuffs Act, section 2, paragraphs (3) and (4), which read "(3) this Act will make it possible for equipment in the United States to be inspected, tested, and certified in accordance with the agreement and the standards specified therein; and (4) this Act will improve the conditions for the movement of perishable foodstuffs in international carriage in equipment owned or operated by United States firms, which will serve to protect existing trade and promote expansion of trade in perishable foodstuffs, and will improve the sale of United States manufactured equipment for use in international carriage."

Under this rule, domestic owners may obtain certification for new equipment manufactured in the United States or in a foreign country. Domestic owners may also obtain certification or recertification for equipment in service. Foreign owners may obtain certification for new equipment manufactured in the United States, but not for equipment manufactured in a foreign county or for equipment in service.

It should be noted that this rule does not make it mandatory that all special transport equipment manufactured, owned, or operated by U.S. firms be certified. Rather, this rule sets up procedures whereby U.S. firms may obtain certification of their equipment, if they so desire and as needed, for transport of perishable foodstuffs among countries which are contracting parties to the Agreement, particularly in Europe.

Since the Agreement is a United Nations intergovernmental agreement, it is necessary that it be administered by a governmental agency.

Thus far, the following 21 countries have become contracting parties to the Agreement: Austria, Belgim, Bulgaria, Czechoslovakia , Denmark, Finland, France, Federal Republic of Germany, Germany Democratic Republic, Italy, Luxembourg, Morocco, Netherlands, Norway, Poland, Spain, Sweden, U.S.S.R., United Kindom, United States of America, and Yugoslavia.

Exemptions

Article 5 of the Agreement provides that the Agreement shall not apply to carriage in containers in which the transport operation involves a movement of more than 150 km by sea. Thus, a container moving from the United States to a country in Europe, or vice-versa, would not have to be certified. It may be noted that Article 5 makes no mention of roll-on roll-off (RoRo) vehicles moving more than 150 km by sea, probably because there was little if any of that type of movement when the Agreement was being drafted. In any event, manufacturers and owners of refrigerated oceangoing containers in the United States would need certification for their equipment when the equipment is to be used for transport of perishable foodstuffs between countries in Europe where the receiving country is a contracting party to the Agreement.

Article 10 of the Agreement provides that a contracting party has the option to declare that the Agreement does not apply to carriage in its territories outside Europe. That Article was placed in the Agreement during its drafting, at the express request of the United States, for the following three reasons: (1) The Agreement was developed primarily for application to transport of perishable foodstuffs in Europe; (2) Industry standards in the United States were considered to be comparable to the standards in the Agreement, and (3) The United States had no need to apply the Agreement to vehicles coming into the United States from Canada or Mexico.

In depositing its instrument of accession with the United Nations, the United States exercised the option available in Article 10 by declaring that the Agreement does not apply to carriage in the United States or its territories.

Considerations Regarding Verification that Production of New Equipment Conforms With the Reference Equipment

The Agreement, in its Annex 1, Appendix 1, paragraphs 2 (a) and (b) reads as follows:

(a) New equipment of a specific type serially-produced may be approved by testing one unit of that type. If the unit tested fulfills the requirements prescribed for the class to which it is presumed to belong, the test report shall be regarded as a Type Approval Certificate * * *

(b) The competent authority shall take steps to verify that production of units is in conformity with the approved type * * *

In deciding how to treat the requirement concerning conformity of production with the reference equipment, the following factors were considered:

(1) In commercial practice, a buyer of equipment may obtain verification from the manufacturer that the manufacturer has complied with specifications

stipulated by the buyer, or the buyer may have an independent agency witness production of the equipment, or the buyer may use both procedures.

(2) The regulations of the United Kingdom, which is a contracting party to the Agreement, allow manufacturers to certify that production conforms to the approved type.

Taking into account the aforementioned factors, it was decided to have the manufacturer submit a statement that production conforms with the reference equipment, and this is reflected in the pertinent part of this rule. At the same time, it should be noted that the statement from the manufacturer required by this rule does not preclude the purchaser of the equipment, on its own, from engaging the services of an independent witnessing agency.

Considerations Regarding Inspection of Containers in Service

The Agreement, in its Annex 1, Appendix 2, paragraphs 29 and 49, requires that equipment in service at the end of the period of validity of its certificate shall either be tested in a testing station or be inspected by experts, in order to obtain renewal of the certificate.

As a practical matter, the United States would not be primarily concerned with testing and inspection of trucks, trailers, semitrailers, and railcars in service, since the United States will not apply the Agreement to transport equipment operating in the United States.

The primary concern of the United States is in connection with inspection of mechanically refrigerated intermodal containers operated by U.S. containership companies and U.S. container leasing firms which need certification of their containers for inter-country operations in Europe.

In deciding how to treat the requirement concerning inspection of containers in service, the following factors were considered:

(1) It is sometimes difficult to schedule a particular container into a particular seaport to coincide with availability of an independent inspector, outside the carrier's organization, to perform an inspection.

(2) Conceivably, a great number of mechanically refrigerated containers in service may require inspection in the coming years.

(3) The inspection requirements in the Agreement are not considered to be stringent. The check of the insulated body is essentially a visual inspection, and when operating the mechanical refrigerating appliance the ambient temperature need only be no lower than +15° C (+59° F), compared to testing of the equipment when new in an ambient of +30° C (+86° F). Also, in an inspection the applicance is turned off as soon as it reaches the required inside air temperature, without having to be operated for 12 hours with a 35 percent additional heat load as in the original test when the equipment was new.

(4) Operators of intermodal mechanically refrigerated containers normally check a container before each trip to ensure that the equipment is in good repair and that the refrigerating unit is operating properly. Also, operators normally perform periodic maintenance inspections of equipment similar to the inspection required by the Agreement.

(5) Independent inspection agencies are available which an owner of equipment might use in lieu of performance of inspection by the owner.

Taking those factors into account, it was decided to place responsibility for inspection on the owner, with the option that the actual performance of inspection may be by the owner or by an independent inspection agency, and this is reflected in the final rule.

Paperwork Reduction

The Office of Management and Budget (OMB) has approved the collection of information under this rule, in accordance with the Paperwork Reduction Act of 1980 (Title 44, Chapter 35, United States Code).

Review of this Proposed Rule

This proposed rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated as a "non-major" rule. Martin F. Fitzpatrick, Jr., Administrator, Office of Transportation, has certified that this proposed action will not have a significant impact on a substantial number of small entities.

Comments From the Public

This rule was first published as a proposed rule in the **Federal Register** on April 21, 1986, Volume 51, No. 76, pages 13519–13526, to allow for public comment. We received comments from the American Bureau of Shipping (ABS), Institute of International Container Lessors (IICL), Sea-Land Service (SLS), and Transamerica ICS (TICS). Following are those comments (in paraphrased form), followed by our (OT) response.

(a) ABS, IICL, SLS: The International Convention for Safe Containers (CSC) permits designation of independent agencies to approve containers, with respect to safety, produced in contracting and non-contracting countries. The American Bureau of Shipping (ABS), a U.S.-based classification society, is an example of such agency. The U.S. Coast Guard, which administers the CSC regulations, has designated the ABS as an agency to approve test facilities, to approve tests, and to issue certificates for containers made in other countries and in the United States. We request that the USDA similarly provide in the ATP rule for designation of approval authorities with respect to the thermal characteristics of containers.

OT: We can appreciate the fact that industry would prefer that the procedures in the ATP rule be essentially the same as those in the CSC regulations. At the same time, we have a basic responsibility to ensure that the ATP rule is in compliance and consistent with the ATP Agreement and the legislation and, where an interpretation is required, to take into account all relevant factors.

(b) ABS, SLS: The proposed rule provides for issuance of certificates by the Department of Agriculture, but there is no provision for delegation of that function to independent classification societies.

OT: Senate Report No. 97–406 of the Senate Committee on Agriculture, Nutrition, and Forestry, 97th Congress, 2nd Session, concerning the International Carriage of Perishable Foodstuffs Act, page 4, paragraph C, Purpose of Legislation, second paragraph, reads:

"The bill authorizes the Secretary to designate appropriate organizations to test or inspect equipment, but retains in the Secretary the sole authority to issue certificates of compliance. The committee believes that private organizations capable of performing the necessary inspection and testing are already in existence, and should be used by the Secretary to perform these functions. However, under the Agreement, certificates of compliance may only be issued by competent authority of the contracting nation. Thus, this authority is retained in the Department."

Accordingly, the USDA cannot delegate the authority to issue certificates, and a sentence to that effect has been added to § 3300.1 in the final rule.

(c) ABS: Reference page 1, Summary, first paragraph, second sentence, the statement would lead one to believe that owners who choose to purchase outside the United States can receive certification "as needed", whereas the container would have to be moved to

the United States at considerable expense.

OT: The words "as needed" were used in the context that application by an owner for certification is voluntary, based upon the owner's need for certification for operation in Europe. In any event, the sentence conveys the meaning intended without those two words and they have been deleted in the final rule.

(d) ABS, IICL, SLS, TICS: There is no provision for approval of testing facilities or approval of tests in countries which are not Contracting Parties to the ATP, as, for instance, in the Far East where most containers are now made. According to the proposed rule a non-contracting party, such as Japan, would have to send a reference container to the United States to be tested. The cost of about $8,000 per container order involved in such tests would be a severe penalty to the U.S. buyer of containers. The USDA should allow independent classification societies of approve testing facilities and monitor and witness tests on behalf of the USDA in non-contracting countries.

OT: The ATP in Annex 1, Appendix 1, paragraph 1, reads, "—checks for compliance with the standards prescribed in this annex shall be made at the testing stations designated or approved by the competent authority of the country in which the equipment is registered or recorded." When the subject of approval of testing stations has come up in meetings in Geneva, there has never been indication that any representative considered that a contracting party could approve a testing station outside its own territory.

In that connection, document TRANS/GE.11/R.76, published by the ECE, reads "The Group of Experts, at its thirty-sixth session, requested the secretariat to prepare a list of testing station officially recognized by the competent authorities of countries Contracting Parties to ATP, the test reports of which would consequently be valid for the issue of ATP certificates." The document then lists the name and address of approved testing stations as reported to the ECE by the following Contracting Parties: Austria, Czechoslovakia, Finland, France, Germany (East), Germany (West), Ireland, Italy, Netherlands, Norway, Poland, Spain, and the United Kingdom. Each station listed is in the country of a Contracting Party.

Senate Report 97–406, page 4, paragraph B, Need for Legislation, third paragraph, last line, reads, "—as soon as the United States becomes a signatory to the Agreement and the Department of Agriculture establishes the testing and certification program authorized in the bill, manufacturers, owners, and operators of U.S. transport equipment may voluntarily have their equipment tested and certified in the United States with the assurance that the U.S.-issued certificates will be recognized by all contracting nations."

If the United States were to approve a testing station in a non-contracting country and issue a certificate based on a test done in such station, the United States would run a risk that the certificate would not be considered valid by other contracting parties.

The estimated cost of $8,000 to test a container in the United States could cover as many as 1,000 units of serially-produced equipment, with the 1,000 divided among any number of buyers, which would amount to $8 per container. In this connection it can be noted that, in ATP, Annex 1, Appendix 1, paragraph 2 (a) and (c), the definition of serially-produced equipment is somewhat flexible. In the example of containers produced in Japan, arrangements might be made to have a container which passes a test in the United States be considered as one of the containers purchased, which would make it unnecessary to return it to Japan.

We have checked with the Transport Division of the Economic Commission for Europe in Geneva, under which the ATP Agreement was developed, and were advised that Japan and other members of the United Nations which have an interest in the ATP may participate in related meetings of the ECE and may become contracting parties to the Agreement.

Article 2 of the Agreement provides that, "Each Contracting Party shall recognize the validity of certificates of compliance issued—by the competent authority of another Contracting Party." If Japan were to become signatory to the Agreement it could test and certify equipment made there, and the United States could then issue certificates based on Japanese certificates.

Taking into account all of the foregoing, we conclude that the United States should not become involved in approval of testing stations or approval of tests in foreign countries. Accordingly, the final rule retains the provision that reference equipment manufactured in non-contracting countries shall be tested in the United States or in another contracting country.

(e) IICL, TICS: There should be a provision for issuance of a U.S. ATP certificate based upon a certificate issued by another contracting country.

OT: We agree. This was intended in the proposed rule but not clearly set forth. This point is covered in the final rule in §§ 3300.58(d) and 3300.76(d).

(f) IICL, TICS: Reference is made to the proposed rule, § 3300.67(h)(1), (i) (1), and (2), which stipulates that test reports for reference equipment, reference mechanical refrigerating appliances, and reference insulated bodies shall expire at the end of 36 months or manufacture of 1,000 units, whichever occurs first. No rational is given for the limit of 1,000 units, and that limitation should be deleted.

(OT): Two provisions in the ATP prescribe the extent to which a test report of a unit of reference equipment can apply to serially-produced equipment. Annex 1, Appendix 1, paragraph (2)a. reads, "This certificate (i.e., test report) shall expire at the end of a period of three years." Paragraph (d) following that paragraph (a) reads, "If, in the course of the three-year period, the production series exceeds 100 units, the competent authority shall determine the precentage of units to be tested."

In 1983 we wrote to the ATP authority in each of six countries in Europe to ask how many units they test when production exceeds 100 units over a period of three years. Their replies, paraphrased, follow:

Denmark—We leave it to the judgment of the authorities. Equipment with a K-coefficient well below the limits of 0.4 or 0.7 $W/m^2 \cdot °C$ in the initial test does not need to be checked as thoroughly as those near the limits. With this policy some retest is done after production of 100 units, and some after 250–300 units.

France—The test report of the prototype of a series can be used for 3 years for production of up to 100 units. If production exceeds 100 units during a 3-year period the authorities determine how many units will be covered by the initial prototype test, depending upon type of equipment and size and homogeneity of the series. For land vehicles (trucks, trailers, semi-trailers, and railcars) the number of units in any one series is not very high, and in such cases it is logical to check at least one prototype for each lot of 100 built. For containers, maritime and land (20' and 40') used for ocean trips of less than 150 km, we have a different problem. Taking into account the homogeneity factor, a test of one prototype can be good for production of 1,000 units in a 3-year period.

Germany (West)—Only a few manufacturers exceed 100 units in a 3-year period. A new test is required after production of 100 units. However, in the case of containers we allow production

of a considerably higher number before another test is required. There is no rigid regulation here, and we determine it on a case-by-case basis. We carry out a random check of the production.

Norway—The biggest producer manufactures a maximum of 40 units per year, and we have not found it necessary to carry out a new test before the end of the 3-year period, even if they should produce more than 100 units covered by the type approval certificate. Providing there is no difference in the body, and the inside surface does not vary more than ±20%, we do not differentiate between type of equipment (railcar, truck, etc.).

Sweden—No manufacturer produces more than 100 units in 3 years, but we believe at least 1 percent of units exceeding the first 100 should be tested.

United Kingdom—We test one unit out of the initial 100. Thereafter, the refrigeration part of the test is not conducted, but only the K-coefficient test of the body. Depending upon the manufacturer's quality control procedures and the K-coefficient of the reference unit, at least 1 out of 50 bodies are tested for K-coefficient. This procedure is used for the 3-year life of the reference test (ATP type authorization).

In the aforementioned replies from 6 countries, the highest number of units covered by a reference test was 1,000 containers. In the absence of definite guidelines in the ATP, and pending the addition of such, we believe that the U.S. ATP rule should not exceed the highest number used by other contracting countries. Accordingly, the final rule in § 3300.58(f), (g) and (h) stipulates that 1,000 is the maximum number of units to be covered by a reference test.

(g) ABS, IICL: The ATP is directed toward equipment and technical requirements, and contains no reference to "domestic" or "foreign" and therefore the ATP rule should make no distinction between "domestic owners" and "foreign owners."

OT: The U.S. ratified the Agreement and passed legislation mainly for the benefit of U.S. manufacturers and owners and operators of the special equipment covered by the Agreement, for operation of the equipment in Europe. The U.S. Government does not mandate that all such equipment be certified. Rather, it is voluntary on the part of an organization with respect to its application to the USDA for certification, based on its need and desire to obtain certification.

Because, in signing the Agreement, the U.S. used the option in Article 10 to declare that the Agreement does not apply to carriage in the United States or its territories, equipment does not have to be certified to operate in the United States.

As indicated in § 3300.58(b) of the final rule, the U.S. will certify for a foreign owner only new equipment manufactured in the United States. For such equipment the owner would have to submit the U.S. certificate to the authority in the country in which the equipment is to be registered, so that country can issue its own certificate. The latter certificate is necessary because, when a carrier crosses a border in Europe, the border authority requires a certificate or certification plate from the country of registry, rather than from the country of manufacture. When the equipment is to be recertified after 6 years in service, it is the responsibility of the country of registry to renew the certificate.

There is no compelling reason for the U.S. to certify equipment for a foreign owner, except in the case where a foreign owner is buying new equipment from a manufacturer in the United States. The ATP rule necessarily must contain definitions of "domestic owner" and "foreign owner", and specify the conditions under which each may obtain certification.

(h) ABS: Reference is made to the proposed rule, page 13520, first column, entitled Considerations Regarding Verification that Production of New Equipment Conforms With the Reference Equipment. Regarding paragraph (b) and the three subparagraphs thereunder:

(1) The normal procedure is for the purchaser of equipment to have a particular witnessing agency verify that production of equipment was done according to specifications.

(2) There is no need to justify the cost of an outside agency to verify production, as such agencies are in place and being used by purchasers of equipment.

(3) The United Kingdom has given accreditation to its only classification society, Lloyds Register of Shipping, to approve thermal containers on its behalf.

OT: Regarding subparagraph (1), we have checked further and find that in commercial practice a purchaser of equipment may obtain verification regarding production from the manufacturer or through an independent witnessing agency, or both. We have revised subparagraph (1) in the final rule accordingly. Also, a sentence has been added to the last paragraph, following new subparagraph (2), to note the prerogative of the purchaser to engage the services of a witnessing agency, separate from the statement which the manufacturer must submit to the USDA according to the rule.

We agree on the comment concerning subparagraph (2), and it has been deleted from the final rule.

Regarding subparagraph (3), the statement in the rule and the above comment concerning Lloyds are consistent. According to the United Kingdom regulations, 1979, No. 415, Part VI, "A certificate of compliance shall not be issued in respect of transport equipment unless—the equipment is certified by its manufacturer as conforming to a type approved—." Document TRANS/GE.11/R.76, 6 July 1982, issued by the Economic Commission for Europe, states that Lloyds Register Industrial Services has been approved by the UK Government to issue certificates of compliance for containers.

(i) ABS: Reference is made to the proposed rule, page 13520, second column, last paragraph, under Considerations Regarding Inspection of Containers in Service. The owner should have the option of using an independent inspection agency to inspect equipment in service.

OT: We agree. A new paragraph (5) has been added in the final rule under the referenced provision and the last paragraph has been revised to reflect the option of the owner to perform its own inspection or to have it done by an independent inspection agency. Also, § 3300.76, (a)(2)(ii) (A) and (B) in the final rule contain that option.

(j) ABS, IICL, TICS: Regarding the 30-day advance notice which a testing station must give to the ATP manager, it is not feasable to ensure 30 days beforehand that a container will be at a testing station on a given date, particularly in the case of containers in service.

OT: We agree. The advance notice requirement has been changed to "as soon as practicable" in § 3300.19(j) and § 3300.43(g) of the final rule.

(k) ABS: Several definitions under § 3300.4, in the proposed rule, are not necessary.

OT: We agree. Six definitions have been deleted in the final rule.

(l)ABS, IICL: The definition of "owner" should include the lessee or bailee of equipment.

OT: We have expanded the definition of "domestic owner" in § 3300.4 of the final rule to include a lessee or bailee.

(m) ABS: The provisions in § 3300.10(b) and § 3300.13 of the proposed rule concerning measurement of the K-coefficient with or without the

appliance installed in the body are repetitive.

OT: We agree. We believe that those two provisions should not be in the rule, and they have been deleted.

(n) ABS: The provision in § 3300.10(c) of the proposed rule concerning the interpretation that the mean wall temperature should be between +19°C (+66°F) and +21°C (+70°F) should be deleted. Unless the definition is going to be interpreted by other Contracting Parties in precisely the same manner it should not apply to testing of containers under the ATP rule. Definitions for technical requirements belong in the ATP Agreement and not in the U.S. rule.

OT: A variation in mean wall temperature (mwt) affects test results when measuring the K-coefficient of a container which has polyurethane insulation. A higher mwt gives a higher K-coefficient, and vice versa. For consistency in measurement and comparability of test results among testing stations in the U.S., it is necessary to set practical limits on the mwt. We agree that the provision should be in the Agreement, but until it is we believe the ATP rule should address the point.

(o) ABS: The provision in § 3300.13(a) of the proposed rule, that only the internal heating method should be used, should be deleted.

OT: The ATP allows use of either the internal cooling method or the internal heating method. However, it is generally agreed that the internal heating method is more accurate than the internal cooling method. In this connection, it can be noted that all testing stations in Europe use the internal heating method. In order to have comparability of test results among testing stations in the United States, and among U.S. and European testing stations, we believe that the rule should specify that only the internal heating method shall be used.

(p) ABS: Reference is made to § 3300.19(g) of the proposed rule which requires from the testing station "A statement that the station will be open to public use, that is, to manufacturers and owners of equipment which may apply to have equipment tested". Is this appropriate? Can't a manufacturer have its facility approved without being forced to use it for its competition?

OT: If we did not have that provision, and if there was not a station available which was independent of manufacturers, there would be no place to which an owner could go to have equipment in service tested. We anticipate that at least one independent station will be available, and we can envision that a manufacturer that does not have a station of its own might use an independent station rather than send its container to another manufacturer for testing.

(q) (ABS: Reference § 3300.19(k), the requirement that the testing station send a copy of each test report to the ATP manager "within 30 days after completion of the test" is unrealistic and serves no purpose.

OT: It is not unusual to impose a time limit when a document is to be submitted. A test station can complete a test report within a few days after a test, and the 30-day stipulation should cause no hardship.

(r) ABS: All references to "testing station" and "testing laboratory" should be changed to "testing facility".

OT: "Testing station" is the term used in the Agreement for the facility used to test the complete unit of equipment. The Agreement does not have a term for the calorimeter-type facility for testing a mechanical refrigerating appliance, and we have assigned the term "testing laboratory" to such facility to differentiate it from a testing station.

(s) ABS: Reference § 3300.67(i)(3)(ii), the formulas listed should be deleted as they are a repeat of the formulas in the ATP Agreement.

OT: The Agreement does not set forth the steps of calculation to show that the mechanical refrigerating appliance has a capacity of 1.75 times the total heat transfer rate of the body. These steps, and the formulas involved, need to be in the application for a certificate so that the applicant is required to perform the necessary calculations.

(t) ABS: The responsibilities of equipment manufacturers in § 3300.91 can be transferred to § 3300.61.

OT: We agree. That provision has been transferred to § 3300.58(l) in the final rule.

(u) ABS: The responsibilities of owners in § 3300.94 can be transferred to § 3300.61 and § 3300.79.

OT: We agree. That provision has been transferred to § 3300.58(m) and § 3300.76(e) in the final rule.

(v) ABS: Reference § 3300.70, first paragraph, first sentence, the provision should allow for application for a certificate for new equipment not only from an officer in the owner's organization, but also from an officer in the organization of the equipment manufacturer acting on behalf of the owner.

OT: In the case of equipment manufactured in the United States, the provision has been changed to allow for the manufacturer to apply for certification on behalf of the owner. See § 3300.64, first paragraph, of final rule.

(w) ABS: Referring to equipment in service, an inspection of each unit of equipment should be required when equipment is transferred from one owner to another.

OT: Agree. Such a requirement for inspection has been added to § 3300.76 (c) and (d) in the final rule.

(x) ABS: A number of other requested changes in particular paragraphs are shown in a marked-up copy of the proposed rule.

OT: Those other requested changes are related to, and hinge upon, previous requests for delegation of authority to classification agencies to issue certificates, approval of testing stations in non-contracting countries, deletion of distinction between domestic and foreign owners, and others, with which we did not concur. Consequently, those other requested changes are not applicable.

(y) ABS: We presume that the amended rule will be published again as "proposed" for interested parties to make final comments.

OT: We believe that industry has reviewed the rule thoroughly, and that the rule is now a better document as a result of comments submitted by industry. Considering that there probably would not be much gain in publishing the rule again for comment, and in view of the fact that the rule has been under development for some time and needs to be put into effect to achieve the goals of the legislation, we believe it should now be published as a final rule for the benefit of all concerned.

Other Changes

In addition to changes made in the final rule as a result of the aforementioned industry comments, we have added to § 3300.64 a paragraph (j)(1) to require the manufacturer to check the operation of each mechanical refrigerating applicance after installation in the body. Also, in the final rule we have made a number of editorial changes and rearranged some of the provisions for purpose of improving the text.

List of Subjects in 7 CFR Part 3300

Foods, Laboratories, Reporting and record keeping requirements, Transportation.

Accordingly, Chapter XXXIII, consisting of Part 3300, is added to Title 7 to read as follows:

CHAPTER XXXIII—OFFICE OF TRANSPORTATION, DEPARTMENT OF AGRICULTURE

PART 3300—AGREEMENT ON THE INTERNATIONAL CARRIAGE OF PERISHABLE FOODSTUFFS AND ON THE SPECIAL EQUIPMENT TO BE USED FOR SUCH CARRIAGE (ATP); INSPECTION, TESTING, AND CERTIFICATION OF SPECIAL EQUIPMENT

Subpart A—Introduction

Sec.

Subpart B—Procedures for Testing of Equipment

Subpart C—Approval of Testing Stations

Subpart D—Procedures for Separate Testing of Mechanical Refrigerating Appliances

Subpart E—Approval of Testing Laboratories

Subpart F—Certification of New Equipment

Subpart G—Certification of Equipment in Service

Subpart H—Other Provisions

Authority: Sec. 4, Pub. L. 97–325, International Carriage of Perishable Foodstuffs Act (7 U.S.C. 4403).

Subpart A—Introduction

§ 3300.1 Scope of authority and purpose.

The International Carriage of Perishable Foodstuffs Act assigns to the Secretary of Agriculture the responsibility for implementation of the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for Such Carriage (ATP). The purpose of this rule is to establish procedures for the inspection, testing, and certification of insulated, refrigerated, mechanically refrigerated, and heated transport equipment in accordance with the Act and the standards specified in the Agreement. In the process, the intent is to utilize existing industry organizations and facilities for testing and inspection of equipment. The Secretary is the sole authority to issue certificates of compliance.

§ 3300.4 Definitions.

"Administrator" means the Administrator, Office of Transportation, U.S. Department of Agriculture, whose address is: 1405 Auditors Building, 201 14th Street, SW., Washington, DC 20250.

"ATP" means the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for Such Carriage (ATP), and the annexes and appendices thereto, done at Geneva, September 1, 1970, under the auspices of the Economic Commission for Europe, and any subsequent amendments thereto.[1]

"ATP Manager" means the person designated by the Administrator to manage the program established by this rule, whose address is: ATP Manager, Office of Transportation, U.S Department of Agriculture, 1405 Auditors Building, 201 14th Street, SW., Washington, DC 20250.

"Contracting party" means a country which is signatory to the ATP.

"Domestic Owner" means an organization incorporated or chartered under the laws of, and with principal office in, the United States, and to which one of the following applies:

(a) The organization owns and operates the equipment directly.

(b) The organization owns and operates the equipment through a wholly owned subsidiary in a foreign country.

(c) The organization is a lessee or bailee of the equipment, and a written lease or bailment provides that the organization is responsible for any inspection, testing, and certification of the equipment with respect to the ATP rule.

"Equipment" means the special transport equipment that meets the definitions and standards set forth in ATP, Annex 1, including, but not limited to, railcars, trucks, trailers, semitrailers, and intermodal freight containers that have an insulated body only, or an insulated body equipped with a refrigerating, mechanically refrigerating, or heating appliance.

"Equipment manufacturer" means an organization which producers or assembles the complete unit of equipment, that is, the insulated body with the thermal appliance installed.

"Foreign owner" means an organization registered under the laws of, or with principal office in, a country outside the United States, and which owns or operates the equipment.

"Foreign-ATP certificate" means a certificate issued by a foreign country which is a contracting party to the ATP, attesting that the equipment listed in the certificate complies with pertinent standards in the ATP.

"Identical mechanical refrigerating appliance" means an appliance which is of the same model number and design as the reference mechanical refrigerating appliance.

"Insulated body" means the six-sided structural component of equipment, consisting of insulated doors, sidewalls, roof, floor, and endwall, inside which perishable foodstuffs are carried.

"International carriage" means transportation of perishable foodstuffs if such foodstuffs are loaded in equipment or the equipment containing them is loaded onto a rail or road vehicle, in the territory of any country and such foodstuffs are, or the equipment containing them is, unloaded in the territory of another country that is a contracting party, where such transportation is by:

(a) Rail,

(b) Road,

(c) Any combination of rail and road, or

(d) Any sea crossing of less than one hundred and fifty kilometers, if preceded

[1] A copy of the agreement can be obtained by request to the ATP Manager, Office of Transportation, U.S. Department of Agriculture, 1405 Auditors Building, 201 14th Street, SW., Washington, DC 20250.

or followed by one or more land journeys as referred to in clauses (a), (b), and (c) of this definition, and the perishable foodstuffs are shipped in the same equipment used for such land journeys without transloading of such foodstuffs.

In the case of any transportation that involves one or more sea crossings other than as specified in clause (d) of this definition, each land journey shall be considered separately.

"New equipment" means equipment produced or assembled on or after the effective date of this rule.

"Perishable foodstuffs" means the quick deep-frozen and frozen food products listed in Annex 2, and the chilled food products listed in Annex 3 to the ATP.

"Reference equipment" means a unit of equipment which has passed a test in an approved testing station, and can thereby serve as a basis for certification of related serially-produced equipment.

"Reference insulated body" means an insulated body which has passed a test in an approved testing station for measurement of the K-coefficient of the body, and can thereby serve as the basis for approval of serially-produced bodies in the case in which the body and the mechanical refrigerating appliance of the equipment are tested separately.

"Reference mechanical refrigerating appliance" means an appliance which has passed a test in an approved testing laboratory, and can thereby serve as the basis for approval of identical mechanical refrigerating appliances in the case in which the appliance and the insulated body of the equipment are tested separately.

"Serially-produced bodies" means insulated bodies which meet the definition in ATP, Annex 1 Appendix 1, paragraph 2(c)(i).

"Serially-produced equipment" means equipment of a specific type (container, semi-trailer, trailer, truck, or container), which meets the definition in ATP, Annex 1, Appendix 1, paragraphs 2(c), (i), (ii), (iii), and (iv).

"Thermal appliance" means the refrigerating, mechanical refrigerating, or heating appliance which is installed in the insulated body of the equipment.

"United States" means the fifty States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands of the United States, the Commonwealth of the Northern Mariana Islands, and any other territory or possession of the United States.

"U.S. ATP certificate" means a certificate issued by the U.S. Department of Agriculture, attesting that the equipment listed in the certificate complies with pertinent standards in the ATP.

"U.S. ATP testing laboratory" means a facility in the United States which has been approved by the Administrator to conduct tests of mechanical refrigerating appliances.

"U.S. ATP testing station" means a facility in the United States which has been approved by the Administrator to conduct tests of equipment.

Subpart B—Procedures for Testing of Equipment

§ 3300.7 General.

Testing of equipment according to the ATP is basically done in two phases:

(a) Measurement of the insulating capacity, that is, the K-coefficient, of the insulated body.

(b) Determination of the efficiency of the thermal appliance as installed in the insulated body. In the case of mechanically refrigerated equipment, the mechanical refrigerating appliance may be tested separate from the body.

§ 3300.10 Measurement of the K-coefficient of an insulated body.

The K-coefficient shall be measured according to the procedures in ATP, Annex 1, Appendix 2, paragraphs 1–28, and the following shall apply:

(a) The internal heating method shall be used.

(b) In ATP, Annex 1, Appendix 2, paragraph 8, last line, "about +20°C" for the mean temperature of the walls of the body shall be interpreted to mean between +19°C (+66°F) and 21°C (+70°F).

(c) A report of each test shall be completed on a form corresponding to the pertinent test report model prescribed in ATP, Annex 1, Appendix 2. Report forms may be obtained by a request to the ATP manager.

§ 3300.13 Determination of the efficiency of the thermal appliances as installed in the insulated body.

In determining the efficiency of a thermal appliance with respect to maintaining a prescribed temperature inside the body, the procedures in ATP, Annex 1, Appendix 2, paragraphs 31–40 and 43–47 shall be used. A report of each test shall be completed on a form corresponding to the pertinent test report model prescribed in ATP, Annex 1, Appendix 2. Report forms may be obtained by a request to the ATP manager.

Subpart C—Approval of Testing Stations

§ 3300.16 General.

Any public or private organization incorporated or chartered under the laws of, and with principal office in, the United States may apply to have one or more of its facilities in the United States designated as a U.S. ATP testing station.

§ 3300.19 Application for approval.

An application by an officer of the organization shall be submitted to the Administrator for each facility for which approval is sought. Copies of the Form, Application for Approval as a U.S. ATP Testing Station, may be obtained by a request to the ATP manager. The following information must be supplied in the application:

(a) A statement that the organization is incorporated or chartered under the laws of, and that it has its principal office in, the United States, including the name, address, and telephone number of the principal office.

(b) The address and telephone number of the testing station, and name and title of person in charge of the station.

(c) A summary of experience at the facility which would indicate the capability to conduct tests of equipment according to Supart B of this rule.

(d) A general description of the station, including drawings on letter size (8 ½ × 11 inches) paper to show the floor plan and cross-sections of the test chamber, basic dimensions, location of heat exchangers and instruments, and any other pertinent information.

(e) An indication of which of the following types of equipment, as defined in ATP, Annex 1, that the station is capable of testing: intermodal freight containers, semi-trailers, trailers, railcars, and trucks.

(f) A statement that the ATP manager or other representative of the Administrator may, before a decision is made concerning the application, observe a test at the station of a Class "C" mechanically refrigerated container or semi-trailer, with Class "C" being defined as in ATP, Annex 1, paragraph 3.

(g) A statement that the station will be open to public use, that is, to manufacturers and owners of equipment which may apply to have equipment tested.

(h) A statement that the fees to be charged by the organization for testing will be reasonable with respect to costs involved, and that such fees will be payable directly to the organization by those who seek testing of their equipment.

(i) A statement that the station will maintain records of basic data developed in each test conducted under this rule, such records to be available for review by the ATP manager or other representative of the Administrator upon request. The record for each test shall be maintained for a period of three years.

(j) A statement that the organization will advise the ATP manager as soon as practicable of its intent to conduct a test under this rule and that it will, as soon as possible, advise when a firm test date has been set so that the ATP manager or other representative of the Administrator may observe the test.

(k) A statement that the organization will send to the ATP manager a copy of each test report for equipment tested at the station according to this rule, within 30 days after completion of the test.

(l) A statement that, should any significant change occur in the facility with respect to structure or test equipment as a result of redesign or other cause during the period of approval, the organization will so advise the ATP manager within 30 days after such change.

(m) Any other pertinent information.

§ 3300.22 Response to application for approval.

The Administrator will, within 30 days of receipt of the application and any relevant information required, advise the applicant whether or not the facility is approved as a testing station. Approval is for a 5-year period.

§ 3300.25 Application for renewal of approval.

If an organization wishes to have an approval renewed at the end of a 5-year period, it shall submit a request for renewal to the Administrator 90 days before expiration of the existing approval. The request for renewal shall contain the same type of information as required in the original application, that is, the information called for in § 3300.19 of Subpart C.

§ 3300.28 Response to application for renewal of approval.

The Administrator will, within 30 days of receipt of application and any relevant information required, advise the applicant whether or not approval is renewed. A renewal is good for 5 years.

§ 3300.31 Termination of approval.

An approved testing station may at any time withdraw as an approved testing station by written notice to the Administrator. Similarly, the Administrator may suspend or terminate for cause the approved status of a testing station by written notice to the organization, setting forth the reasons for such action. Examples of causes for suspension or termination of approval of a testing station would be a change in equipment or operations at the station which would render the station incapable of performing tests according to the standards in the ATP, or noncompliance of the station with pertinent portions of this rule.

Subpart D—Procedures for Separate Testing of Mechanical Refrigerating Appliances

§ 3300.34 General.

ATP, Annex 1, Appendix 2, paragraph 41, provides that approval of mechanically refrigerated equipment may be done on the basis of separate testing of the mechanical refrigerating appliance.

§ 3300.37 Testing of a mechanical refrigerating appliance.

For separate testing of a mechanical refrigerating appliance, the following shall pertain:

(a) The calibrated-box method shall be used, as set forth in ARI Standard 1110, Standard for Mechanical Refrigeration Units, of the Air-Conditioning and Refrigeration Institute.

(b) The appliance shall be rated according to the class, or classes, of service for which the appliance is intended, with classes being defined as in ATP, Annex 1, paragraph 3.

(c) A report of each test shall be completed on a form corresponding to the pertinent test report model prescribed in ATP, Annex 1, Appendix 2. Report forms may be obtained by a request to the ATP manager.

Subpart E—Approval of Testing Laboratories

§ 3300.40 General.

Any public or private organization incorporated or chartered under the laws of, and with principal office in, the United States may apply to have one or more of its facilities in the United States designated as a U.S. ATP testing laboratory.

§ 3300.43 Application for approval.

An application by an officer of the organization shall be submitted to the Administrator for each facility for which approval is sought. Copies of the Form, Application for Approval as a U.S. ATP Testing Laboratory, may be obtained by a request to the ATP manager. The following information must be supplied in the application:

(a) A statement that the organization is incorporated or chartered under the laws of, and that it has its principal office in, the United States, including the address and telephone number of the principal office.

(b) The address and telephone number of the testing laboratory, and name and title of person in charge of the laboratory.

(c) A summary of the experience at the facility which would indicate a capability to conduct tests of mechanical refrigerating appliances according to Subpart D of this rule.

(d) A general description of the laboratory, including drawings on letter size (8½ x 11 inches) paper to show the floor plan and cross-section of the test chamber, basic dimensions, location of heat exchangers and instruments, and any other pertinent information.

(e) A statement that the ATP manager or other representative of the Administrator may, before a decision is made concerning the application, observe a test at the laboratory of a mechanical refrigerating appliance for a Class "C" mechanically refrigerated container or trailer, with Class "C" as defined in ATP, Annex 1, paragraph 3.

(f) A statement that the laboratory will maintain records of basic data developed in each test conducted under this rule, such records to be available for review by the ATP manager or other representative of the Administrator, upon request. The record for each test shall be maintained for a period of three years.

(g) A statement that the organization will advise the ATP manager as soon as practicable of its intent to conduct a test under this rule and that it will, as soon as possible, advise when a firm test has been set so that the ATP manager or other representative of the Administrator may observe the test.

(h) A statement that the organization will send to the ATP manager a copy of each test report for an appliance tested at the laboratory according to this rule, within 30 days after completion of the test.

(i) A statement that, should any significant change occur in the facility with respect to structure or test equipment as a result of redesign or other cause during the period of approval, the organization will so advise the ATP manager within 30 days after such change.

(j) Any other pertinent information.

§ 3300.46 Response to application for approval.

The Administrator will, within 30 days of receipt of an application and any relevant information required, advise the applicant whether or not the facility is approved as a testing

laboratory. Approval is for a 5-year period from date of approval.

§ 3300.49 Application for renewal of approval.

If an organization wishes to have an approval renewed at the end of a 5-year period, it shall submit a request for renewal to the Administrator 90 days before expiration of the existing approval. The request for renewal shall contain the same type of information as required in the original application, that is, the information called for in § 3300.43 of Subpart E.

§ 3300.52 Response to application for renewal of approval.

The Administrator will, within 30 days of receipt of application and any relevant information required, advise the applicant whether or not approval is renewed. A renewal extends the period of approval for 5 years.

§ 3300.55 Termination of approval.

An approved testing laboratory may at any time withdraw as an approved testing laboratory by written notice to the Administrator. Similarly, the Administrator may suspend or terminate for cause the approved status of a testing laboratory by written notice to the organization, setting forth the reasons for such action. Examples of causes for suspension or termination of approval would be a change in equipment or operations at the laboratory which would render it incapable of performing tests according to the standards in the ATP, or noncompliance of the laboratory with pertinent portions of this rule.

Subpart F—Certification of New Equipment

§ 3300.58 General.

The following shall apply for certification of new equipment:

(a) Domestic owners are eligible to receive U.S. ATP certificates for equipment produced or assembled in the United States or in a foreign country.

(b) Foreign owners are eligible to receive U.S. ATP certificates only for equipment produced or assembled in the United States.

(c) For equipment manufactured (i.e., produced or assembled) in the United States:

(1) When the complete unit of equipment is tested, the test shall be performed in a U.S. ATP testing station.

(2) When the mechanical refrigerating appliance and the insulated body are tested separately, such tests shall be performed in approved testing facilities in the United States or in test facilities located in, and approved by, a foreign country which is a Contracting Party.

(d) For equipment manufactured in a foreign country which is a Contracting Party, a domestic owner may receive a U.S. ATP certificate in exchange for the Foreign-ATP certificate issued by the country of manufacture.

(e) For equipment manufactured in a foreign country which is not a Contracting Party, tests shall be performed in approved testing facilities in the United States or in facilities located in and approved by a foreign country which is a Contracting Party.

(f) In accordance with ATP, Annex 1, Appendix 1, paragraphs 2(a) and (d), the validity of a test report for a reference equipment shall expire at the end of a period of 3 years or at the end of the manufacture of 1,000 units of serially-produced equipment, whichever occurs first.

(g) The validity of a test report for a reference mechanical refrigerating appliance shall expire at the end of a period of three years, or at the end of the manufacture of 1,000 identical mechanical refrigerating appliances, whichever occurs first.

(h) The validity of a test report for a reference insulated body shall expire at the end of a period of three years, or at the end of the manufacture of 1,000 serially-produced bodies, whichever occurs first.

(i) Serially-produced equipment shall be produced or assembled by the same manufacturer and at the same manufacturing plant as the reference equipment.

(j) Identical mechanical refrigerating appliances shall be manufactured by the same manufacturer and at the same manufacturing plant as the reference mechanical refrigerating appliance.

(k) Serially-produced bodies shall be manufactured by the same manufacturer and at the same manufacturing plant as the reference insulated body.

(l) Equipment manufacturers shall notify the ATP manager 30 days before start of manufacture so that the ATP manager or other representative of the Administrator may observe the manufacturing operation.

(m) Owners who receive a U.S. ATP certificate have the responsibility to manitain the equipment in good repair and operating condition with the understanding that the certificate is valid only so long as:

(1) The insulated body and the thermal appliance are maintained in good condition;

(2) No material alteration is made to the thermal appliance which decreases its refrigerating capacity, and;

(3) If the thermal appliance is replaced, it is replaced by an appliance of equal or greater refrigerating capacity.

§ 3300.61 Testing and verification requirements.

In accordance with ATP, Annex 1, Appendix 1, paragraphs 1, 1(a), 2(a), 2(b), 2(c) and 3, and Appendix 2, paragraph 41, certification of new equipment is based upon the following:

(a) For a unit of equipment, a test of the equipment in an approved testing station.

(b) For serially-produced equipment:

(1) A test of one unit of equipment in an approved testing station, such unit to serve as the reference equipment.

(2) Verification that production of other units of equipment is in conformity with the reference equipment.

(c) For mechanically refrigerated equipment, certification may be based upon a separate test of the mechanical refrigerating appliance and a separate test of the insulated body.

§ 3300.64 Application for Certificate for new equipment produced or assembled in the United States or in a foreign country which is not a contracting party to the ATP.

Application for certification shall be submitted to the ATP manager by an officer in the organization of the owner of the equipment. In the case of equipment manufactured in the United States, application may be made by an officer in the organization of the equipment manufacturer, acting on behalf of the owner. Copies of the Form, Application for U.S. ATP Certificate for New Equipment Produced or Assembled in the United States or in a Foreign Country Which is not a Contracting Party to the ATP, may be obtained by a request to the ATP manager. The following information must be supplied in the application:

(a) A statement whether the owner is a domestic owner or a foreign owner, with the name, address and telephone number of its principal office, and the name and title of person to contact.

(b) If the operator of the equipment is different from the owner, the name and address of the operator.

(c) Type of equipment (intermodal freight container, semi-trailer, trailer, railcar, or truck).

(d) Total number of units of equipment.

(e) Definition and distinguishing mark of the equipment for which certification is sought, referring to ATP, Annex 1, paragraph 3 and Appendix 4.

(f) Name, address, and telephone number of the principal office of the

equipment manufacturer, and name and title of the person to contact.

(g) Name and address of the plant at which the equipment was manufactured.

(h) In the case of a unit of equipment (i.e., the insulated body with its mechanical refrigerating appliance installed) that has been tested to serve as the reference equipment for serially-produced equipment:

(1) The original or certified true copy of the test report for the reference equipment.

(2) For the serially-produced equipment:

(i) The manufacturer's make and model number for the equipment, including a brief description of the equipment and enclosure of any brochure on the equipment which might be available.

(ii) The basis upon which the equipment meets the definition of serially-produced equipment, with respect to the reference equipment.

(iii) A statement that the equipment was manufactured at the same plant at which the reference equipment was manufactured.

(iv) A statement that production of the equipment was in conformity with the reference equipment.

(i) In the case where the mechanical refrigerating appliance and the insulated body have been tested separately:

(1) For the reference mechanical refrigerating appliance:

(i) The original or certified true copy of the test report.

(ii) From the test report, the effective refrigerating capacity, W, in watts, of the appliance at an outside temperature of +30°C and the inside temperature (*see* ATP, Annex 1, paragraph 3 and Appendix 4) for the class of equipment for which certification is sought. "W" must be equal to, or greater than, the increased heat transfer rate, H_t, for the reference insulated body. See paragraph (3)(iii) below.

(2) For the identical mechanical refrigerating appliances:

(i) Name and address of the plant at which the identical appliances and reference appliance were manufactured.

(ii) The manufacturer's make, model number, and a brief description of the appliances with enclosure of any brochure on the appliances which might be available.

(iii) A statement that the appliances meet the definition of identical mechanical refrigerating appliances.

(3) For the reference insulated body:

(i) The original or certified true copy of the test report.

(ii) The total heat transfer rate of the body, $H_t = S \times K \times \Delta T$, in watts, where: "S" is the mean surface area of the body, from the test report; "K" is the heat transfer coefficient of the body, from the test report; and, "ΔT" is the difference in degrees Kelvin between an outside temperature of +30 °C and the inside temperature for the class of equipment for which certification is sought.

(iii) The increased beat transfer rate, H_t, obtained by multiplying the total heat transfer rate H_t, by the factor of 1.75.

(4) For the serially-produced insulated bodies:

(i) Name and address of the plant at which the serially-produced bodies and reference body were manufactured.

(ii) The manufacturer's make, model number, and a brief description of the bodies, with any brochure on the bodies which might be available.

(iii) The basis upon which the bodies meet the definition of serially-produced bodies, with respect to the reference insulated body.

(iv) A statement that production of the bodies was in conformity with the reference insulated body.

(j) Information on the equipment after manufacture:

(1) A statement that each mechanical refrigerating appliance, after it was installed in the body, was operated and thoroughly checked and that each appliance functioned properly.

(2) A statement that each body and each appliance has affixed to it a manufacturer's plate or other means of identification which shows the items of information required by ATP, Annex 1, paragraph 6.

(3) A statement that each unit of equipment, before it is put into service, will have affixed to it a certification plate and distinguishing mark as specified in ATP, Annex 1, Appendix 1, paragraphs 4 and 5, and Appendixes 3 and 4.

(4) A list showing, for each unit of equipment, the serial number of the body and the corresponding owner's equipment identification number.

§ 3300.67 Application for certificate for new equipment produced or assembled in a foreign country which is a contracting party to the ATP.

An application for certification of equipment shall be submitted to the ATP manager by an officer in the organization of the owner of the equipment. Copies of the Form, Application for U.S. ATP Certificate for New Equipment Produced or Assembled in a Foreign Country Which is a Contracting Party, may be obtained by a request to the ATP manager. The following information must be submitted in the application:

(a) A statement that the owner is a domestic owner, with the name, address and telephone number of its principal office, and the name and title of the person to contact.

(b) If the operator of the equipment is different from the owner, the name and address of the operator.

(c) The type of equipment (intermodal freight container, trailer, semi-trailer, railcar, or truck.)

(d) Total number of units of equipment.

(e) Definition of the equipment for which certification is sought, referring to ATP, Annex 1, paragraph 3, and Appendix 4.

(f) Name, address, and telephone number of the manufacturer of the equipment, and the name and title of the person to contact.

(g) The manufacturer's make and model number for the equipment, including a brief description of the equipment and any brochure on the equipment which might be available.

(h) The original or certified true copy of the test report for the reference equipment.

(i) The original or certified true copy of the Foreign-ATP certificate issued for the equipment.

(j) A statement that each unit of equipment, before it is put into service, will have affixed to it a certification plate and distinguishing mark as specified in ATP, Annex 1, Appendix 1, paragraphs 4 and 5, and Appendixes 3 and 4.

(k) A list showing, for each unit of equipment, the serial number of the body and the corresponding owner's equipment identification number.

§ 3300.70 Issuance of certificate.

The ATP manager will evaluate the documents received and, for equipment deemed qualified, will issue a U.S. ATP certificate to the applicant within 30 days of the receipt of an application and any relevant information required. The certificate will be in the format prescribed in ATP, Annex 1, Appendix 3. For equipment deemed not qualified, the applicant will be advised of the reasons for non-qualification within 30 days of the receipt of an application and any relevant information required.

§ 3300.73 Period of validity of certificates.

In accordance with ATP, Annex 1, Appendix 1, paragraphs 1(a) and 1(b), certificates issued for new equipment are valid for a period of 6 years from date of issue.

Subpart G—Certification of Equipment in Service

§ 3300.76 General.

Only domestic owners are eligible to receive U.S. ATP certificates for equipment in service, with certification based upon the following:

(a) For equipment which has not previously been certified:

(1) For each unit of equipment, a test in a U.S. ATP testing station or in a testing station located in and approved by a country which is a Contracting Party, to measure the K-coefficient of the insulated body and the efficiency of the thermal appliance in accordance with § 3300.10 and § 3300.13 of this rule.

(2) If the equipment consists of serially-produced equipment manufactured by a particular equipment manufacturer, and belonging to one owner, certification may be based upon the following:

(i) A test of 1 percent of the units of equipment as prescribed in preceding paragraph (a)(1) of this section, the units tested to serve as reference equipment.

(ii) An inspection of each unit of equipment, using the procedures set forth in ATP, Annex 1, Appendix 2, paragraphs 29 and 49. The inspections shall be performed by one of the following, at the choice of the owner:

(A) Persons in the owner's organization whom the owner deems qualified to perform inspections, or;

(B) By an independent inspection agency which the owner deems competent to perform inspections. Fees charged by such inspection agency shall be payable directly to the agency by the owner.

(iii) A report of each inspection shall be completed on a form corresponding to the pertinent test report model in ATP, Annex 1, Appendix 2. Report forms may be obtained by a request to the ATP manager.

(b) For renewal of a U.S. ATP certificate which is nearing its expiration date, any of the following three procedures:

(1) For each unit of equipment, a test as prescribed in preceding paragraph (a)(1) of this section, or;

(2) If the equipment is serially-produced by a particular manufacturer and belongs to one owner, test and inspection of the equipment according to the procedures prescribed in preceding paragraphs (a)(2)(i), (ii), and (iii) of this section, or;

(3) An inspection of each unit of equipment as prescribed in paragraphs (a)(2)(ii) and (iii) of this section.

(c) For equipment which is currently certified according to a U.S. ATP certificate, and which has been transferred from one domestic owner to another, the new owner may obtain a U.S. ATP certificate by submitting the original or certified true copy of the certificate issued to the previous owner, and by performing an inspection and submitting an inspection report for each unit of equipment.

(d) For equipment which is currently certified according to a Foreign-ATP certificate, and which has been transferred from a foreign owner to a domestic owner, the domestic owner may obtain a U.S. ATP certificate by submitting the original or certified true copy of the test report for the reference equipment and the original or certified true copy of the foreign certificate, and by performing an inspection and submitting an inspection report for each unit of equipment.

(e) Owners who receive a U.S. ATP certificate have the responsibility to maintain equipment in good repair and operating condition with the understanding that the certificate is valid only so long as:

(1) The insulated body and the thermal appliance are maintained in good condition;

(2) No material alteration is made to the thermal appliance which decreases its refrigeration capacity, and;

(3) If the thermal appliance is replaced, it is replaced by an appliance of equal or greater refrigerating capacity.

§ 3300.79 Application for certificate.

An application shall be submitted to the ATP manager by an officer in the organization of the owner of the equipment. Copies of the Form, Application for U.S. ATP Certificate for Equipment in Service, may be obtained by a request to the ATP manager. The following information is requested in the application:

(a) A statement that the owner is a domestic owner, with the name, address, and telephone number of its principal office, and name and title of person to contact.

(b) If the operator of the equipment is different from the owner, the name and address of the operator.

(c) The type of equipment (intermodal freight container, trailer, semi-trailer, railcar, or truck).

(d) The total number of units of equipment.

(e) The definition of the equipment for which certification is sought, referring to ATP, Annex 1, paragraph 3 and Appendix 4.

(f) For equipment which has not been previously certified, one of the following:

(1) For each unit of equipment, the original or certified true copy of the test report, or;

(2) If the equipment is serially-produced by one manufacturer:

(i) Name of manufacturer.

(ii) The original or certified true copy of the test report(s) of 1 percent of the equipment which was tested to serve as reference equipment.

(iii) A report of inspection for each unit of equipment.

(g) For renewal of a U.S. ATP Certificate which is nearing its expiration date:

(1) The original or certified true copy of that certificate, and;

(2) One of the following, (i) (ii), or (iii):

(i) For each unit of equipment, the original or certified true copy of the test report.

(ii) If the equipment is serially-produced by one manufacturer:

(A) Name of manufacturer.

(B) The original or certified true copy of the test report(s) of 1 percent of the equipment which was tested to serve as reference equipment.

(C) A report of inspection from each unit of equipment.

(iii) A report of inspection for each unit of equipment.

(h) For equipment which is currently certified according to a U.S. ATP certificate, and which has been transferred from one domestic owner to another:

(1) The original or certified true copy of that certificate.

(2) A report of inspection for each unit of equipment.

(i) For equipment which is currently certified according to a Foreign-ATP certificate, and which has been transferred from a foreign owner to a domestic owner:

(1) The original or certified true copy of the test report for the reference equipment.

(2) The original or certified true copy of the Foreign-ATP certificate.

(3) A report of inspection for each unit of equipment.

(j) A statement that each unit of equipment has, or will have, affixed to it a certification plate and distinguishing mark as prescribed in ATP, Annex 1, Appendix 1, paragraphs 4 and 5, and Appendices 3 and 4.

(k) A list showing, for each unit of equipment, the serial number of the body and the corresponding owner's equipment identification number.

§3300.82 Issuance of certificate.

The ATP manager will evaluate documents received and, for equipment deemed qualified, will issue a U.S. ATP

certificate to the applicant within 30 days of receipt of the application and any relevant information required. The certificate will be in the format prescribed in ATP, Annex 1, Appendix 3. For equipment deemed not qualified, the applicant will be advised of reasons for non-qualification within 30 days of receipt of an application and any relevant information required.

§ 3300.85 Period of validity of certificates.

In accordance with ATP, Annex 1, Appendix 1, paragraphs 1(b), and Appendix 2, paragraphs 29(c) and 49(b) and (d), considered in combination, certificates will be valid for periods as follows:

(a) For equipment which passes a test, 6 years.

(b) For serially-produced equipment of which 1 percent have passed a test, and all units have been inspected and passed such inspection, 6 years.

(c) For renewal of a U.S. ATP certificate which is nearing its expiration date, where the equipment has passed an inspection but has not been tested, 3 years.

(d) For equipment currently certified according to a U.S. ATP certificate, where the equipment has been transferred from one domestic owner to another and the equipment has passed an inspection, 3 years or the date of expiration of the current U.S. ATP certificate, whichever gives the later expiration date on the new U.S. ATP certificate.

(e) For equipment currently certified according to a Foreign-ATP certificate, where the equipment has been transferred from a foreign owner to a domestic owner and the equipment has passed an inspection, 3 years or the date of expiration of the foreign certificate, whichever gives the later expiration date on the newly issued U.S. ATP certificate.

Subpart H—Other Provisions

§ 3300.88 Fees for U.S. ATP certificates.

The fee schedule for issuance of U.S. ATP certificates by the U.S. Department of Agriculture will be calculated according to the criteria in Circular A-25 [2], issued by the Office of Management and Budget. Fees may be revised as required on an annual basis.

[2] A copy of Circular A-25 can be obtained by a request to the Office of Management and Budget (OMB), 17th Street and Pennsylvania Avenue, NW., Washington, DC 20503.

§ 3300.91 List of approved testing stations, approved testing laboratories, and fees for certificates.

A current list of U.S. ATP testing stations, U.S. ATP testing laboratories, and fees for issuance of U.S. ATP certificates may be obtained by request to the ATP manager.

§ 3300.94 Appeals.

Any organization aggrieved by an action in connection with this rule may obtain a review of such action by submitting pertinent information by letter to the Administrator. The decision of the Administrator is the final agency action.

Dated: September 19, 1986.

Wesley R. Kriebel,

Acting Administrator, Office of Transportation, U.S. Department of Agriculture.

[FR Doc. 86-21549 Filed 9-23-86; 8:45 am]

BILLING CODE 3410-GS-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 84-ANE-24; Amdt. 39-5414]

Airworthiness Directives; Hartzell ( )HC-( )( )(X,V) Series Propellers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends an existing airworthiness directive (AD) which requires inspection or replacement of certain blade clamp assemblies on Hartzell ( )HC-( )( )(X,V) series propellers. This amendment is needed to provide an inspection procedure for clamps manufactured prior to 1959 as an equivalent means of compliance to mandatory replacement for those operators wishing to keep these clamps in service. A small extension to the September 27, 1986, compliance date is being granted to allow time to accomplish the initial inspection on clamps prior to S/N D5294.

DATES: Effective-September 25, 1986.

Compliance required within the next 60 days after the effective date of this amendment, unless already accomplished.

Note.—Incorporation by Reference—Approved by the Director of the Federal Register on September 25, 1986.

ADDRESSES: The applicable specification may be obtained from Hartzell Propeller Products Division, TRW Aircraft Components Groups, 350 Washington, Avenue, Piqua, Ohio 45356.

A copy of the specification is contained in the Rules Docket, Office of Regional Counsel, FAA, Attn: Rules Docket No. 84-ANE-24, 12 New England Executive Park, Burlington, Massachusetts 01803, and may be examined weekdays, except Federal holidays, between 8:00 a.m. and 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Alpiser, Chicago Aircraft Certification Office, ACE-140C, FAA, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (312) 694-7130.

SUPPLEMENTARY INFORMATION: This amendment further amends Amendment 39-5098, 50 FR 30417, AD 85-14-10 as amended by Amendment 39-5334, 51 FR 23732, AD 85-14-10-R1, which currently requires inspection or replacement of certain blade clamp assemblies on Hartzell ( )HC-( )( )(X,V) series propellers. After issuing Amendment 39-5098, the FAA has determined, through correspondence with affected owners and operators, that an inspection procedure for clamps manufactured prior to 1959 was desired as an equivalent means of compliance to mandatory replacement. It has been determined that an acceptable level of safety can be maintained by inspecting these clamps. Therefore, the FAA is further amending Amendment 39-5098, as amended by Amendment 39-5334, by providing an inspection procedure for clamps manufactured prior to 1959 as an equivalent means of compliance to mandatory replacement and by granting a small extension to the September 27, 1986, compliance date.

Since this amendment provides an equivalent means of compliance which is relieving in nature and must be made available prior to the current compliance date of September 27, 1986, notice and public procedure hereon are impracticable, unnecessary, and contrary to the public interest, this amendment may be made effective in less than 30 days.

Conclusion

The FAA has determined that this regulation provides an equivalent means of compliance which is relieving in nature and imposes no additional burden on any person. Therefore, I certify that this action: (1) Is not a "major rule" under Executive Order 12291, and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the final evaluation prepared for this action is contained in

the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption "FOR FURTHER INFORMATION CONTACT."

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the FAA amends § 39.13 of the Federal Aviation Regulations (FAR) as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By amending Amendment 39-5098, (50 FR 30417), AD 85-14-10, as amended by Amendment 39-5334, (51 FR 23732), AD 85-14-10 R1, as follows:

(a) By revising the compliance statement to read as follows:

"Compliance required within the next 60 days after the effective date of Amendment 39-5414, unless already accomplished."

(b) By revising Paragraph (a) of the amendment to read as follows:

"(a) Replace all propeller blade clamp assemblies which have serial numbers ranging from 0 through D5293 with airworthy clamp assemblies, or inspect as follows:

(1) Visually inspect the internal, inboard radius area of the clamp, especially next to the clamp bolt hole, for corrosion. Remove from service all clamps showing signs of corrosion (rework is not permitted) and replace with airworthy clamp assemblies.

(2) Magnetic particle inspect all internal and external surfaces of the clamp for evidence of cracks in accordance with TRW Hartzell Propeller Process Manual No. H-S-7 dated August 4, 1981, or FAA approved equivalent. Replace all cracked clamps with airworthy clamp assemblies.

(3) Penetrant inspect all external surfaces of the blade clamp assemblies with 100 hours since inspection in Paragraphs (a) (1) and (2) above and at intervals not to exceed 100 hours since last inspection. Replace all clamps showing signs of cracks with airworthy clamp assemblies."

TRW Hartzell Propeller Process Manual No. H-S-7 dated August 4, 1981, is incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received this document from the manufacturer may obtain a copy upon request to Hartzell Propeller Products Division, TRW Aircraft Components Group, 350 Washington Avenue, Piqua, Ohio 45356. This document also may be examined at the Office of Regional Counsel, FAA, Attn: Rules Docket No. 84-ANE-24, 12 New England Executive Park, Burlington, Massachusetts 01803, weekdays, except Federal holidays, between 8:00 a.m. and 4:30 p.m.

This amendment becomes effective on September 25, 1986.

This amendment amends Amendment 39-5098, (50 FR 30417), AD 85-14-10, as amended by Amendment 39-5334, (51 FR 23732), AD 85-14-10 R1.

Issued in Burlington, Massachusetts on September 2, 1986.

Clyde DeHart, Jr.,

Acting Director, New England Region.

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB 63]

Publication of Staff Accounting Bulletin

AGENCY: Securities and Exchange Commission.

ACTION: Publication of Staff Accounting Bulletin.

SUMMARY: The interpretations in this staff accounting bulletin express certain views of the staff regarding accounting for research and development arrangements.

DATE: September 11, 1986.

FOR FURTHER INFORMATION CONTACT: John A. Heyman, Office of the Chief Accountant (202-272-2130), or Howard P. Hodges, Jr., Division of Corporation Finance (202-272-2553), Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The statements in staff accounting bulletins are not rules or interpretations of the Commission nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal Securities laws.

Jonathan G. Katz,

Secretary.

September 11, 1986.

PART 211—[AMENDED]

Accordingly, Part 211 of Title 17 of the Code of Federal Regulations is amended by adding Staff Accounting Bulletin No. 63 to the table found in Subpart B.

Staff Accounting Bulletin No. 63

The staff herein adds Section 0 to Topic 5 of the staff accounting bulletin Series. This section discusses the staff's position regarding the application of the provisions of Statement of Financial Accounting Standards No. 68, "Research and Development Arrangements," when the parties that fund an enterprise's research and development activities are affiliated or related to the enterprise performing those activities.

Topic 5: Miscellaneous Accounting

* * * * *

O. Research and Development Arrangements

Facts: FASB Statement No. 68 paragraph 7 states that conditions other than a written agreement may exist which create a presumption that the enterprise will repay the funds provided by other parties under a research and development arrangement. Paragraph 8(c) lists as one of those conditions the existence of a "significant related party relationship" between the enterprise and the parties funding the research and development.

Question 1: What does the staff consider a "significant related party relationship" as that term used in paragraph 8(c) of FASB Statement No. 68?

Interpretive Response: The staff believes that a significant related party relationship exists when 10 percent or more of the entity providing the funds is owned by related parties.[1] In unusual circumstances, the staff may also question the appropriateness of treating a research and development arrangement as a contract to perform service for others at the less than 10 percent level. In reviewing these matters the staff will consider, among other factors, the percentage of the funding entity owned by the related parties in relationship to their ownership in and degree of influence or control over the enterprise receiving the funds.

Question 2: Paragraph 7 of FASB Statement No. 68 states that the presumption of repayment "can be overcome only by substantial evidence to the contrary." Can the presumption be overcome by evidence that the funding parties were assuming the risk of the research and development activities since they could not reasonably expect the enterprise to have

[1] Related parties as used herein are as defined in paragraph 24 of SFAS No. 57.

resources to repay the funds based on its current and projected future financial condition?

Interpretive Response: No. Paragraph 5 of FASB Statement No. 68 specifically indicates that the enterprise "may settle the liability by paying cash, by issuing securities, or by some other means." While the enterprise may not be in a position to pay cash or issue debt, repayment could be accomplished through the issuance of stock or various other means. Therefore, an apparent or projected inability to repay the funds with cash (or debt which would later be paid with cash) does not necessarily demonstrate that the funding parties were accepting the entire risks of the activities.

[FR Doc. 86-21646 Filed 9-23-86; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 85F-0036]

Indirect Food Additives; Adhesives and Components of Coatings

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, as a component of adhesives intended for use in contact with food. This action responds to a petition filed by American Cyanamid Co.

DATES: Effective September 24, 1986; objections by October 24, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 25, 1985 (50 FR 7657), FDA announced that a petition (FAP 5B3845) had been filed by American Cyanamid Co., One Cyanamid Plaza, Wayne, NJ 07470, proposing that the food additive regulations be amended to provide for the safe use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, as a component of adhesives intended for use in contact with food.

FDA, in the evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. Although sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, has not been found to cause cancer, it may contain minute amounts of ethylene oxide and 1, 4-dioxane as byproducts of its production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong. 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney Clause of the Food Additives Amendment (section 409(c)(3)(A)) of the act (21 U.S.C. 348(c)(3)(A)) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6 published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent.

Since that decision, FDA has approved the use of other color additives and food additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for those decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney anticancer clause is applicable only when the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic constituent, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical, but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

Because adhesives used in food packaging must be separated from food by a functional barrier or contact food only at seam edges in accordance with current good manufacturing practice (21 CFR 175.105), FDA estimates that the petitioned use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, will result in levels of exposure to this additive that are quite small. FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such small exposure levels (Refs. 1 and 2) and has not required such testing here. Because sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, has not been shown to cause cancer, the anticancer clause does not apply to it.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented

by the carcinogenic chemicals that may be present as impurities in the additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018, 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities ethylene oxide and 1,4-dioxane has two aspects: (1) Assessment of the worst case exposure to the impurities from the proposed use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, as well as the level of 1,4-dioxane that may be present in the additive (Ref. 5), FDA estimated the hypothetical worst case exposure to 1,4-dioxane from the use of this additive to be 10 nanograms per person per day. The agency used data in a carcinogenesis bioassay on 1,4-dioxane conducted for the National Cancer Institute (Ref. 4) to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the subject additive. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinomas and heptacellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The committee further concluded that an estimate of the upper bound limit of lifetime human cancer risk from potential exposure to 1,4-dioxane stemming from the proposed use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, could be made from the bioassay.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additive. Based on a worst case exposure of 10 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from potential exposure to 1,4-dioxane from the use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, is 4×10^{-10} or less than 4 in 10 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and therefore the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that results from the use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, as a component of adhesives.

B. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, as well as the level of ethylene oxide that may be present in the additive (Ref. 5), FDA also estimated the hypothetical worst case exposure to ethylene oxide from the use of this additive to be 10 nanograms per person per day. The agency used data in a carcinogenesis bioassay on ethylene oxide conducted at the Institute of Hygiene, University of Mainz, West Germany (Ref. 3), to estimate the upper bound level of lifetime human risk from exposure to ethylene oxide stemming from the proposed use of the adhesive containing this ethoxylated compound. The results of the bioassay on ethylene oxide indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinoma of the forestomach and carcinoma in situ of the glandular stomach.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that this information on ethylene oxide supported the finding of carcinogenicity. The committee further concluded that an estimate of the upper bound limit of lifetime human cancer risk from potential exposure to ethylene oxide could be made from the bioassay.

Based on a worst case exposure of 10 nanograms per person per day, FDA estimates, using a linear proportional model, that the upper bound limit of individual lifetime risk from potential exposure to ethylene oxide from the use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt, in 2×10^{-8} or less than 2 in 100 million. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that results from the use of sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt.

C. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of ethylene oxide and 1,4-dioxane in the food additive. The agency finds that a specification is not necessary for the following reasons: (1) Because of the levels at which ethylene oxide and 1,4-dioxane are used in the production of the additive, the agency would not expect these impurities to become components of food at other than very low levels; and (2) The upper bound limit of lifetime risk from exposure, even under worst case assumptions, is very low, less than 2 in 100 million for ethylene oxide and 4 in 10 billion for 1,4-dioxane.

D. Conclusion on Safety

FDA has evaluated the available toxicity data and the exposure calculation for this additive. The agency has determined that the additive is safe for its proposed use.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated assessment under 21 CFR 25.31a(b)(1).

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday:

1. Carr, G.M., "Carcinogenicity Testing Programs" *in* "Food Safety: Where Are We.? Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

4. "Bioassay of 1,4-Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI–CG–TR–80, 1978.

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaulation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxide (EO) and 1,4-Dioxane (DX)."

Any person who will be adversely affected by this regulation may at any time on or before October 24, 1986, 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 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 175.105(c)(5) by alphabetically inserting a new item in the list of substances to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole of nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4)	
* * * * *	

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21562 Filed 9–23–86; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 79F–0449]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxy-poly(oxyethylene)poly(oxypropylene) of average molecular weight between 950 and 1,120, as components of a sanitizing solution used on food-contact surfaces. This action responds to a petition filed by the Diversey Wyandotte Division of the Diversey Corp.

DATES: Effective September 24, 1986; objections by October 24, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690. .

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 28, 1979 (44 FR 76862), FDA announced that a petition (FAP OB3480) had been filed by Diversey Wyandotte Division of the Diversey Corp. (formerly BASF Wyandotte Corp.), 1532 Biddle Ave., Wyandotte, MI 48192, proposing that the food additive regulations be amended to provide for the safe use of elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly (oxyethylene) poly (oxypropylene) of average molecular weight between 950 and 1,120, as components of a sanitizing solution to be used on food-contact surfaces.

FDA reviewed the safety of the individual food additives that are the components of the sanitizing solution as well as the starting materials used to manufacture these food additives. Although iodine and the two ethoxylated emulsifiers, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly-(oxyethylene)poly (oxypropylene) and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene)poly (oxypropylene), have not been shown to cause cancer, the two ethoxylated emulsifiers may contain minute amounts of ethylene oxide and 1,4-dioxane as byproducts of their production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as ethylene oxide and 1,4-dioxane, are commonly found as contaminants in all chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the food additives amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further than no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent.

Since that decision, FDA has approved the use of other color additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for these decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney anticancer clause is not applicable unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic constituent, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use of Additives

Sanitizing solutions are mixtures of additives in which each additive has a functional effect. The subject sanitizing solution contains one additive, iodine, that is the active sanitizing agent and two ethoxylated compounds that function as emulsifiers and aid the penetration of cells by the active ingredient.

A. Iodine

Iodine is used in this and in other currently regulated sanitizing solutions as the active ingredient. Iodine has a long history of use for this purpose. FDA finds that iodine is safe and effective at the use levels established in this regulation, based on efficacy data submitted by the petitioner and on toxicity studies on iodine that are available in the scientific literature.

B. Ethoxylated Emulisifiers

FDA estimates that the petitioned use of *alpha*-alkyl-(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl-(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) will result in extremely low levels of exposure to these additives. The agency has calculated an estimated daily intake of *alpha*-alkyl-(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl-(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) based on considerations such as the migration of the additives under the most severe intended use conditions and the probable concentration of the additives in the daily diet from food-contact articles that contain these substances. The estimated daily intake for these two additives is 0.4 milligram and 0.6 milligram per day 1.35 and 2.13 parts per million in the diet) for a 60 kilogram person.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2) and has not required such testing here. FDA has evaluated the safety of the ethoxylated emulsifiers under the general safety cause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additives. Because these ethoxylated emulsifiers have not been shown to cause cancer, the anticancer clause does not apply to them. Based on its evaluation, the agency has concluded that the additives are safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018, 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities ethylene oxide and 1,4-dioxane has two aspects: (1) Assessment of the worst case exposure to the impurities from the proposed use of the sanitizing solution, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

C. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl-($C_{12}C_{18}$)-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene), as well as the level of 1,4-dioxane that may be present in these additives (Ref. 5), FDA estimated the hypothetical worst case exposure to 1,4-dioxane from the use of these additives to be 10 nanograms per person per day. The agency used data in a carcinogenesis bioassay on 1,4-dioxane conducted for the National Cancer Intstitute (Ref. 4) to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the two ethoxylated emulsifiers in the sanitizing solution. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The committee further concluded that an estimate of the upper bound level of lifetime human risk from potential exposure to 1,4-dioxane stemming from the proposed use of the two ethoxylated emulsifiers could be calculated from the bioassay.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the ethoxylated emulsifiers. Based on a worst case exposure of 10 nanograms per person per day, FDA estimates that the upper bound limit of individual lifetime risk from potential exposure to 1,4-dioxane from the use of the two ethoxylated emulsifiers is 4×10^{-10} or less than 4 in 10 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and therefore the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that results from the use of the two ethoxylated emulsifiers.

D. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly (oxyethylene) poly (oxypropylene) and *alpha*-alkyl-(C_{12}-C_{18})-*omega*-hydroxypoly (oxyethylene)poly(oxypropylene), as well as the level of ethylene oxide that may be present in these additives (Ref. 5), FDA estimated the hypothetical worst case exposure to ethylene oxide from the use of these ethoxylated emulsifiers to be 10 nanograms per person per day.

The agency used data in a carcinogenesis bioassay on ethylene oxide conducted for the Institute for Hygiene, University of Mainz, West Germany (Ref. 3), to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of the ethoxylated emulsifiers. The results of the bioassay on ethylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinoma of the forestomach and carcinoma in situ of the glandular stomach.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that this information on ethylene oxide supported the finding of carcinogenicity. The committee further concluded that an estimate of the upper bound limit of lifetime human cancer risk from potential exposure to ethylene oxide could be made from the bioassay.

Based on a worst case exposure of 10 nanograms per person per day, FDA estimates, using a linear proportional model, that the upper bound limit of individual lifetime risk from potential exposure to ethylene oxide from the use of *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)-poly(oxypropylene) and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxy-poly(oxyethylene)poly(oxypropylene) is 2×10^{-8} or less than 2 in 100 million. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that results from the use of *alpha*-alkyl-(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly(oxypropylene) and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene-poly(oxypropylene).

E. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of the ethylene oxide and 1,4-dioxane impurities in the ethoxylated emulsifiers. The agency finds that a specification is not necessary for the following reasons: (1) Because of the levels at which ethylene oxide and 1,4-dioxane are used in the production of these additives, the agency would not expect these impurities to become components of food at other than small levels; and (2) The upper bound limit of lifetime risk from exposure to these impurities, even under worst case assumptions, is very low, less than 2 in 100 million.

F. Conclusion on Safety

FDA, has evaluated the available toxicity data and the exposure calculations for the components of the sanitizing solution and has determined that these food additives are safe for their proposed use.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday:

1. Carr, G.M., "Carcinogenicity Testing Program" *in* "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkleberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastic Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

4. "Bioassay of 1,4-Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI–CG–TR–80, 1978.

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxide (EO) and 1,4-Dioxane (DX)."

Any person who will be adversely affected by this regulation may at any time on or before October 24, 1986, 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 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 178.1010 by adding new paragraphs (b)(31) and (c)(26) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(31) An aqueous solution containing elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene) poly(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(c) * * *

(26) The solution identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

* * * * *

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21564 Filed 9–23–86; 8:45 am]
BILLING CODE 4160–01–M

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21 CFR Part 178

[Docket No. 83F–0156]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous dispersion of polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, polyoxyethylene (minimum (min.) 3 moles ethylene oxide) cetyl alcohols, and polyoxyethylene (min. 20 moles ethylene oxide) oleyl ether, for use in aqueous dispersions of vinylidene chloride copolymers intended for use in contact with food. This action responds to a petition filed by Morton Thiokol, Inc.

DATES: Effective September 24, 1986; objections by October 24, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of June 3, 1983 (48 FR 24984), FDA announced that a petition (FAP 3B3707) had been filed by Morton Chemical Division of Morton Thiokol, Inc., Two North Riverside Plaza, Chicago, IL 60606, proposing that the food additive regulations be amended to provide for the safe use of an aqueous dispersion of polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, poly(oxyethylene) (min. 3 moles ethylene oxide) cetyl alcohols, and poly(oxyethylene) (min. 20 moles ethylene oxide) oleyl ethers for use in aqueous dispersions of polyvinylidene chloride copolymers intended for use in contact with food.

The aqueous dispersion that is subject of this petition is a blend of three substances, each of which has a functional effect when the dispersion is used in polyvinylidene chloride polymers. No adverse toxic effects were observed in a 2-year rat feeding study of the aqueous dispersion. Because the dispersion is merely a blend and not a compound or polymer, however, the dispersion is not a food additive, but its component substances are. Therefore, in acting on this petition, FDA has evaluated the safety of each of the food additives that made up the dispersion. This evaluation includes a review of the safety of each additive and of the starting materials used to manufacture the additives.

Two of three additives, polyoxyethylene (min. 3 moles ethylene oxide) cetyl alcohol and polyoxyethylene (min. 20 moles oxyethylene) oleylether (sometimes referred to as "the ethoxylated additives"), although not shown to cause cancer, may contain minute amounts of ethylene oxide and 1,4-dioxane as byproduct of their production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives

Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4, 1958.) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409 (c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole has not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6 published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent.

Since that decision, FDA has approved the use of other color additives and food additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for those decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney anticancer clause is not applicable unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer, but that contains a carcinogenic constituent, may properly be evaluated under the general safety clause of the statute using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use of Additives

A. Diesters of Oxidatively Refined Montan Wax Acids

The first additive, polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids is safe and effective for the use established in this regulation. This finding is based upon the data presented in the petition and other available data.

B. Ethoxylated Additives

FDA estimates that the petitioned use of the polyoxyethylene (min. 3 moles ethylene oxide) cetyl alcohols and polyethylene (min. 20 moles ethylene oxide) will result in extremely low levels of exposure to these additives. The agency has calculated an estimated daily intake of polyoxyethylene cetyl alcohols and polyoxyethylene oleyl ether based on considerations such as the migration of the additives under the most severe intended use conditions and the probable concentration of the additives in the daily diet from food-contact articles that contain these substances. The estimated daily intake for these two additives is less than 20 parts per billion each in the diet.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2) and has not required such testing here. Evaluation of the safety of the exthoxylated emulsifiers was based upon the data in the petition and other available information. Because these ethoxylated additives have not been shown to cause cancer, the anticancer clause does not apply to them.

FDA has evaluated the safety of the ethoxylated emulsifiers under the general safety clause, using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additive. Based on this evaluation, the agency has concluded that these additives are safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that it has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see, e.g., 49 FR 13018, 13019; April 2, 1984). This risk evaluation of the carcinogenic impurities ethylene oxide and 1,4-dioxane, has two aspects: (1) Assessment of the worst case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

C. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing polyoxyethylene (min. 3 moles oxyethylene) cetyl alcohols and polyoxyethylene (min. 20 moles oxyethylene) oleyl ether, as well as the level of 1,4-dioxane that may be present in these additives (Ref. 5), FDA estimated the hypothetical worst case exposure to 1,4-dioxane from the use of these additives to be 0.7 nanogram per person per day. The agency used data in a carcinogenesis bioassay on 1,4-dioxane conducted from the National Cancer Institute (Ref. 4) to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of polyoxyethylene (min. 3 moles oxyethylene) cetyl alcohols and polyoxyethylene (min. 20 moles ethylene oxide) oleyl ether. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The committee further concluded that an estimate of the upper bound limit of lifetime human cancer risk from potential exposure to 1,4-dioxane stemming from the proposed use of the ethoxylated additives could be made from the bioassay.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed contitions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent

with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the food additives. Based on a worst case exposure of 0.7 nanogram per person per day, FDA estimates that the upper bound limit of individual lifetime risk from potential exposure to 1,4-dioxane from use of polyoxyethylene (min. 3 moles oxyethylene) cetyl alcohols and polyoxyethylene (min. 20 moles oxyethylene) oleyl ether is 3×10^{-11} or less than 3 in 100 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake, and therefore the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to 1,4-dioxane that results from the use of poly(oxyethylene) (min. 3 moles ethylene oxide) cetyl alcohols and poly(oxyethylene) (min. 20 moles ethylene oxide) oleyl ether.

D. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing polyoxyethylene (min. 3 moles ethylene oxide) cetyl alcohols and polyoxyethylene (min. 20 moles oxyethylene) oleyl ether, as well as the level of ethylene oxide that may be present in the additive (Ref. 5), FDA estimated the hypothetical worst case exposure to ethylene oxide from the use of these additives to be 0.7 nanogram per person per day. The agency used data in a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, West Germany (Ref. 3), to estimate the upper bound level of lifetime human risk from exposure to this chemical stemming from the proposed use of these additives. The results of the bioassay on ethylene oxide demonstrated that this material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidences of squamous cell carcinoma of the forestomach and carcinoma in situ of the glandular stomach.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee reviewed this bioassay and other relevant data available in the literature and concluded that this information on ethylene oxide supported the finding of carcinogenicity. The committee further concluded that an estimate of the upper bound of lifetime human cancer risk from potential exposure to ethylene oxide could be made from the bioassay.

Based on a worst case exposure of 0.7 nanogram per person per day, FDA estimates, using a linear proportional model, that the upper bound limit of individual lifetime risk from potential exposure to ethylene oxide from the use of these two ethoxylated additives is 1×10^{-9} or less than 1 in 1 billion. Because of numerous conservatisms in the exposure estimate, lifetime averaged individual exposure to ethylene oxide is expected to be substantially less than the estimated daily intake. Therefore, the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that results from the use of these ethoxylated additives.

E. Need for Specifications

The agency has also considered whether a specification is necessary to control the amount of the ethylene oxide and 1,4-dioxane impurities in the ethoxylated food additives. The agency finds that a specification is not necessary for the following reasons: (1) Because of the levels at which ethylene oxide and 1,4-dioxane are used in production of these additives, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper bound limit of lifetime risk from exposure to these impurities, even under worst case assumptions, is very low, less than 1 in 1 billion.

F. Conclusion of Safety

FDA has evaluated the available toxicity data and the exposure calculation for the additive and has determined that these additives are safe for their proposed use.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 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.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(1).

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G.M., "Carcinogenicity Testing Programs" *in* "Food Safety: Where Are We?," Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979, p. 59.

2. Kokoski, C.J., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

4. "Bioassay of 1,4-Dioxane for Possible Carcinogenicity," National Cancer Institute, NCI–CG–TR–80, 1978.

5. Memorandum dated February 13, 1986, from Food Additive Chemistry Evaluation Branch to Indirect Additives Branch, "Exposure to Ethylene Oxiode (EO) and 1,4-Dioxane (DX)."

Any person who will be affected by this regulation may at any time on or before October 24, 1986 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 178

Food additives, Food packaging, Production aids.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10, 4.61.

2. In § 178.3770 by adding a new paragraph (c) to read as follows:

§ 178.3770 Polyhydric alcohol diesters or oxidatively refined (Gersthoffen process) montan wax acids.

* * * * *

(c) The polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, identified in paragraph (a) or (b) of this section, may also be used as a component of an aqueous dispersion of vinylidene chloride copolymers, subject to the conditions described in paragraphs (c)(1) and (2) of this section.

(1) The aqueous dispersion of the additive contains not more that 18 percent polyhydric alcohol diesters of oxidatively refined (Gersthoffen process) montan wax acids, not more than 2 percent poly(oxyethylene) (minimum 20 moles of ethylene oxide) oleyl ether (CAS Reg. No. 9005–98–2), and not more than 1 percent poly(oxyethylene) (minimum 3 moles ethylene oxide) cetyl alcohols (CAS Reg. No. 9004–95–9).

(2) The aqueous dispersion described in paragraph (c)(1) of this section is used as an additive to aqueous dispersions of vinylidene chloride copolymers, regulated in §§ 175.300, 175.320, 175.360, 176.170, 176.180, and 177.1630 of this chapter, at levels not to exceed 1.5 percent (solids basis) in the finished coating.

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21563 Filed 9–23–86; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 184

[Docket No. 82N–0103]

Gras Status of Glucono Delta-Lactone

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that glucono delta-lactone is generally recognized as safe (GRAS) for use as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective October 24, 1986.

The Director of the **Federal Register** approves the incorporation by reference of certain publications in 21 CFR 184.1318 effective on October 24, 1986.

FOR FURTHER INFORMATION CONTACT: Damon Larry, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 17, 1982 (47 FR 35778), FDA published a proposal to affirm that glucono delta-lactone is GRAS for use as a direct human food ingredient. FDA published this proposal in accordance with its review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review, mutagenic and teratology reports, and the report of the Select Committee on GRAS Substances (the Select Committee) on glucono delta-lactone are available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of glucono delta-lactone, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for glucono delta-lactone were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

FDA received three comments in response to the agency's proposal on glucono delta-lactone. One comment was from a manufacturer of the substance, a second was from an importer of glucono delta-lactone, and the third was from a user of glucono delta-lactone. The comments and the agency's responses to them follow.

1. The first two comments requested that FDA modify the description of the manufacturing process for glucono delta-lactone in proposed § 184.1318(a). The comments asserted that the method for producing gluconic acid (an initial step in the production of glucono delta-lactone) that is included in § 184.1318(a) (oxidation of *D*-glucose with bromine water) is not the common method for commercially producing this substance. The comments stated that the more widely used method is to produce gluconic acid by oxidizing food-grade glucose in the presence of suitable strains of microorganisms that are non-pathogenic and non-toxicogenic to man or animals or in the presence of enzymes derived from such microorganisms. One comment identified the microorganisms used in the manufacture of gluconic acid from glucose as *Aspergillus niger* and *Acetobacter suboxydans*.

The agency has carefully evaluated these comments. The agency agrees that the comments describe the method that is currently used to produce food-grade glucono delta-lactone. This method is used by the major producer of gluconic acid and glucono delta-lactone in the United States and also by the supplier for a major importer into the United States of food-grade glucono delta-lactone. Glucono delta-lactone prepared for food use by the procedure described in the comments meets the specifications of the Food Chemicals Codex, which are being adopted by the agency. Because the product meets the specifications of the Food Chemicals Codex and is prepared using strains of

nonpathogenic and nontoxicogenic microorganisms that are safe and suitable, the agency concludes that the product is GRAS. The agency has modified the final rule to include the current methods of manufacture of glucono delta-lactone in response to these comments.

The agency is not, however, listing specific organisms or enzymes in § 184.1318(a). Such a listing is unnecessary and would merely introduce an element of rigidity that is not needed to ensure the safety of the product. The two microorganisms mentioned in the comments, *Aspergillus niger* and *Acetobacter suboxydans*, are well recognized by the scientific community as not presenting a toxicogenic or pathogenic concern. The agency believes that there may be other microorganisms that are suitable for the production of gluconic acid and that do not present such concerns. Therefore, a listing of specific microorganisms is unnecessary.

2. The third comment requested that FDA affirm that glucono delta-lactone is GRAS for use as a pH control agent in fats and oils. The comment included no current information on this use and no data on the effectiveness of this use of glucono delta-lactone. A contact by telephone with the company that submitted the comment revealed that the use of glucono delta-lactone in fats and oils was the subject of active research, and that if this food category was not included in the regulation, the company would consider discontinuing this research.

In this final rule, FDA is taking actions that, in essence, grant this request. FDA proposed to affirm that glucono delta-lactone is GRAS for use as a pH control agent and, in the absence of information that raises questions about the safety of this use, is adopting that aspect of the proposal. Moreover, the agency is deleting the food categories that were listed in the proposal from the regulation. Both the Select Committee and the agency have concluded that a large margin of safety exists for the use of this ingredient, and that a reasonably foreseeable increase in the level of consumption of this ingredient will not adversely affect human health. Further, this ingredient is used in a large number of food categories.

Accordingly, the agency has concluded that it is not necessary to list food categories of use to ensure its safe use of this ingredient. Therefore, the agency has modified § 184.1318 by deleting the food categories and is affirming that glucono delta-lactone is GRAS when used in accordance with current good manufacturing practice under § 184.1(b)(1) (21 CFR 184.1(b)(1). To make clear, however, that the affirmation of the GRAS status of Glucono delta-lactone is based on the evaluation of currently known uses, the regulations set forth the technical effects that FDA has evaluated.

Finally, FDA has concluded that the description of glucono delta-lactone in the proposal could be misleading because it does not fully describe glucono delta-lactone as a crystalline material. FDA, therefore, has modified the description in § 184.1318(a) to include the crystallization step and to describe the crystalline material as the GRAS ingredient. The agency concludes that this change in the regulation is not significant because the proposed regulation has referenced the Food Chemicals Codex specifications for the ingredient, which describe glucono delta-lactone as a "crystalline powder."

The agency has previously determined under 21 CFR 25.24(d)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

2. Part 184 is amended by adding new § 184.1318, to read as follows:

§ 184.1318 Glucono delta-lactone.

(a) Glucono delta-lactone ($C_6H_{10}O_6$, CAS Reg. No. 90–80–2), also called *D*-gluconic acid delta-lactone or *D*-glucono-1,5-lactone, is the cyclic 1,5-intramolecular ester of *D*-gluconic acid. It is prepared by direct crystallization from the aqueous solution of gluconic acid. Gluconic acid may be produced by the oxidation of *D*-glucose with bromine water, by the oxidation of *D*-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals, or by the oxidation of *D*-glucose with enzymes derived from these microorganisms.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 134, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; and sequestrant as defined in § 170.3(o)(26) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: September 17, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21565 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 433

[Docket No. 894N-0373]

Antibiotic Drug Products for Over-the-Counter Human Use; Exemption From Certification; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that amended the antibiotic drug regulations to specifically exempt from batch certification antibiotic drug products for over-the-counter (OTC) human use (51 FR 25523; July 15, 1986). This document corrects a typographical error.

FOR FURTHER INFORMATION CONTACT: Robert J. Meyer, Center for Drugs and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION: In FR Doc. 86-15850 appearing on page 25523, in the issue of Tuesday, July 15, 1986, the following correction is made on page 25523: In the second column, under "Background", the second paragraph, line 2, "(21 CFR 443.1)" is corrected to read "(21 CFR 433.1)".

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-21557 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 510 and 558

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

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADA's) from Abbott Laboratories to Fleming Laboratories, Inc.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc. P.O. Box 34384, Charlotte, NC 28234, informed FDA of acquiring two NADA's from Abbott Laboratories. Fleming is now sponsor of NADA's 8-019 (Pro-Gen Arsanilic Acid) and 8-966 (Pro-Gen Sodium Arsanilate). Abbott confirmed the change. Fleming will assume all responsibilities for the cited NADA's as required by 21 CFR 510.300 and 21 CFR Part 514. The NADA's and the regulations are amended to reflect the new sponsor.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal Feeds.

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, Parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. Section 510.600 is amended by adding a new entry alphabetically in paragraph (c)(1) and numerically in paragraph (c)(2), to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
* * * * *	

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 558.60 [Amended]

4. Section 558.60 *Arsanilate sodium* is amended in paragraph (a) by removing the sponsor number "043731" and replacing it with "015565."

§ 558.62 [Amended]

5. Section 558.62 *Arsanilic acid* is amended in paragraph (a) by removing the sponsor number "043731" and replacing it with "015565."

Dated: September 18, 1986.

Marvin A. Norcross,

Associate Director for New Animal Drug Evaluation.

[FR Doc. 86-21558 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Furst-McNess Co., providing for the use of a 48-gram-per-pound pyrantel tartrate Type A medicated article in making 9.6- and 19.2-gram-per-pound pyrantel tartrate Type A medicated articles. The pyrantel tartrate Type A medicated articles subject to this approval are subsequently used to make Type C medicated feeds for swine.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: Furst-McNess Co., Freeport, IL 61032, is sponsor of NADA 140-825 submitted on

its behalf by Pfizer, Inc. The NASA provides for use of a 48-gram-per-pound pyrantel tartrate Type A medicated article to make 9.6- and 19.2-gram-per-pound pyrantel tartrate Type A medicated articles. The pyrantel tartrate Type A medicated articles are for making Type C medicated feeds to aid in prevention or migration and establishment and for removal and control of large roundworm (*Ascaris suum*) infections; and to aid in prevention of establishment and for removal and control of nodular worm (*Oesophagostomum* spp.) infections.

The NADA is approved and the regulations are amended to reflect this approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 of Veterinary Medicine, Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

2. In § 558.485 by adding new paragraph (a)(27) to read as follows:

§ 558.485 Pyrantel tartrate.

(a) * * *

(27) To 010439: 9.6 and 19.2 grams per pound, paragraphs (e) (1) through (3) of this section.

* * * * *

Dated: September 17, 1986.

Gerald B. Guest,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 86-21560 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Parts 904 and 941

[Docket No. N-86-1602; FR-2190]

Public Housing Development; Cost Containment Policy Statement

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Policy statement.

SUMMARY: The Department of Housing and Urban Development-Independent Agencies Appropriations Act, 1986 (Pub L. 99-160, approved November 25, 1985) repealed section 6(b) of the United States Housing Act of 1937. Section 6(b) required the Secretary to establish prototype costs for the development of public and Indian housing. These prototype costs were used to limit costs associated with public and Indian housing development and modernization. The purpose of this statement is to announce the interim public housing development cost containment policies to be applied by the Department pending the issuance of rules amending existing regulations. This policy notice is applicable to public housing development projects only. A related notice will be published to explain interim cost containment policies for modernization and Indian housing development projects.

FOR FURTHER INFORMATION CONTACT: Nancy Chisholm, Director, Policy Staff, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, telephone (202) 755-6713.

SUPPLEMENTARY INFORMATION:

Background

Until recently, section 6(b) of the United States Housing Act of 1937 required the Secretary of HUD to establish prototype costs for the development of public housing projects. These prototype costs were established for different areas of the country and were based on construction costs of new dwelling units of various sizes and types that were suitable for occupancy by persons assisted under the Act. Section 6(b) required every contract for loans (other than preliminary loans) or annual contributions to provide that the cost of construction and equipment of the project (excluding land, demolition, and nondwelling facilities) on which the computation of annual contributions under the Act was based not exceed by more than 10 percent the appropriate prototype costs for the area. These statutory requirements were incorporated in HUD's public housing development regulations. In addition, HUD promulgated other regulations that limited total development costs for projects to 160 percent of project prototype costs for detached, semi-detached, row or walk-up projects and to 145 percent of project prototype costs for elevator projects (*see* 24 CFR 941.406(a)). The percentage limitations set for total development costs are higher than the percentage limitations for dwelling construction and equipment because total development costs include additional project cost items such as land, demolition and nondwelling facilities. Cost containment requirements based on the Department's prototype cost determination were also imposed in other program regulations.

In 1985, Congress expressed its concern that the available data for the calculation of prototype costs were inadequate. It believed that this shortcoming, coupled with what congressional critics saw as the relatively inflexible approach that the Department adopted in applying prototype cost requirements, has become a significant and unreasonable impediment to the utilization of funds provided for public housing development. (S. Rep. No. 99-129, 99th Cong. 1st Sess. 10). Accordingly, section 6(b) was repealed in the Department of Housing and Urban Development—Independent Agencies Appropriations Act, 1986 (Pub. L. 99-160).

Purpose of Statement

The repeal of section 6(b) eliminated the statutory requirement that HUD limit dwelling construction and equipment costs based on prototype cost determinations. It did not, however, eliminate HUD's responsibility to approve public housing development applications on the basis of reasonable criteria designed to promote economy. (S. Rep. No. 99-129, at 10.) Despite the absence of statutory prototype limitations, HUD believes that it is essential to limit costs in assisted housing programs so that the Department can develop the largest number of units with available funds.

Since the cost containment regulations based on prototype cost determinations and contained in 24 CFR Part 941 are no longer mandated by statute, HUD is now responsible for developing its own cost containment policy for public housing development. HUD intends to develop this new cost containment policy in a rulemaking procedure which will include a notice of proposed rulemaking and an opportunity for public comment. The development of a final rule under this procedure, however, will be time-consuming. Accordingly, it is necessary to announce the cost containment policy that the Department will follow pending the effective date of the final rule. The features of this interim policy are discussed below.

This policy notice is applicable to public housing development projects only. A related notice will be published to explain interim cost containment policies for modernization and Indian housing development projects.

Guidelines

HUD's public housing development cost containment procedures will be based upon cost guidelines. These guidelines will be contained in HUD Field Notices issued by the Department on a regular basis. The guidelines will reflect the dwelling construction and equipment costs for various unit sizes, housing types and market areas. (*I.e.*, areas within much trade conditions and economic influences tend to make construction costs substantially the same.) The guidelines will be based on development data for HUD-insured and public housing projects within market areas or, where there are insufficient data within a market area, the guidelines will reflect a commercial index, or appropriately adjusted data from adjacent areas.

To ensure that the cost guidelines will reflect more accurately actual construction and equipment costs than the prototype costs procedures, PHAs may request revisions to the cost guidelines for their market area or to establish a separate market area for their jurisdictions. To assist PHAs in the preparation of their request, HUD will issue with the guidelines a description of the methodology used to compute the guidelines and information concerning the documentation that must be submitted in support of the requests. HUD's first Field Notice announcing the cost guidelines and providing this additional data was PIH Notice 86–5, issued May 9, 1986.

PHA documentation supporting revised guidelines will be reviewed by the appropriate HUD Field Office. After review, the Field Office will forward the PHA's documentation with a recommendation to HUD Headquarters through the Regional Office. The Assistant Secretary will review the PHA's documentation and the Field Office recommendation and will issue revised guidelines for a market area (or establish guidelines for a new market area within an existing market area) if the evidence shows that the revised guidelines are reasonable and necessary to develop a project which is durable, safe and secure and which provides for economical maintenance, healthy family life in a neighborhood environment, good design and energy conservation.

Application of Guidelines

The cost guidelines will be applied in a significantly more flexible manner than were past prototype cost limits. Prototype costs served as an absolute limit on dwelling construction and equipment costs. The cost guidelines, on the other hand, will not serve as a limit on dwelling construction and equipment costs. Moreover, while the guidelines, like the prototype costs, will be used to compute total development cost, the Department will, under certain circumstances, permit a project to exceed the costs computed under the cost guidelines.

1. *Fund reservation.* The amount of the initial reservation of funds for the development of a public housing project will be computed by applying the most recently issued cost guidelines for the market area. (While PHAs may request revised guidelines at any time following their issuance, to affect the initial reservation of funds for a project, the Assistant Secretary must have approved revised guidelines before the initial reservation is made.) The Field Office will multiply the cost guideline issued for each unit size and structure type times the number of units proposed for that unit and structure type. These figures will be totaled. Because the cost guidelines are based on dwelling construction and equipment costs, this total will be multiplied by 160 percent (for nonelevator projects) or 145 percent (for elevator projects) to impute total development costs. The Field Office will reserve this amount for the development of the project. At the initial reservation stage, total project costs above the 160/145 percent level may not be authorized.

2. *Cost amendments.* Field Offices may approve proposals, annual contribution contracts (ACCs) and amended ACCs for projects with total development costs up to 160 percent (for nonelevator projects) or 145 percent (for elevator projects) of the most recently issued cost guidelines.

The Regional Administrator may authorize the Field Office to approve proposals, ACCs and amendments to ACCs up to 168 percent (nonelevator projects) or 152 percent (elevator projects) of the latest guidelines. Similarly, the Assistant Secretary may authorize the Field Office to approve project costs in excess of the 168/152 percent limitations.

Costs in excess of 160 percent (nonelevator projects) or 145 percent (elevator projects) of the latest guidelines may be approved by the Regional Administrator or Assistant Secretary, as appropriate, if the costs are reasonable and necessary to the development of a project that provides durability, safety, security, and economical maintenance, healthy family life in a neighborhood environment, good design and energy conservation. For example, higher costs for a project may be justified on the basis of special circumstances relating to security in high crime areas, unusual environmental or site considerations, relocation expenses, land values, etc.

The Field Office cannot terminate a project merely because the total development cost will exceed approved or approveable cost limits, unless such termination has been approved by Headquarters.

Effect of Existing Regulations

Based on the statutory repealer, HUD could immediately issue a final rule (without notice and public comment) removing prototype cost provisions contained in 24 CFR Part 941. The removal of the provisions of existing regulations, however, involves certain technical problems. For administrative simplicity, the formal removal will be consolidated with the rulemaking implementing the new cost containment provisions. While the provisions of existing regulations will remain a part of the Code of Federal Regulations pending their formal removal, they have no binding effect, in light of the repeal of section 6(b), and will be disregarded in favor of the policies announced in this statement. Affected public housing development regulations include:

24 CFR 904.103(b)
24 CFR 941.203(c)
24 CFR 941.204
24 CFR 941.406(a)
24 CFR 941.502 (b)(3) and (c)(4).

A Findng 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 during regular business hours in the Office of the Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

Dated: June 26, 1986.

J. Michael Dorsey,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 86-21652 Filed 9-23-86; 8:45 am]

BILLING CODE 4210-33-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 5E3264/R852; FRL-3085-4]

Pesticide Tolerance for Hexakis [2-Methyl-2-Phenylpropyl] Distannoxane

AGENCY: Environmental Protection Agency (EPA or Agency).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for the combined residues of the insecticide hexakis [2-methyl-2-phenylpropyl] distannoxane and its organotin metabolites in or on the raw agricultural commodity raspberries. The regulation, to establish maximum permissible levels for residues of hexakis in on raspberries, was requested in a petition by the Interregional Research Project No. 4 (IR-4).

EFFECTIVE DATE: Effective on September 24, 1986.

ADDRESS: Written objections, identified by the document control number, [PP 5E3264/R852, may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Jack Housenger, Emergency Response and Minor Use Section (TS-767C), Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 716B, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-1806).

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule, published in the **Federal Register** of June 11, 1986, (51 FR 21189), which announced that the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, submitted pesticide petition 5E3264 to EPA, on behalf of Dr. Robert H. Kupelian, IR-4 Project National Director, and the Agricultural Experiment Stations of New York, Oregon, and Washington proposing a tolerance for the combined residues of the insecticide hexakis [2-methyl-2-phenylpropyl] distannoxane and its organotin metabolites calculated as hexakis [2-methyl-2-phenylpropyl] distannoxane in or on the raw agricultural commodity raspberries at 10.0 parts per million (ppm); that the use on raspberries be limited to Oregon and Washington based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

There were no comments nor requests for referral to an advisory committee received in response to the notice of proposed rulemaking.

The data submitted in the petition and other relevent material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 15, 1986.

Douglas D. Campt,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR Part 180 is amended as follows:

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.362 is amended by designating the current paragraph and list of tolerances as paragraph (a) and adding paragraph (b) to read as follows:

§ 180.362 Hexakis (2-methyl-2-phenylpropyl) distannoxane; tolerances for residues.

(a) * * *

(b) Tolerances with regional registration are established for residues of the insecticide hexakis [2-methyl-2-phenylpropyl] distannoxane and its organotin metabolites calculated as hexakis [2-methyl-2-phenylpropyl] distannoxane in or on the raw agricultural commodities:

Commodities	Parts per million
Raspberries	10.0

[FR Doc. 86-21494 Filed 9-23-86; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172 and 174

[Docket No. HM-180; Amdt. Nos. 171-88, 172-104, and 174-60]

Placarding Tank Cars Which Contain Hazardous Material Residue; Delay of Effective Date

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Delay of effective date.

SUMMARY: RSPA published a final rule in the **Federal Register** on June 25, 1986, [51 FR 23075], under Docket HM-180 [FR Document 86-14276]. This final rule amended the Department's Hazardous Materials Regulations by changing the definition of the word "RESIDUE" and requiring the use of RESIDUE placards instead of EMPTY placards on tank cars which contain hazardous materials residue. The final rule has an effective date of October 1, 1986. RSPA has received numerous telephone calls from shippers and carriers regarding the unavailability of RESIDUE placards from suppliers. Based on these calls and to allow shippers and carriers adequate time to obtain RESIDUE placards, RSPA believes it is necessary to delay the effective date of the final rule.

In consideration of the foregoing, the effective date of the final rule issued under Docket HM-180, Amendment Nos.

171–88, 172–104 and 174–60 is changed from October 1, 1986 to March 3, 1987.

EFFECTIVE DATE: March 3, 1987.

FOR FURTHER INFORMATION CONTACT:
Lee Jackson, Standards Division, Office of Hazardous Materials Transportation, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Telephone (202) 366–4488.

Issued in Washington, DC on September 17, 1986 under the authority delegated in 49 CFR Part 1.

M. Cynthia Douglass,
Administrator, Research and Special Programs Administration.

[FR Doc. 86–21599 Filed 9–23–86; 8:45 am]
BILLING CODE 4910–60–M

Proposed Rules

Federal Register
Vol. 51, No. 185
Wednesday, September 24, 1986

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 86-NM-191-AD]

Airworthiness Directives; British Aerospace Model BAe-125-800 Series Airplanes

AGENCY: Federal Aviation Administration (FFA), DOT.

ACTION: Notice of Proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt an airworthiness directive (AD) that would require the installation of reinforcing plates on the canopy upper rail at each Frame 2 intersection on certain British Aerospace Model BAe 125-800A and -800B series airplanes. This action is necessary because testing has revealed that cracking of the canopy upper rail is likely to occur, which could result in loss of structural integrity and loss of airplane pressurization.

DATE: Comments must be received no later than November 17, 1986.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel (Attention: ANM-103), Attention: Airworthiness Rules Docket No 86-NM-191-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from British Aerospace, Inc., Librarian for Service Bulletins, Box 17414, Dulles International Airport, Washington DC 20041. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Golder, Standardization Branch, ANM-113; telepone (206) 431-2909. Mailing address: FAA, Northwest Moutain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Office of the Regional Counsel (Attention: ANM-103), Attention: Airworthiness Rules Docket No. 86-NM-191-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

Discussion: The United Kingdom Civil Aviation Authority (CAA) has, in accordance with existing provisions of a bilateral airworthiness agreement, notified the FAA of an unsafe condition which may exist on British Aerospace Model BAe 125-800 series airplanes. Fatigue testing by the manufacturer has shown that cracking is likely to occur in the canopy upper rail at each Frame 2 intersection. Failure to detect and correct this condition could result in loss of structural integrity and loss of airplane pressurization.

British Aerospace has issued Service Bulletin 53-59-(3031B), dated June 5, 1986, which describes the installation of two reinforcing plates on the canopy upper rail at each Frame 2 intersection. Accomplishment of this modification will preclude the potential for cracking to occur in this area. The CAA has classified this service bulletin as mandatory.

This airplane model is manufactured in the United Kingdom and type certificated in the United States under provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since these conditions are likely to exist or develop on airplanes of this model registered in the United States, an AD is proposed that would require the installation of reinforcing plates on the canopy upper rail at each Frame 2 intersection on British Aerospace Model BAe 125-800A and -800B series airplanes, in accordance with the service bulletin previously mentioned.

It is estimated that 16 airplanes of U.S. registry would be affected by this AD, that it would take approximately 24 manhours per airplane to accomplish the required actions, and that the average labor cost would be $40 per manhour. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $15,360.

For the reasons discussed above, the FAA has determined that this document: (1) Involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities because of the minimal cost of compliance per airplane ($960). A final evaluation has been prepared for this regulation and placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

British Aerospace: Applies to Model BAe 125-800A and -800B series airplanes, listed in British Aerospace Service Bulletin 53-59(3031B), dated June 5, 1986, certificated in any category. Compliance is required prior to the accumulation of a total of 3,000 flight cycles, or within the next 90 days after the effective date of this AD, whichever occurs later. To prevent the possible rapid loss of cabin pressurization, accomplish the following, unless previously accomplished:

A. Modify the fuselage canopy upper rail in accordance with section 2, "Accomplishment Instructions," of British Aerospace Service Bulletin 53-59-(3031B), dated June 5, 1986.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this proposed directive who have not already received the appropriate service document from the manufacturer may obtain copies upon request to British Aerospace, Inc., Librarian for Service Bulletins, Box 17414, Dulles International Airport, Washington DC 20041. This document may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on September 17, 1986.

Joseph W. Harrell,

Acting Director, Northwest Mountain Region.

[FR Doc. 86-21554 Filed 9-23-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 86-ACE-2]

Proposed Establishment of VOR Federal Airways V-580 and V-582

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish new Federal Airways V-580 between St. Louis, MO, and Burlington, IA, and V-582 between St. Louis and Quincy, IL. These new airways are designed to enhance and improve traffic flow in the St. Louis terminal area. This action would reduce delays and controller workload.

DATE: Comments must be received on or before November 7, 1986.

ADDRESSES: Send comments on the proposal in triplicate to: Director FAA, Central Region, Attention: Manager, Air Traffic Division, Docket No. 86-ACE-2, Federal Aviation Administration, 601 East 12th Street, Federal Building, Kansas City, MO 64106.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Lewis W. Still, Airspace and Air traffic rules Branch (ATO-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington DC 20591; telephone: (202) 267-9254.

SUPPLEMENTARY INFORMATION:

Comments invited

Interested parties are invited to participated in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the propsal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 86-ACE-2." The postcard will be data/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-430, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2 which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations [14 CFR Part 71] to establish new Federal Airways V-580 and V-582 located in the St. Louis, MO, area. The Kansas City Air Route Traffic Control Center has designed a plan to realign the traffic flow north of St. Louis to enhance and improve traffic flow in that area. Currently, extensive use of radar control is used to maneuver traffic, and these new airways would provide designated airways along these radar tracks. This would reduce controller workload and enhance traffic flow in the St. Louis terminal area. Section 71.123 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6B dated January 2, 1986.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a "major rule" under Executive Order 12291; (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, when promulgated, 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

Aviation safety, VOR Federal airways.

The Proposed Amendment

PART 71—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

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

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

2. Section 71.123 is amended as follows:

V-580 [New]

From St. Louis, MO, via INT St. Louis 355°T(350°M) and Burlington, IA, 165°T(160°M) radials; to Burlington.

V-582 [New]

From St. Louis, MO, via INT St. Louis 355°T(350°M) and Quincy, IL, 127°T(122°M) radials; to Quincy.

Issued in Washington, DC, on September 18, 1986.

Harold H. Downey,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 86-21550 Filed 9-23-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 145

[Docket No. 85N-0502]

Canned Fruit Cocktail; Termination of Consideration of Codex Standard

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking; termination of consideration.

SUMMARY: The Food and Drug Administration (FDA) is terminating consideration of whether to propose to amend the U.S. standards for canned fruit cocktail to make them consistent with the Codex Standard for Canned Fruit Cocktail (Codex Standard 78-1981) (Codex standard), because there is neither sufficient interest nor need to warrant such a proposal.

FOR FURTHER INFORMATION CONTACT: Catherine R. Calvert, Center for Food Safety and Applied Nutrition (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0121.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 29, 1985 (50 FR 49066), FDA published an advance notice of proposed rulemaking offering interested persons an opportunity to review the Codex standard for canned fruit cocktail and to comment on the desirability of, and need for, an amendment to make the U.S. standards of identity, quality, and fill of container for canned fruit cocktail consistent with the Codex standard. FDA requested comments by January 28, 1986, and stated that it would not propose to amend the standards for canned fruit cocktail if the comments that it received did not support this action. The agency extended the comment period to March 31, 1986 (see 51 FR 3797; January 30, 1986), to allow the industry adequate time to evaluate the Codex standard properly and to determine a proper course of action.

FDA received 13 comments on the advance notice of proposed rulemaking. None of the comments supported amending the U.S. standards of identity, quality, and fill of container for canned fruit cocktail based on the Codex standard.

Having considered the comments, FDA concludes that at this time, there is neither sufficient interest nor need to warrant a proposal to amend the U.S. standards for canned fruit cocktail under authority of section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

Therefore, under the procedures in 21 CFR 130.6, notice is given that the Commissioner of Food and Drugs has terminated consideration of whether to propose to amend the U.S. standards of identity, quality, and fill of container for canned fruit cocktail to make them consistent with the Codex standard. This action is without prejudice to further consideration of such a proposal upon appropriate justification.

FDA will inform the Codex Alimentarius Commission that an imported food that complies with the requirements of the Codex standard may move freely in interstate commerce in this country, provided that it complies with applicable U.S. laws and regulations.

Dated: September 18, 1986.

Sanford A. Miller,

Director, Center for Food and Safety and Applied Nutrition.

[FR Doc. 86-21568 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Parts 904 and 941

[Docket No. R-86-1299; FR-2191]

Public Housing Development—Cost Containment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of proposed rulemaking.

SUMMARY: Elsewhere in today's issue of the **Federal Register**, HUD is publishing a statement announcing the public housing cost containment policies to be applied as a replacement for recently repealed statutory prototype requirements. This notice of proposed rulemaking references that policy statement, states HUD's intention to use the substance of the policy statement as the basis for a final rule amending Parts 904 and 941, and invites public comment on the announced cost containment policies. A related procedure will be used to develop cost containment regulations for modernization and Indian housing development projects.

DATE: Comments must be submitted on or before November 24, 1986.

ADDRESSES: Comments on proposal: Interested persons are invited to submit comments to the Rules Docket Clerk, Office of the General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Comments should refer to the above docket number and title. A copy of each comment received will be available for public inspection during regular business hours at the above address. Comments on the information collection requirements contained in the proposal (which include docket number and title) should be submitted both to the HUD Rules Docket Clerk at the above address and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC. 20503, Attention: Desk Officer for HUD.

FOR FURTHER INFORMATION CONTACT: Nancy Chisholm, Director, Policy Staff, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC. 20410, telephone (202) 755-6713. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Department of Housing and Urban Development-Independent Agencies

Appropriations Act, 1986 (Pub. L. 99–160, approved November 25, 1985) repealed section 6(b) of the United States Housing Act of 1937. Section 6(b) required the Secretary to establish prototype costs based on dwelling construction and equipment costs for the development of public and Indian housing. These prototype costs were used to limit costs associated with public and Indian housing development and modernization.

Elsewhere in today's **Federal Register**, HUD is publishing a statement announcing the public housing development cost containment policies to be applied as a replacement for the statutory prototype requirements. The policy statement announces that HUD will develop cost guidelines and will use these guidelines to limit total development costs for public housing projects. The policy statement also describes procedures under which a public housing agency may request revisions to the cost guidelines for an entire market area (or establish a new market area within an existing market area) and circumstances under which the Department will permit a specific project to exceed the total development cost limitation computed under the cost guideline.

HUD intends to use today's policy statement as the basis for a final rule amending the cost containment provisions contained in 24 CFR Parts 904 and 941. For this reason, HUD is inviting public comment on the policy statement so that the final rule on the subject matter will have the benefit of public participation. This notice applies only to public housing development projects. A related procedure will be used to develop cost containment regulations for modernization and Indian housing development projects and will be published separately.

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the Rules Docket Clerk, Room 10276, at the address listed above.

This proposal does not constitute a "major rule," as that term is defined in section 1(b) of Executive Order 12291 issued by the President on February 17, 1981. Analysis of the proposal indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Under the Regulatory Flexibility Act (5 U.S.C. 601), the Undersigned hereby certifies that this proposal does not have a significant economic impact on a substantial number of small entities. Since the proposal is intended to have the effect of containing development costs for public housing projects, it may have an economic impact on builders or developers of public housing, some of whom may constitute small entities, but it is not believed that the number of small entities affected will be substantial.

This proceding was listed as item 948 in the Department's Semiannual Agenda of Regulations published April 21, 1986 (51 FR 14036, 14075A) in accordance with Executive Order 12291 and the Regulatory Flexibility Act.

The information collection requirements contained in this proposal have been submitted to the Office of Management and Budget for review under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520). No person may be subject to a penalty for failure to comply with these information collection requirements until they have been approved and assigned an OMB control number. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

The Catalog of Federal Domestic Assistance Program numbers and titles are 14.850 Public and Indian Housing (for Part 941), and 14.851, Low-Income Housing Homeownership Opportunities for Low Income Families (for Part 904).

List of Subjects

24 CFR Part 904

Grant programs—housing and community development, Loan programs—housing and community development, Low and moderate income housing, Public housing, Homeownership.

24 CFR Part 941

Loan programs—Housing and community development, Public housing, Prototype costs, Cooperative agreements, Turnkey.

Authority. Secs. 4, 5 and 9, United States Housing Act of 1937 (42 U.S.C. 1437b, 1437e, and 1437g); sec. 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: July 17, 1986.

J. Michael Dorsey,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 86–21653 Filed 9–23–86; 8:45 am]

BILLING CODE 4210–33–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 773 and 843

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Extension of Comment Period for Permit Condition and Rescission Rule

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

ACTION: Extension of comment period.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) of the United States Department of the Interior is extending the comment period on a proposed rule amending its regulations which govern the permitting process in order to afford additional time for public comment.

DATE: The comment period on the proposed rule is extended until October 24, 1986.

ADDRESSES: Written comments may be hand-delivered to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 5315, 1100 L Street NW, Washington, DC; or mailed to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 5315–L, 1951 Constitution Avenue NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Andrew F. DeVito, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue NW, Washington, DC 20240; Telephone: 202–343–5950 (Commercial or FTS).

SUPPLEMENTARY INFORMATION: On July 16, 1986 (51 FR 25822) OSMRE published a proposed rule which would amend its regulations governing the permitting process by: (1) Revising the procedures for conditionally approving a permit pending the outcome of a good faith appeal contesting the validity of any existing violations; (2) requiring the regulatory authority to make written findings prior to permit issuance that the applicant, and any operation owned or controlled by either the applicant or any person who owns or controls the applicant, is not responsible for unpaid

civil penalties or AML fees; (3) requiring the regulatory authority to make its decision to appove or disapprove a permit on the basis of up-to-date information concerning the applicant's compliance record; (4) making the payment of all final civil penalties a condition of a permittee's continued right to mine; (5) requiring the regulatory authority to rescind a permit if it determines that any surface coal mining operation owned or controlled by either the permittee or any person who owns or controls the permittee is responsible for outstanding, unabated and unappealed violations, civil penalties, or AML fees which arose prior to permit approval; and (6) enabling OSMRE to order cessation of surface mining operations and commencement or continuation of reclamation if a State fails or lacks authority to rescind a permit. These amendments if adopted, will ensure that persons do not obtain and/or hold permanent program permits if they are in violation of the Surface Mining Control and Reclamation Act of 1977.

OSMRE has received a written request from the Kentucky Department for Surface Mining Reclamation and Enforcement to extend the comment period on the proposed rule in order to afford interested members of the public additional time to comment. As a result, OSMRE is extending the comment period until October 24, 1986, and will accept written comments on the proposed rule until 5 p.m. Eastern time on that date.

Dated: September 18, 1986.

Jed D. Christensen,

Director, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 86-21635 Filed 9-23-86; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300150; FRL-3083-5]

Tolerance Exemptions for Certain Pesticide Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that: (1) Low erucic acid rapeseed oil, when used as an inert ingredient (surfactant, related adjuvants of surfactant) in pesticide formulations applied to growing crops only and (2) oleic acid, when used as inert ingredient (defoaming agent) in pesticide formulations applied to animals, be exempted from the requirement of a tolerance. These proposed regulations were requested by Collins Agricultural Consultants, Inc. and Thompson-Hayward Chemical Co. respectively.

DATE: Written comments, identified by the document control number [OPP-300150], should be received on or before October 24, 1986.

ADDRESS: By mail, submit comments to: Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Registration Support and Emergency Response Branch, Registration Division (TS-767C), Environmental Protection Agency, Rm. 716, CM #2, 1921 Jefferson Davis Highway, Arlington VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Rm. 236 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: N. Bhushan Mandava, Registration Support and Emergency Response Branch, Environmental Protection Agency, 401 M St., SW., Washington, DC. 20460. Office location and telephone number: Registration Support and Emergency Response Branch, Rm. 724A, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-7700).

SUPPLEMENTARY INFORMATION: At the request of the companies named in this document, the Aministrator proposes to amend: (1) 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for low erucic acid rapeseed oil when used as a surfactant, related adjuvants of surfactant in pesticide formulations applied to growing crops only and (2) 40 CFR 180.1001(e) by establishing an exemption from the requirement of a tolerance for oleic acid when used as a defoaming agent in pesticide formulations applied to animals.

Inert ingredients are ingredients that are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting and spreading agents; and propellants in aerosol dispensers and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

Preambles to proposed rulemaking documents of this nature include the common or chemical name of the substance under consideration, the name and address of the firm making the request for the exemption, and toxicological and other scientific bases used in arriving at a conclusion of safety in support of the exemption.

Name of inert ingredient. Low erucic acid rapeseed oil.

Name and address of requestor. Collins Agricultural Consultants, Inc., Route 2—Box 344, Hillsboro, OR 97123.

Bases for approval. Low erucic acid rapeseed oil is affirmed as Generally Recognized As Safe (GRAS) as a food additive under 21 CFR 184.1555(c), for use as edible fats and oils in food, except in infant formula, at levels not to exceed current good manufacturing practice.

Name of inert ingredient. Oleic acid.

Name and address of requestor. Thompson-Hayward Chemical Company, P.O. Box 2383, Kansas City, KS 66110.

Bases for approval. 1. Oleic acid is cleared under 40 CFR 180.1001(c) when used as a diluent in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

2. Oleic acid is cleared under 21 CFR 173.340 as a defoaming agent in processed foods, provided it conforms to 21 CFR 172.862.

3. Oleic acid is cleared under 21 CFR 172.862 as a direct food additive.

4. Oleic acid occurs naturally in the human diet.

EPA has initiated new review procedures for tolerance exemptions for inert ingredients. Under these procedures the Agency conducts a review of the data base supporting any prior clearances, the data available in the scientific literature, and any other relevant data. Based on a review of such data, the Agency has determined that no

additional test data will be required to support these regulations.

Based on the above information and review of its use, it has been found that when used in accordance with good agricultural practices these ingredients are useful and do not pose a hazard to humans or the environment. In conclusion, the Agency has determined that the proposed amendments to 40 CFR Part 180 will not endanger the public health or the environment. It is therefore proposed that the regulations be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, that contains these inert ingredients may request within 30 days after publication of this document in the **Federal Register** that these rulemaking proposals be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulations. Comments must bear a notation indicating both the subject and the petition and document control number [OPP–300150]. Written comments filed in response to these proposals will be available for public inspection in the Registration Support and Emergency Response Branch at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 12, 1986.

James W. Akerman,

Acting Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, it is proposed that 40 CFR Part 180 be amended as follows:

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.1001 is amended by adding and alphabetically inserting the inert ingredients in paragraphs (d) and (e) to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits and Uses
* * *	* *
Low erucic acid rapeseed oil, conforming to 21 CFR 184.1555(c) (CAS Reg. No. NONE).	Surfactant, related adjuvants of surfactant.
* * *	* *
(e) * * *	
* * *	* *
Oleic acid, conforming to 21 CFR 172.862 (CAS Reg. No. 112–80–1).	Defoaming agent.
* * *	* *

[FR Doc. 86–21252 Filed 9–23–86; 8:45 am]

BILLING CODE 6560–50

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. MMPAH–1986–1]

Regulations Governing the Taking and Importing of Marine Mammals

AGENCY: Office of the Administrative Law Judge, Department of Commerce, for the National Marine Fisheries Service (NMFS), NOAA.

ACTION: Notice of revision and supplement relating to formal rulemaking proceeding.

SUMMARY: On August 15, 1986, a Notice announcing the convening of a formal hearing was announced (51 FR 29674 August 20, 1986). This Notice revises and supplements those dates.

DATES: The formal hearing to consider the issuance of an incidental take permit and the population status of Dall's porpoise will commence at 9:30 a.m. December 1, 1986, in Seattle, Washington.

Other dates pertaining to the hearing are set forth in the **"SUPPLEMENTARY INFORMATION"** Section.

ADDRESS: Office of the Administrative Law Judge, Suite 6716, U.S. Department of Commerce, 14th and Constitution Ave., NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Docket Clerk, Office of the Administrative Law Judge, Suite 6716, U.S. Department of Commerce, 14th & Constitution Ave., NW., Washington, DC 20230, Telephone: 202–377–3135.

SUPPLEMENTARY INFORMATION: This matter has now been received and docketed for formal hearing pursuant to the Administrative Procedure Act and the Marine Mammal Protection Act. The above docket number has been assigned by this office and must accompany all submissions. While the matter is before this office, it is the only number which should be used, and replaces Docket No. 60231–6147 contained in the notice published on August 20, 1986. All future submissions in this matter are to be made to this office, unless otherwise directed by the Administrative Law Judge.

As a result of the conference call to the representatives of the parties to this proceeding, the following Order was issued and is here published. Any individual or association not represented in that conference call, who represents that they should be recognized as parties, should show cause to the Administrative Law Judge within 5 days of the publication of this Notice why they should be so named.

In the Matter of: Proposed Regulations to Govern the Taking of Marine Mammals (Dall's Porpoise) Incidental to Commercial Salmon Fishing Operations.

[Docket No. MMPAH–1986–1]

Order

Pursuant to the discussion held with the representatives of the parties to this proceeding on September 12, 1986, the following revision and supplement to the schedule published in the **Federal Register** of August 20, 1986 (51 FR 29674), is hereby promulgated:

Written testimony due: October 14

ALJ publish preliminary issues: October 23
Pre-Hearing Conference: November 3
Final agenda and witness list published: November 10
New testimony submitted on issues not in the Notice of Hearing: November 17
Rebuttal testimony due: November 24
Comments on DEIS due: November 24
Hearing: December 1
Initial Post-Hearing Briefs: December 23
Closing briefs: January 5
Receipt and release of ALJ decision: February 2
Exceptions to ALJ decision: February 23

Dated: September 17, 1986.

Hugh J. Dolan,

Administrative Law Judge.

Dated: September 19, 1986.

Hugh J. Dolan,

Administrative Law Judge.

[FR Doc. 86-21639 Filed 9-23-86; 8:45 am]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 51, No. 185
Wednesday, September 24, 1986

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Public Information Collection Requirements Submitted to OMB for Review

The Agency for International Development submitted the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96–511. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of the entry no later than (ten days after publication). Comments may also be addressed to, and copies of the submissions obtained from the Reports Management Officer, Fred D. Allen, (703) 865–1573, IRM/PE, Room 1100–B, SA–14, Washington, DC 20523.

Date Submitted: September 15, 1986.

Submitting Agency: Agency for International Development

OMB Number:

Form Number:

Type of Submission: Renewal

Title: Collection of information for the Ocean Freight Reimbursement Program

Purpose: A.I.D.'s Ocean Freight program reimburses approved Private and Voluntary Organizations (PVOs) registered with the Agency for their transportation costs incurred when transporting donated goods overseas. To effectively monitor the program, A.I.D. has developed a proposal solicitation package and a monitoring document to collect necessary information from qualified and interested PVOs.

Reviewer: Francine Picoult (202) 395–7231, Office of Management and Budget, Room 3201, New Executive Office Building, Washington, DC 20503.

Dated: September 15, 1986.

Fred D. Allen

Planning and Evaluation Division.

[FR Doc. 86–21595 Filed 9–23–86; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Federal Grain Inspection Service

Soybean Damage Interpretation

AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Notice—revision of soybean interpretative line slide for mold damage.

SUMMARY: FGIS issued a notice in the **Federal Register** on August 1, 1986 (51 FR 27573) that tightened certain soybean damage interpretations to more adequately reflect the implications of damaged soybeans to the domestic and foreign soybean crushing industries. The new interpretations were effective September 1, 1986.

FGIS has evaluated the new damage interpretations on both old and new crop soybeans since the effective date. As a result of evaluation and in consultation with plant pathologists, and various industry and inspection groups, FGIS has determined that the interpretation on line slide "ILS:SB–8.0 Mold Damage, B. Surface Mold Growth" can be relaxed without impairing soybean marketability. The slide depicts soybeans with a grayish, crusty surface mold with little or no apparent internal deterioriation. The fungas *Peronospora manshurica* is often referred to as downy mildew. Damage caused by *P. manshurica* is relatively minor when compared to soybeans which are internally invaded by other fungi/molds due to adverse weather, storage or other conditions. *P. manshurica* causes little or no deterioration to soybean oil quality, but does detract from the overall appearance of the soybeans.

FGIS has reviewed the interpretative line slide for mold damage. FGIS has determined that the revised interpretation should provide that soybeans with mold growth covering 50 percent or more of the seed coat shall be considered damaged. Accordingly the following revised wording will appear on the caption card for SB–8.0:

B. Surface Mold Growth—Soybeans with little or no apparent deterioration having a milky white or grayish crusty growth caused by downy mildew with no splits, cracks or fissures in the seed coat. Seedcoat not discolored. Soybeans that contain downy mildew on 50 percent or more of the seedcoat as shown shall be considered damage.

DATE: This revised interpretation will become effective on September 24, 1986.

Updated caption cards with the new wording may be obtained from S/J Systems, Inc., 647 West Virginia St., Milwaukee, Wisconsin 53204, telephone (414) 271–7112.

Dated: September 19, 1986.

D.R. Galliart,

Acting Administrator, FGIS.

[FR Doc. 86–21643 Filed 9–23–86; 8:45 am]

BILLING CODE 3410–EN–M

Food and Nutrition Service

Availability of Surplus Commodities; Fiscal Year 1987

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces that for the period October 1, 1986 through September 30, 1987, the Department of Agriculture will continue to make available surplus cheese, butter, nonfat dry milk, honey, rice, flour and cornmeal to requesting State agencies for distribution to eligible recipients. The foods are being made available by this announcement under the Temporary Emergency Food Assistance Program (TEFAP) authorized under section 202 of the Temporary Emergency Food Assistance Act of 1983 (Title II of Pub. L. 98–8, as amended).

EFFECTIVE DATE: October 1, 1986.

FOR FURTHER INFORMATION CONTACT: Beverly King, Chief, Program Administration Branch, Food Distribution Division, Park Office Center, Alexandria, Virginia 22302, Telephone (703) 756–3660.

SUPPLEMENTARY INFORMATION: This action has been reviewed under Executive Order 12291 and Secretary's Memorandum No. 1512. It has been classified as "nonmajor", because it meets none of the three criteria in the Executive Order: The action will not have an annual effect on the economy of $100 million or more, will not cause a

major increase in costs, and will not have a significant impact on competition, employment, productivity, innovation, or the ability of U.S. enterprises to compete.

This is not a rule as defined in the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq), and thus is exempt from the provisions of that Act. The purpose of the action is to notify States of the types and quantities of foods to be made available for household distribution during Fiscal Year 1987.

This notice imposes no new reporting or recordkeeping provisions that are subject to Office of Management and Budget review.

The Secretary anticipates that the following commodities and amounts will be made available during Fiscal Year 1987 to agencies of State govenments which request them for distribution to eligible recipients: cheese, 420 million pounds; flour, 144 million pounds; rice, 180 million pounds; nonfat dry milk, 96 million pounds; honey, 96 million pounds; butter, 72 million pounds; and cornmeal, 48 million pounds.

The actual types and quantities of commodities made available by the Department may differ from these estimates. The foods made available under this notice will be targeted to needy persons, including low-income and unemployed persons. These foods are being offered under the provisions of Title II of Pub. L. 98–8, as amended by Pub. L. 99–198, the Food Security Act of 1985, approved December 23, 1985.

Authority: Sec. 210(c), Pub. L. 98–8, as amended.

(Catalog of Federal Domestic Assistance No. 10.550)

Dated: August 26, 1986.

Robert E. Leard,

Administrator, Food and Nutrition Service.

[FR Doc. 86–21632 Filed 9–23–86; 8:45 am]

BILLING CODE 3410-30-M

DEPARTMENT OF COMMERCE

National Technical Information Service

Intent of Grant Exclusive Patent License; Robert Laboratories, Inc.

The National Technical Information Service (NTIS), U.S. Department of Commerce, intends to grant to Roberts Laboratories, Inc. having a place of business in Red Bank, NJ and Porton Products, Ltd. of Encino, CA, a co-exclusive right in the United States to practice the invention entitled "Process for Manufacture of L-Asparaginase from Erwinia Carotovora," U.S. Patent Application Serial Number 6–808,729. The patent rights in this invention have been assigned to the United States of America, as represented by the Secretary of Commerce.

The proposed co-exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The proposed license may be granted unless, within sixty days from the date of this published Notice, NTIS receives written evidence and argument which establishes that the grant of the proposed license would not serve the public interest.

Inquiries, comments and other materials relating to the proposed license must be submitted to Papan Devnani, Office of Federal Patent Licensing, NTIS, Box 1423, Springfield, VA 22151.

Douglas J. Campion,

Patent Licensing Specialist, Office of Federal Patent Licensing, U.S. Department of Commerce, National Technical Information Service.

[FR Doc. 86–21594 Filed 9–23–86; 8:45 am]

BILLING CODE 3510-04-M

CONSUMER PRODUCT SAFETY COMMISSION

Labeling of Asbestos-Containing Household Products; Enforcement Policy

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of enforcement policy.

SUMMARY: The Commission is issuing an enforcement policy for household products containing intentionally added asbestos that, under reasonably foreseeable conditions of handling and use, are likely to release asbestos fibers.[1] Under the Federal Hazardous Substances Act, such products are hazardous substances and, if not labeled properly, misbranded hazardous substances. Human evidence has shown asbestos fibers to cause cancer and other chronic illness, and the fibers can be inhaled when released into homes. Once the policy applies to asbestos products, the Commission intends to bring individual enforcement actions against products that are not properly labeled (or against their manufacturers, distributors, or importers). Such actions will provide full opportunities for the Commission's technical data and legal conclusions to be contested. In addition, such enforcement actions will be preceded by opportunities for industry members and Commission staff to discuss the applicability of the enforcement policy to particular products containing asbestos.

DATE: The enforcement policy becomes effective on December 23, 1986, and applies to asbestos products that are manufactured or initially distributed for consumer use on or after that date.

FOR FURTHER INFORMATION CONTACT: Charles M. Jacobson, Division of Regulatory Management, Directorate for Compliance and Administrative Litigation, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 492–6400.

SUPPLEMENTARY INFORMATION:

A. Background

For several years, the Commission has investigated household products containing asbestos as an intentionally-added substance. With the Commission's encouragement, some manufacturers and distributors of these products have replaced the asbestos with substitute materials or marketed substitute products. However, some household products remaining on the market are capable of releasing asbestos fibers during such reasonably foreseeable uses as installation, manipulation, removal, and other stresses.

The Commission has investigated categories of asbestos-containing household products, but stresses that not every product in these categories will necessarily present a significant risk of asbestos fiber releease. By the same token, there may be household products that present such a risk but are not in one of the categories (because the Commission is currently unaware of them). The categories of products are: paper and millboard products, dry mix furnace cement, wood and coal burning stove door gaskets, laboratory and artists' materials, gloves, stove pads, iron rests, duct connectors, bulk asbestos fibers, and asbestos cement sheet.

The Commission considered numerous options for addressing the health risks presented by some household asbestos products. Among them were initiating a proceeding to ban them, pursuing enforcement actions under section 15 of the Consumer Product Safety Act, seeking additional voluntary remedies, issuing a safety alert, and commenting on a ban proposed by the Environmental Protection Agency (EPA). On June 26,

[1] Commissioner Anne Graham and Commissioner Carol G. Dawson voted to publish this notice. Chairman Terrence M. Scanlon dissented from the decision to issue an enforcement policy.

1986, the Commission decided to (1) issue an enforcement policy concerning the requirements for labeling certain asbestos products under the Federal Hazardous Substances Act (FHSA), (2) issue a safety alert on asbestos products, and (3) comment on EPA's proposed rule.

B. Health Risks Presented

A Chronic Hazard Advisory Panel (CHAP) on Asbestos, convened by the Commission and composed of outside experts, concluded in its 1983 final report that "[a]sbestos of many fiber types and fiber sizes is clearly linked to the production of cancer, with risk increasing as the amount of asbestos exposure increases . . . it is prudent to behave as if asbestos fibers may be carcinogenic at low exposure levels and at small particle sizes."

Case studies and epidemiological studies reported after the CHAP report further support an association between asbestos exposure in humans and mesothelioma, lung cancer, cancer of the gastrointestinal tract and non-malignant diseases of the respiratory system.

Exposure testing on asbestos products was conducted at two Commission laboratories and under two EPA contracts. In each test, the product was placed inside a sealed container or room and subjected to a manipulation designed to simulate some aspect of consumer use. The tests were selected to represent conditions, ranging from mild disturbance to destructive handling, under which the products would be used in the home. These laboratory experiments demonstrated that readily measurable quantities of asbestos are released during reasonably foreseeable consumer use of asbestos products tested. Estimates were made of personal breathing zone exposure, closed workroom exposure, and average home exposure.

Estimated risks vary with the amounts of fibers estimated to be inhaled. The highest lifetime estimated risk of lung cancer/mesothelioma was estimated from installation of asbestos cement sheet on a wall behind a stove using an abrasive wheel saw and drill in a closed room, when age of the installer at first exposure is between 20 and 50 years of age. This risk ranged from 6.8 to 68 per million. The lowest estimated risk of lung cancer/mesothelioma ranged from 0.002 to 0.02 per million when asbestos paper is wrapped around duct work in an average home and the age of someone in the house (not the installer) at first exposure is under 50 years of age. These estimates do not include or fully account for release that may occur over time due to deterioration of the product.

C. Market Data

The Commission believes that asbestos paper, millboard, cement sheet, burner pads, furnace cement, stove door gaskets, gloves, and duct connectors are available for use or purchase by consumers, although some of these products are no longer being manufactured. Most production and private labeling of these products for household use ceased in the late 1970's.

For the asbestos products still produced, the number of manufacturers or private labelers involved is very small. Asbestos substitutes, developed for industrial applications, are available for the products at various prices and are widely used.

D. EPA Proposed Ban

In January 1986 the Environmental Protection Agency proposed an immediate ban on the manufacture of the following asbestos products; roofing and flooring felts, vinyl asbestos floor tile, asbestos clothing, and asbestos-cement pipe and fittings (51 FR 3738; Jan. 29, 1986). The proposal would also ban other asbestos products within ten years, including the household products of concern to the Commission (asbestos cement sheet could be banned immediately under some EPA alternatives). Under the Toxic Substances Control Act, EPA has regulatory jurisdiction that overlaps the Commission's.

The enforcement policy described below, concerning FHSA labeling requirements, is an interim measure that will alert consumers to risks presented by some household asbestos products until those products are no longer marketed.

E. Conclusion

Based on the information summarized above, the Commission has reached a conclusion about household products containing intentionally-added asbestos that, under any reasonably foreseeable conditions of handling and use, are likely to release asbestos fibers. The Commission believes that such products are "misbranded hazardous substances" under the FHSA when they are not appropriately labeled under that Act. This belief is based on the FHSA statutory provisions and available technical data.

Certain FHSA definitions underlie the Commission's statutory authority concerning asbestos-containing household products: Under section 2(g), "[t]he term 'toxic' shall apply to any substance . . . which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." Under section 2(f)(1)(A), "[t]he term 'hazardous substance' means . . . [a]ny substance or mixture of substances which . . . is toxic . . . if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use. . . ." Under setion 2(p), "[t]he term 'misbranded hazardous substance' means a hazardous substance . . . intended, or packaged in a form suitable, for use in the household . . . if such substance . . . fails to bear [specified precautionary labeling]. . . ."

Section 2(p)(1) of the FHSA requires hazardous substances, to avoid being misbranded, to state (1) the name and place of business of the manufacturer, packer, distributor, or seller; (2) the name of the hazardous substance; (3) a signal word; (4) an affirmative statement of the principal hazard(s); (5) precautionary measures; (6) instructions for handling and storage; and (7) "Keep out of the reach of children."

The specific labeling required for asbestos-containing household products depends, to some extent, on the type of product. While the firms marketing the products are responsible for assuring adequate labeling under section 2(p), the Commission's compliance staff is available to provide advice upon written request. The procedures for obtaining such labeling assistance can be found at 16 CFR 1500.128.

As one example of labeling, the Commission believes that the following language (drawn primarily from current occupational labeling) would be adequate for any asbestos cement sheet products that require labeling:

WARNING: BREATHING FIBERS MAY CAUSE CANCER

Contains asbestos which is known to cause cancer in humans.
Manipulation may release fibers.
Wear respirator approved for use with asbestos.
Do not dry sweep; use wet procedures for clean-up.
Dispose of any residue, unused material, and materials used in clean-up in a manner that will not create airborne fibers.
Operations with high speed power operated machinery with abrasive cutting or sanding discs can increase respirable dust levels.
Once in place, asbestos structural products should be disturbed as little as possible.

[Additional product-specific language as appropriate]

KEEP OUT OF THE REACH OF CHILDREN.

The Commission encourages firms to continue voluntarily phasing out the use of asbestos in household products and using less hazardous substitutes. The enforcement policy should not be taken as an encouragement to firms to market properly-labeled asbestos products. In addition, the Commission recognizes that the rule proposed by EPA may eventually ban some or all of the products. If so, the enforcement policy issued below will have served as an interim measure only.

Under the enforcement policy, certain household products containing asbestos are subject to cautionary labeling designed to protect consumers from chronic health risks, including lung cancer and mesothelioma. As a result, states and local governments are prohibited from "[establishing] or [continuing] in effect a cautionary labeling requirement applicable to such [products] or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p). . . ." 15 U.S.C. 1261n (FHSA, section 18(b)(1)(A)). In short, the Commission intends that any such nonidentical labeling requirements are preempted by the enforcement policy.

E. Enforcement policy

For the reasons discussed above, the Commission believes that household products that conttain intentionally-added asbestos and are likely to release asbestos fibers under any reasonably foreseeable conditions of handling or use are toxic under section 2(g) of the FHSA. When such asbestos fibers are inhaled, these products can cause chronic illness, including lung cancer and mesothelioma. In addition, test data and risk assessments show that, during or as a proximate result of any customary or reasonably foreseeable handling or use, they may release asbestos fibers that can cause substantial illness. Such asbestos-containing products are therefore "hazardous substances" under section 2(f)(1)(A) of the FSHA and, if not properly labeled, "misbranded hazardous substances" under section 2(p)(1).

Under the FHSA, firms are responsible for deciding whether their asbestos products meet the "hazardous substance" definition. The Commission recognizes that this decision may be a difficult one, and will therefore assist firms to the fullest extent possible. Specifically, one portion of the enforcement policy will involve an informal process in which firms can present to the Commission staff evidence that their individual products do not release asbestos fibers that can cause substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use. The policy can only be fairly administered with such a case-by-case approach that recognizes differences in the levels of risk presented by different household products containing asbestos.

For example, the staff is already aware of an asbestos product that it believes does not meet the definition. In asbestos roofing cement the asbestos is bound up in a tar-like substance and the product is not "worked" or manipulated during use. Few, if any, fibers are released and the staff's opinion is that asbestos roofing cement need not be labeled under the Commission's enforcement policy.

In addition, a firm has already raised the question of whether the policy would apply to products containing trace quantities of naturally occurring asbestos contaminants. The Commission intends the policy to be applied only to products to which asbestos has been intentionally added.

The Commission's policy will be to bring enforcement cases against persons committing acts prohibited by section 4 of the FHSA relating to misbranded hazardous substances that are intended or packaged in a form suitable for use in the household and that, under reasonably foreseeable conditions of handling or use, are likely to release asbestos fibers. Such misbranded hazardous substances themselves may also be subject to actions for seizure under section 6 of the FHSA.

This enforcement policy will become effective on December 23, 1986. It will be applied to household products that are manufactured or initially distributed for consumer use on or after that date. It will *not* be applied to products that have been sold to consumers, have been in the hands of retailers, or have been in retail channels of distribution before that date. The Commission expects this period of time to be adequate to permit a smooth transition to proper labeling of all household asbestos products.

For the purposes of the enforcement policy, an asbestos product used both industrially and by consumers would be considered to be "manufactured" when it is packaged (or repackaged) for consumer use or otherwise diverted from industrial to consumer channels. It is at that time that the *household* asbestos product is manufactured.

The Commission emphasizes that the enforcement policy will not affect any household asbestos products that are labeled in accordance with section 2(p) of the FHSA. In addition, the policly is not a binding rule but merely a notice of the Commission's intention to bring appropriate enforcement actions under the FHSA. In any such actions, any parties who disagree about whether particular asbestos products are misbranded hazardous substances will have the opportunity to challenge the Commission's technical data and legal conclusions in federal district court.

Because this enforcement policy is not a proposed or final rule, the Regulatory Flexibility Act is inapplicable. Further, neither the publication of this notice nor the bringing of enforcement cases under the policy has any significant potential for affecting the environment, and no environmental assessment or environmental impact statement is required.

Dated: September 18, 1986.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 86-21603 Filed 9-23-86; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Organization of the Joint Chiefs of Staff; Joint Strategic Target Planning Staff (JSTPS), Scientific Advisory Group; Closed Meeting

AGENCY: Joint Strategic Target Planning Staff, Department of Defense.

ACTION: Notice of closed meeting.

SUMMARY: The Director, Joint Strategic Target Planning Staff, has scheduled a closed meeting of the Scientific Advisory Group.

DATE: The meeting will be held 21 and 22 October 1986.

ADDRESS: The meeting will be held at Offutt AFB, Nebrasks.

FOR FURTHER INFORMATION CONTACT: The Joint Strategic Target Planning Staff, Scientific Advisory Group, Offutt AFB, Nebraska 68113.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to discuss strategic issues which relate to the development of the Single Integrated Operational Plan (SIOP). Full development of the topics will require discussion of information classified TOP SECRET in accordance with Executive Order 12356, 2 April 1982. Access to this

information must be strictly limited to personnel having requisite security clearances and specified need-to-know. Unauthorized disclosure of the information to be discussed at the SAG meeting could have exceptionally grave impact upon national defense. Accordingly, the meeting will be closed in accordance with 5 U.S.C. 552b(c)(1).

Linda M. Lawson,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

September 18, 1986.

[FR Doc. 86-21611 Filed 9-23-86; 8:45 am]

BILLING CODE 3810-01-M

DEPARTMENT OF ENERGY

Conduct of Employees; Divestiture Requirements

Section 602(a) of the Department of Energy Organization Act (Pub. L. 95-91, hereinafter referred to as the "Act") prohibits a "supervisory employee" (defined in section 601(a) of the Act) of the Department from knowingly receiving compensation from, holding any official relation with, or having any pecuniary interest in any "energy concern" (defined in section 601(b) of the Act).

Section 602(c) of the Act authorizes the Secretary of Energy to waive the requirements of section 602(a) in cases of exceptional hardship or where the interest is a pension, insurance, or other similarly vested interest.

Mr. Stephen H. Kale is under consideration for the position of Associate Director for Geologic Repositories in the Office of Civilian Radioactive Waste Management of the Department of Energy. Mr. Kale has an interest in the Westinghouse Electric Corporation Pension Plan as a result of his past employment by the company.

It has been established to my satisfaction that requiring Mr. Kale to divest his interest in the Westinghouse Electric Corporation Pension Plan would impose an exceptional hardship on him and that such interest is a vested pension interest, within the meaning of section 602(c) of the Act. Accordingly, I have granted Mr. Kale a waiver of the divestiture requirements of section 602(a) of the Act, for the duration of his employment with the Department, with respect to his interest in the Westinghouse Pension Plan.

In accordance with section 208 of title 18, United States Code, Mr. Kale will be directed not to participate personally and substantially, as a Government employee, in any particular matter the outcome of which could have a direct and predictable effect upon the Westinghouse Electric Corporation unless his supervisor and the Counselor agree that his financial interest in the particular matter is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect of him.

In addition, in accordance with subsection (a) and (b) of section 606 of the Department of Energy Organization Act, Mr. Kale will be directed not to participate—

1. For a period of one year after terminating his employment with Westhinghouse Electric Corporation, in any Department proceeding in which the company is substantially, directly, or materially involved, other than a rulemaking proceeding having a substantial effect on numerous energy concerns; and

2. For a period of one year after commencing service in the Department, in any Department proceeding for which he had direct responsibility, or in which he participated personally and substantially, within the previous five years while in the employment of Westinghouse Electric Corporation;

unless the Secretary makes a written finding that the application of such prohibition would be contrary to the national interest.

Dated: September 16, 1986.

John S. Herrington,

Secretary of Energy.

[FR Doc. 86-21607 Filed 9-23-86; 8:45 am]

BILLING CODE 6450-01-M

National Petroleum Council, Historical Factors Task Group; Meeting

Notice is hereby given that the Historical Factors Task Group will meet in October 1986. The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas or the oil and natural gas industries. The Historical Factors Task Group is responsible for the identification and analysis of events, governmental policies, and actions (federal, state, and local), and the reactions of the oil and gas industries to such events, policies and actions (i.e, the "factors") that affect the supply of and demand for oil and gas in the U.S. since the end of World War II.

The Historical Factors Task Group will hold its eighth meeting on Monday, October 20, 1986, starting at 10:00 a.m., in the Conference Room of the National Petroleum Council, 1625 K Street, NW., Washington, DC.

The tentative agenda for the Historical Factors Task Group meeting follows:

1. Opening remarks by the Chairman and Government Cochairman.

2. Discussion of the factors affecting petroleum supply and demand.

3. Discuss any other matters pertinent to the overall assignment from the Secretary of Energy.

The meeting is open to the public. The Chairman of the Historical Factors Task Group 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 Historical Factors Task Group will be permitted to do so, either before or after the meeting. Members of the public whos wish to make oral statements should inform Ms. Pat Dickinson, Advanced Fuels, Technology, Extraction and Environmental Controls, Fossil Energy, 301/353-2430, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Summary minutes of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room 1E-190, DOE Forrestal Building, 1000 Independence Avenue SW., Washington, DC., between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on September 16, 1986.

Donald L. Bauer,

Acting Assistant Secretary for Fossil Energy.

[FR Doc. 86-21606 Filed 9-23-86; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. CP86-480-001 and CP84-654-016]

Algonquin Gas Transmission Co; Amendment and Petition to Amend

September 15, 1986.

Take notice that on September 11, 1986, Algonquin Gas Transmission Company (Applicant), 1284 Soldiers Field Road, Boston, Massachusetts 02135, filed in Docket No. CP86-480-001 an amendment to its application filed in Docket No. CP86-480-000 pursuant to section 7(c) of the Natural Gas Act, and filed in Docket No. CP84-654-016 a petition to amend the order issued August 15, 1985, in Docket Nos. CP84-654-000 and CP84-654-001 (32 FERC ¶ 61,227) pursuant to section 7(c) of the Natural Gas Act so as to reflect changes

in the construction and operation of facilities, all as more fully set forth in the amendment and petition to amend which is on file with the Commission and open to public inspection.

Applicant states that by the order issued August 15, 1985, the Commission granted Texas Eastern Transmission Corporation (Texas Eastern) a certificate to sell natural gas to various customers including Applicant under its Rate Schedule DCQ. Applicant further states that in Docket No. CP84–654–001 it was authorized to provide sales service to its customers totalling 69.084 billion Btu equivalent of natural gas per day under its Rate Schedule F–4 from its share of the additional Texas Eastern supply which was to be implemented in three phases: (1) Interruptible service; (2) Development period service; and (3) Full firm service. It is stated that the full firm service is scheduled to commence on November 1, 1986.

Applicant alleges that due to unavoidable delays it will not be able to complete all the facility construction necessary to implement the full firm service phase on November 1, 1986, but would have sufficient capacity to deliver a reduced quantity of 62.243 billion Btu equivalent of natural gas per day. As a result, Applicant now requests authorization in Docket No. CP84–654–016 to amend the August 15, 1985, order to provide for a second development period of firm service at the reduced level of 62.254 billion Btu equivalent of natural gas per day from November 1, 1986, through October 31, 1987. Applicant states that the facilities demand handling charge under Rate Schedule F–4 for the second development period would be $22.756 per billion Btu equivalent.

Applicant states further that the Commission on August 1, 1986, in Docket Nos. CP84–429–012, *et al.*, authorized Texas Eastern, among other things, to increase its Rate Schedule DCQ service to Applicant on November 1, 1985, by an additional 4.612 billion Btu equivalent of natural gas per day. Applicant states that it in turn filed an application in Docket No. CP86–480–000 requesting authority to increase its Rate Schedule F–4 service by such amount which is currently pending before the Commission.

In conjunction with the need to delay commencement of a portion of the original authorized Rate schedule F–4 service, Applicant requests authority in Docket No. CP86–480–001 to delay commencement of firm service for the additional 4.612 billion Btu equivalent of natural gas per day increment pending authorization in Docket No. CP86–480–000 until November 1, 1987. Applicant states that the full service of 73.696 billion Btu equivalent of natural gas per day under Rate Schedule F–4 would commence on November 1, 1987.

Applicant also requests that the Commission consolidate Docket Nos. CP84–654–000 and 001 and Docket No. CP86–480–000 with the amendments filed herein for purposes of considering this revised schedule for Rate Schedule F–4 service.

Any person desiring to be heard or to make any protest with reference to said amendment and petition to amend should on or before September 29, 1986, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. All persons who have heretofore filed need not file again.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86–21572 Filed 9–23–86; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TA86–19–20–000 & 001]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

September 18, 1986.

Take notice that Algonquin Gas Transmission Company ("Algonquin Gas") on September 11, 1986 tendered for filing Fifteenth Revised Sheet No. 203 to its FERC Gas Tariff, Second Revised Volume No. 1.

Algonquin Gas states that such tariff sheet is being filed to reflect in its Rate Schedule F–2 a change in the rates of Texas Eastern Transmission Corporation's ("Texas Eastern") underlying Rate Schedule FTS, as reflected in Texas Eastern's September 2, 1986 filing of Eighty-first Revised Sheet No. 14, proposed to be effective September 2, 1986.

Algonquins Gas requests that the Commission accept Fifteenth Revised Sheet No. 203 to be effective September 2, 1986 to coincide with the proposed effective date of Texas Eastern's rate change.

Algonquin Gas notes that a copy of this filing is being served upon each affected party and interested state commission.

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, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 26, 1986. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86–21573 Filed 9–23–86; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER86–643–000]

Arkansas Power & Light Co.; Filing

September 15, 1986.

Take notice that on August 1, 1986, Arkansas Power & Light Company (AP&L) tendered for filing in Docket No. ER85–563–002 its annual update to reflect the true-up of actual costs for the preceding year for service under its M33 and M33A Rate Schedules to Arkansas Municipally Owned Electric Distribution Systems and Rural Electric Cooperatives. AP&L states that the rate filings reflect estimated charges for the period beginning September 1, 1986. AP&L states in its filing that under the terms of the rate schedules the updated rates are to take effect as of September 1, 1986.

Notice of this filing was previously issued in Docket Number ER85–563–002 and was published in the **Federal Register** on August 19, 1986. AP&L's filing has now been redesignated as being Docket Number ER86–643–000.

AP&L states that copies of its filing have been sent to the wholesale customers affected by the filing and to the Public Service Commissions of Arkansas, Louisiana, Missouri and Tennessee.

Any person desiring to be heard or to protest this application should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance

with Section 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 22, 1986. 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 application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-21574 Filed 9-23-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TA86-2-14-002]

Lawrenceburg Gas Transmission Corp.; Proposed Change in FERC Gas Tariff

September 18, 1986.

Take notice that on September 12, 1986, Lawrenceburg Gas Transmission Corporation (Lawrenceburg) Tendered for filing two (2) substitute revised gas tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1, both of which are dated as issued on September 9, 1986, proposed to become effective August 1, 1986, and, identified as follows:

Substitute Thirty-ninth Revised Sheet No. 4
Substitute Thirty-fifth Revised Sheet No. 18.

Lawrenceburg states that its substitute revised tariff sheets were filed under its Purchased Gas Adjustment (PGA) Provision and to comply with the Commission's July 30, 1986 order in this docket that required Lawrenceburg to track any reduction in the rates being tracked of its pipeline supplier. On September 2, 1986, Texas Gas Transmission Corporation filed to reduce its August 1, 1986 PGA, prompting Lawrenceburg to refile its previously approved August 1, 1986 PGA.

Copies of this filing were served upon Lawrenceburg's jurisdictional customers and interested state commissions.

Lawrenceburg has also filed a Petition For Waiver Of Filing Fee. In support of this petition, Lawrenceburg submits it is suffering from a severe financial hardship, as shown on Exhibit 1 attached to the filing. Lawrenceburg states it has already paid $4,000 in filing fees in connection with this PGA filing which the Commission approved in its July 30, 1986 order; and that this filing is a revision in accordance with that order which requires Lawrenceburg to file to track subsequent rate reductions of its pipeline supplier, Texas Gas Transmission Corporation.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before September 26, 1986. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-21575 Filed 9-23-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP86-161-000]

MIGC, Inc.; Tariff Filing

September 18, 1986.

Take notice that on September 12, 1986, MIGC, Inc. (MIGC) tendered for filing to its FERC Gas Tariff, Original Volume No. 1 the following tariff sheets applicable to form and interruptible transportation of natural gas for others by MIGC:

Ninth Revised Sheet No. 1
Original Sheet No. 1A
Thirty-Eighth Revised Sheet No. 32
Original Sheet Nos. 267 through 270
Original Sheet Nos. 274 through 277
Original Sheet Nos. 282 through 311
Original Sheet Nos. 317 through 326
Original Sheet Nos. 330 through 339

In its transmittal letter, MIGC states that it has been performing non-discriminatory 311 transportation service on a blanket basis for others both before and since June 30, 1986, based on its waiver request in Docket No. RP86-134-000. Furthermore, MIGC states that it intends to become an "open access" transporter, as reflected in its blanket certificate application in Docket No. CP86-596-000. The rate charged for this service is the 25 cent rate appearing in both the T-1 rate schedule approved in Docket No. RP84-15-000 and the ITS rate schedule in the 436 application.

MIGC explains that it has already filed its rates, rate schedules, and general terms and conditions for firm and interruptible transportation in conformity with § 284.7 of the Regulations in Docket No. CP86-596-000. MIGC states that it is making essentially the same filing herein as appears in the earlier blanket certificate application; the only difference is that this filing is nominated with an RP docket.

Included in the instant filing are the pro forma tariff sheets applicable to the transportation services which MIGC would perform under this blanket certificate. Thirty-Eighth Revised Sheet No. 32 contains the Statement of Rates showing the rates applicable to ITS-1 and FTS-1 transportation service. According to MIGC, these rates are derived from the "Period III" rates recently approved by the Commission in Docket No. RP84-15, et al. The only change to these rates is the calculation of minimum rates and the addition of firm transportatin rates reflecting a reservation charge and a commodity charge, consistent with § 284.7 of the Commission's regulations and the Commission's precedent thereunder. The transmittal letter also notes that the T-1 rate, from which the ITS-1 and FTS-1 rates are derived, is an "unbundled" rate, again consistent with § 284.7 of the Commission's regulations; that the reservation charge is calculated by extracting the fixed costs included in the T-1 (interruptible transportation) rate approved in Docket No. RP84-15, et al, using the same methodology approved for the calculation of Period III sales rates in RP84-15; and that the FTS-1 maximum rate is equal to the ITS-1 rate when service is provided at 100% of Transportation Demand.

MIGC requests that the existing interruptible transportation Rate Schedule T-1 be cancelled and Rate Schedules FTS-1 and ITS-1 be made applicable to all firm and interruptible self-implementing transportation service and all existing transportation services to which existing Rate Schedule T-1 currently applies. Rate Schedule ITS-1 rates continue to be unbundled and 100% volumetric, incorporate minimum and maximum rates in compliance with Order No. 436, and otherwise satisfy the requirements of § 284.7.

Original Sheet Nos. 267-270 include Rate Schedule ITS-1 applicable to interruptible transportation service to be offered under the blanket certificate authorization and the interim 311 service. Original Sheet Nos. 274-277 include Rate Schedule FTS-1 for comparable firm transportation.

Original Sheet Nos. 282-311 include General Transportation Terms and Conditions applicable to both ITS-1 and FTS-1 transportation service. Among

other things, these General Terms and Conditions allocate capacity first to existing firm sales customers, then to interruptible transportation customers with executed transportation service agreements in effect with MIGC prior to June 30, 1986. Finally, capacity is allocated to parties requesting service on or after June 30, 1986 or requesting changes in existing agreements on a first come, first served basis, with requests for amendments being treated as new requests for service.

Original Sheet Nos. 317–326 include a pro forma ITS–1 interruptible transportation service agreement. Original Sheet Nos. 330–339 include a pro forma FTS–1 firm transportation service agreement.

MIGC requests an effective date of July 1, 1986 for all tendered tariff sheets. MIGC requests waiver of §§ 284.7 and 154.22 of the Commission's Regulations to the extent necessary to allow for this effective date, along with whatever other waivers the Commission may deem necessary for the acceptance of this filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before September 26, 1986. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86–21576 Filed 9–23–86; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER86–705–000]

The Montana Power Co.; Filing

September 16, 1986.

Take notice that on September 11, 1986, The Montana Power Company (MPC) tendered for filing pursuant to section 205 of the Federal Power Act the following agreements for the sale of excess energy by MPC to other electric utilities:

Purchaser	Date of agreement
Pacific Gas and Electric Company	Oct. 23, 1985.
Western Area Power Administration	Oct. 24, 1985.
San Diego Gas & Electric Company	Nov. 15, 1985.
City of Glendale, California	Dec. 31, 1985.
City of Pasadena, California	Dec. 31, 1985.
City of Burbank, California	Dec. 31, 1985.
San Diego Gas & Electric Company	Mar. 7, 1985.
Portland General Electric Company	May 1, 1986.

MPC states that the rates for electric service under these agreements are negotiated rates which are based in part on existing electric supply conditions in the Pacific Northwest. Montana has requested waiver of the notice provisions of § 35.3 of the Commission's regulations in order to make each of these agreements effective as of the date on which service thereunder commenced.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before September 29, 1986. 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 proceedings. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86–21577 Filed 9–23–86; 8:45 am]

BILLING CODE 6717–01–N

[Docket No. RP86–162–000]

Natural Gas Pipeline Co., of America; Change in FERC Gas Tariff

September 18, 1986.

Take notice that on September 15, 1986, Natural Gas Pipeline Company of America (Natural) submitted for filing Original Volume No. 1A of its FERC Gas Tariff to be effective October 1, 1986.

Natural states that the purpose of this filing is to set out the provisions under which it intends to operate while providing firm transportation service pursuant to §§ 284.8 and 284.10 of the Commission's Regulations.

A copy of this filing was mailed to Natural's jurisdictional customers and to interested state regulatory agencies.

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, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211. All such motions or protests must be filed on or before September 26, 1986. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86–21578 Filed 9–23–86; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TA87–1–37–000, 001]

Northwest Pipeline Corp.; Change in Rates Pursuant to Purchased Gas Cost Adjustment

September 18, 1986.

Take notice that on September 15, 1986, Northwest Pipeline Corporation ("Northwest") submitted for filing a proposed change in rates applicable to service rendered under rate schedules affected by and subject to Article 16, Purchased Gas Cost Adjustment Provision ("PGA"), of its FERC Gas Tariff, First Revised Volume No. 1. Such change in rates is for the purpose of: (1) Reflecting changes in Northwest's estimated cost of purchased gas; and (2) Projecting incremental surcharges to be assessed Northwest's affected direct and sales for resale customers pursuant to Order No. 49.

The current PGA adjustment, for which notice is given herein, aggregates to a decrease of 1.247¢ per therm in the commodity rate for all rate schedules affected by and subject to the PGA as set forth on Twenty-Ninth Revised Sheet No. 10. There is no change in the demand rate. Alternate Twenty-Ninth Revised Sheet No. 10 is also submitted in the event the Commission accepts the alternate case proposed in Northwest's August 29, 1986 filing in Docket Nos. RP84–59 and RP85–13. The annual change in Northwest's rates is a decrease of approximately $23 million. Northwest, on July 31, 1986, filed a request for delay in both the filing and effective date of this PGA filing; therefore, Northwest has requested an effective date of November 1, 1986 for the tariff sheets contained herein. Northwest also tendered for filing and acceptance Thirteenth Revised Sheet No. 10–B setting forth revised projected incremental pricing surcharges and

Sixth Revised Sheet No. 128 to correct a textural reference specifying the location in the Commission's regulations where the calculation of carrying charges associated with Account No. 191 are discussed.

A copy of this filing has been mailed to all parties of record in Docket No. RP72-154-000, upon all jurisdictional customers, and affected state regulatory commissions.

Any persons desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before September 26, 1986. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-21579 Filed 9-23-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP86-404-001]

Texas Eastern Transmission Corp.; Amended Application

September 15, 1986.

Take notice that on September 3, 1986, Texas Eastern Transmission Corporation (Applicant), P.O. Box 2521, Houston, Texas 77252, filed in Docket No. CP86-404-001 an amended application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the interruptible transportation of natural gas for certain shippers, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant requests authorization to transport natural gas on an interruptible basis for the City of Norwich Department of Public Utilities (Norwich) and Colonial Gas Company (Colonial) in addition to transporting natural gas for the eleven shippers described in the original application, Docket No. CP86-404-000. Applicant specifically requests authorization to transport up to the maximum daily quantities (MDQ), 12,000 dt equivalent of natural gas for Norwich and 15,000 dt equivalent of natural gas for Colonial, and such additional daily quantities in excess of the MDQ as Applicant in its sole judgement determines it is able to transport, pursuant to submitted gas transportation agreements.

Applicant further requests that the authorization granted under this application, as amended, be limited to a term commencing upon acceptance of the certificate and terminating on and including October 31, 1987, and that such authorization include the right of pregranted abandonment at the end of such term.

It is stated that pursuant to the terms of the agreements with each shipper, Applicant would receive on an interruptible basis for the account of each shipper, at the points of receipt(s), quantities of natural gas up to the specified MDQ, and such additional daily quantities of gas in excess of the MDQ as Applicant in its sole judgement determines it is able to transport. Such quantities would be delivered by Applicant, less applicable shrinkage, to Algonquin Gas Transmission Company (Algonquin) for each shipper's account, at specified points of delivery. Applicant also states that transportation is required to be provided by Algonquin.

Applicant states that beginning with the month in which the requested transportation commences, the shipper would pay Applicant each month a charge equivalent to the rate in Applicant's Rate Schedule TS-3 and where applicable, the currently effective Gas Research Institute (GRI) surcharge per dt equivalent of gas transported. Applicant further states that it would retain applicable shrinkage, gas retained for use by Applicant in providing transportation, and that Applicant should have the right to change the amount of applicable shrinkage from time-to-time in order to insure Applicant retains a quantity of gas sufficient to meet its requirements in providing transportation service. It is stated that the applicable shrinkage is currently one percent per dt of natural gas received by Applicant per zone within which the natural gas is transported.

Applicant also states that the agreements provide that in the event of need to prorate interruptible services, the transportation would be subject to § 12.6 of the General Terms and Conditions of Applicant's FERC Gas Tariff Fourth Revised Volume No. 1.

Any person desiring to be heard or to make any protest with reference to said amendment should on or before October 6, 1986, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. All persons who have heretofore filed need not file again.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-21580 Filed 9-23-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ER86-623-000 et al.]

Electric Rate and Corporate Regulation Filings; Green Mountain Power Corp. et al.

September 19, 1986.

Take notice that the following filings have been made with the Commission:

1. Green Mountain Power Corporation

[Docket No. ER86-623-000]

Take notice that on September 11, 1986, Green Mountain Power Corporation (GMP) tendered for filing as an amendment to its rate schedule, filed July 31, 1986, and to be effective October 1, 1986, a letter clarifying certain respects of the executed agreement dated as of March 28, 1986, between GMP and UNITIL Power Corporation (UNITIL Power). The proposed rate schedule provides for the sale of capacity and energy by GMP to UNITIL Power.

Copies of the filing were served on UNITIL Power, the Vermont Public Service Board and the Vermont Department of Public Service.

Comment date: September 30, 1986, in accordance with Standard Paragraph E at the end of this notice.

2. Green Mountain Power Corporation

[Docket No. ER86-625-000]

Take notice that on September 11, 1986, Green Mountain Power Corporation (GMP) tendered for filing as an amendment to its rate schedule, filed July 31, 1986, and to be effective October 1, 1986, a letter clarifying certain respects of the executed agreement dated as of June 20, 1986, between GMP and UNITIL Power Corp. (UNITIL Power). The proposed rate schedule

provides for the sale of capacity and energy by GMP to UNITIL Power.

Copies of the filing were served on UNITIL Power, the Vermont Public Service Board and the Vermont Department of Public Service.

Comment date: September 30, 1986, in accordance with Standard Paragraph E at the end of this notice.

3. Green Mountain Power Corporation

[Docket No. ER86-624-000]

Take notice that on September 11, 1986, Green Mountain Power Corporation (GMP) tendered for filing as an amendment to its rate schedule, filed July 31, 1986, and to be effective November 1, 1986, a letter clarifying certain respects of the executed agreement dated as of June 20, 1986, between GMP and Fitchburg Gas and Electric Company (FG&E). The proposed rate schedule provides for the sale of capacity and energy by GMP to FG&E Power.

Copies of the filing were served on FG&E, the Vermont Public Service Board and the Vermont Department of Public Service.

Comment date: September 30, 1986, in accordance with Standard Paragraph E at the end of this notice.

4. New England Power Company

[Docket No. ER86-706-000]

Take notice that on September 12, 1986, New England Power Company (NEP) tendered for filing as initial rate schedules two Support Agreements between NEP and Boston Edison Company (BECO) that provide for the increased capability of two NEP transmission lines and the basis on which BECO will support the costs associated with such increase in capability. NEP requests effective dates of December 15, 1985 and October 1, 1986 for the agreements and requests waiver of this Commission's Regulations for prior notice to allow such effective dates.

NEP states that the Support Agreements will produce first year aggregate annual revenues of $409,800.

Copies of the filing were served upon BECO and the MDPU.

Comment date: September 30, 1986, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-21641 Filed 9-23-86; 8:45 am]

BILLING CODE 6717-01-M

Western Area Power Administration

Stampede Division, Washoe Project, CA; Rate Order

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of a rate order—Stampede Division, Washoe Project power rates.

SUMMARY: Notice is given of Rate Order No. WAPA-30 of the Under Secretary of the Department of Energy for placing power rates into effect on an interim basis for the sale of power from the Stampede Division (Stampede), Washoe Project by the Western Area Power Administration (Western).

The nonfirm energy rate of 40.45 mills per kWh will be used in the event that the Government operates and maintains the Stampede power-related facilities. The nonfirm energy rate of 27.86 mills per kWh will be used in the event that the customer operates and maintains the Stampede power-related facilities at its own expense.

The rate order further explains the rate development and discusses the principal factors leading to the decisions on the final rates.

EFFECTIVE DATE: The rates will become effective the date Stampede Powerplant is placed in commercial service.

FOR FURTHER INFORMATION CONTACT:

Mr. David G. Coleman, Area Manager, Sacramento Area Office, Western Area Power Administration, 1825 Bell Street, Suite 105, Sacramento, CA 95825, ((916) 978-4452.

Mr. Conrad K. Miller, Chief, Rates and Statistics Branch, Western Area Power Administration, P.O. Box 3402, Golden, CO 80401, (303) 231-1535.

Mr. Ronald K. Greenhalgh, Assistant Administrator for Washington Liaison, Western Area Power Administration, Room 8G061, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 252-5581.

SUPPLEMENTARY INFORMATION: By Amendment No. 1 to Delegation Order No. 0204-108, effective May 30, 1986 (51 FR 19744, May 30, 1986), the Secretary of Energy delegated:

1. To the Administrator of Western the authority to develop power and transmission rates;

2. To the Under Secretary of the Department of Energy the authority to confirm, approve, and place such rates in effect on an interim basis; and

3. To the Federal Energy Regulatory Commission the authority to confirm, approve, and place in effect on a final basis, remand or to disapprove such rates.

The proceeding for the proposed power rates and a 30-day customer consultation and comment period were initiated on May 28, 1986, with a notice in the **Federal Register** at 51 FR 19260. On June 2, 1986, letters were sent to interested parties transmitting the **Federal Register** notice. Public information and comment forums were not held. Under Department of Energy procedures, 10 CFR 903, such forums are optional for power systems with installed capacity of less than 20,000 kilowatts. Stampede Powerplant capacity is 3,650 kilowatts, well under the 20,000 kilowatt limit, making the forums optional for Stampede. Western's decision not to hold public forums was primarily due to the absence of public interest and involvement in the rate development proceedings. Written comments were accepted through June 28, 1986. No comments were received.

Rate Order No. WAPA-30 confirming and approving power rates on an interim basis is hereby issued, and the rates will be promptly submitted to the Federal Energy Regulatory Commission for confirmation and approval on a final basis.

Issued at Washington, DC, September 17, 1986.

Joseph F. Salgado,

Under Secretary.

Order Confirming, Approving, and Placing Power Rates in Effect on an Interim Basis

September 17, 1986.

In the Matter of: Western Area Power Administration, Stampede Division, Washoe Project Power Rates; Rate Order No. WAPA-30

Pursuant to section 302(a) of the Department of Energy (DOE) Organization Act, 42 U.S.C. 7101, *et seq.*, the power marketing functions of the Secretary of the Interior and the Bureau

of Reclamation (Reclamation) under the Reclamation Act of 1902, 43 U.S.C. 372, *et seq.*, as amended and supplemented by subsequent enactments, particularly section 9[c] of the Reclamation Act of 1939, 43 U.S.C. 485h(c), and the act of August 1, 1956, 70 Stat. 775, authorizing construction of the Washoe Project, were transferred to and vested in the Secretary of Energy. By Amendment No. 1 to Delegation Order No. 0204–108, effective May 30, 1986 (51 FR 19744, May 30, 1986), the Secretary of Energy delegated (1) the authority to develop power and transmission rates to the Administrator of the Western Area Power Administration (Administrator); (2) the authority to confirm, approve, and place in effect such rates on an interim basis to the Under Secretary of Energy; and (3) the authority to confirm, approve, and place in effect on a final basis, to remand or to disapprove those rates to the Federal Energy Regulatory Commission (FERC). This rate order is issued pursuant to the delegation to the Administrator and the Under Secretary and the rate adjustment procedures at 10 CFR Part 903, published at 50 FR 37837 on September 18, 1985.

Background

Project History

Stampede Dam and Reservoir are located on the Little Truckee River approximately 8 miles above the confluence of the Little Truckee and Truckee Rivers. The dam and reservoir are in Sierra County, California, about 11 miles northeast of the town of Truckee. The water source for Stampede Reservoir is the Little Truckee River drainage basin containing about 136 square miles of densely wooded slopes and grass meadowlands.

When the Stampede Dam and Reservoir project was authorized in 1956, hydrolelectric power development was included. However, power facilities were not constructed at the time Stampede Dam was built during the period 1966-1970 because the power function was not economically justified. Nevertheless, provisions were made to facilitate the addition of power facilities at a later date.

A preliminary reevaluation of a powerplant at Stampede was published in a special Reclamation report, "Adding Powerplants at Existing Federal Dams in California," July 1976. The report recommended construction of a Stampede powerplant. As a result, definite plan studies were initiated in fiscal year 1977, and construction of the powerplant is nearly complete.

Stampede Dam and Reservoir are presently operated to fulfill three purposes: Flood control, fisheries enhancement, and recreation. Power generation, resulting from the addition of the 3.65-megawatt powerplant at the dam, will add a fourth purpose. It is estimated that Stampede Powerplant will provide approximately 9.6 million kWh annually. The powerplant will be operated as an unattended plant with automatic means for maintaining relatively constant downstream water releases in the event of unit shutdown.

Under contract with Western Area Power Administration (Western), the Sierra Pacific Power Company (Sierra) constructed a ½-mile, 60-kilovolt transmission line between the Stampede power facility and Sierra's existing 60-kilovolt transmission system for the purpose of delivering energy to Sierra's system. All plant and switchyard controls are centrally located inside the powerplant.

The energy generated by the Stampede Powerplant has an initial priority reservation for designated Washoe Project loads. The Lahontan National Fish Hatchery and the Marble Bluff Fish Facility have been designated by Reclamation and Western as project loads of the Washoe Project. Such designation makes the Fish and Wildlife Service facilities eligible to be served by the Stampede Powerplant on a priority basis. The projected demand of these facilities should not exceed 500-kW peakload and two million kWh annually. Energy generated at the Stampede Powerplant will be nonfirm in nature and, except for the energy designated to service the project loads, will be sold to the Truckee Donner Public Utility District as a preference agency.

Power Repayment Study

The basic purpose of the power repayment study (PRS) is to determine if the revenues available will be sufficient to pay the power costs within the allowed time and at the appropriate interest rates. In order to determine if these requirements will be met, a year-by-year analysis of future projections of revenues and costs must be made.

A PRS for each of the proposed rates was prepared for the Stampede Division, Washoe Project in accordance with authorizing legislation for the Washoe Project and with DOE Order RA 6120.2, entitled, "Power Marketing Administration Financial Reporting," dated September 20, 1979, as amended October 1, 1983.

The two proposed rates are based on power related costs associated with Stampede nonfirm energy, as delivered to the customer at the Stampede Powerplant switchyard. These rates are different from those previously published due to a revision of replacements.

1. SNF–1

In the event that the Government operates and maintains the Stampede facilities, the customer will pay cost of service, now calculated at 40.45 mills per kWh. The customer will pay this rate for each kWh of nonfirm energy delivered to the customer at the Stampede Powerplant, except for the energy designated to service the project loads. The cost of service is defined as payment of the following costs, as allocated to the commercial power function: (1) The annual operation and maintenance expenses, to be repaid in the year of occurrence; (2) the annual interest expenses, to be repaid in the year of occurrence; (3) the replacement costs, to be repaid over the service lives of the replaceable items of 50 years, whichever is shorter, such replacements to be repaid with interest; and (4) the power investment and associated planning costs, to be repaid over a 50-year repayment period at the Stampede power facility's authorized 2.591-percent interest rate.

2. SNF–2

In the event that the customer operates and maintains all of the Stampede Powerplant facilities at its own expenses, the customer will pay the cost of service, less the operation and maintenance expenses, now calculated at 27.86 mills per kWh. The customer will pay this rate for each kWh of nonfirm energy delivered to the customer at the Stampede Powerplant, except for the energy designated to service the project loads. The costs to be repaid by the SNF–2 rate are the same costs as those defined for the SNF–1 rate, as reduced by the annual operation and maintenance expenses.

Public Notice and Comments

The procedures for public participation for rate adjustments as set forth in title 10 CFR Part 903 have been followed in the development of this rate. The following discussion summarizes the steps Western took to assure involvement of interested parties in the rate process:

1. A **Federal Register** notice (51 FR 19260, May 28, 1986) initiated the public proceedings for a minor new service, announcing the proposed power rates and the beginning of the 30-day consultation and comment period.

2. On June 2, 1986, letters were sent to interested parties transmitting the **Federal Register** notice (51 FR 19260, May 28, 1986).

3. A public information and comment forum was not held. Under DOE procedures, such forums are optional for power systems with installed capacity of less than 20,000 kilowatts. Stampede Powerplant capacity is 3,650 kilowatts, well under the 20,000-kilowatt limit, making the forums optional for Stampede. Western's decision not to hold public forums is primarily due to the absence of public interest and involvement in the rate-development proceedings.

4. No comment were received by the end of the consultation and comment period, June 27, 1986.

Certification of Rates

Western transmits and disposes of power and energy in such a manner as to encourage the most widespread use thereof at the lowest possible rates consistent with sound business principles. With these power rates in effect, the Administrator has certified that the Stampede Division, Washoe Project power rates are the lowest possible rates consistent with sound business principles. Rates have been developed in accordance with administrative policies and applicable laws.

Environmental Evaluation

In compliance with the National Environmental Policy Act of 1969 (NEPA) and DOE regulations published in the **Federal Register** (45 FR 20694–20701, March 28, 1986, as amended), Western has reviewed the environmental impacts of the power rate for the Stampede Division and has determined that it clearly does not involve a major Federal action having a significant adverse impact on the human environment. The preparation of an environmental assessment or environmental impact statement is not required.

Executive Order 12291

DOE has determined that this is not a major rule within the meaning of the criteria of section 1(b) of Executive Order 12291. In addition, Western has received an exemption from sections 3, 4, and 7 of that order and, therefore, will not prepare a regulatory impact statement.

Availability of Information

All studies, comments, letters, memorandums, and other documents made or kept by Western for the purposes of developing the power rates are and will be available for inspection and copying at the Sacramento Area Office, Western Area Power Administration, 1825 Bell Street, Suite 105, Sacramento, CA 95925, (916) 978–4418.

Submission to FERC

The rates herein confirmed, approved, and placed in effect on an interim basis, together with supporting documents, will be submitted to the FERC for confirmation and approved on a final basis.

Order

In view of the foregoing and pursuant to the authority delegated to me by the Secretary of Energy, I hereby confirm and approve on an interim basis, effective the date Stampede Powerplant because operational, Rate Schedules SNF–1 and SNF–2. These rates shall remain in effect on an interim basis pending the FERC confirmation and approval of them or substitute rates, on a final basis, or until they are superseded.

Issued at Washington, DC, September 17, 1986.

Joseph F. Salgado,

Under Secretary.

[Schedule SN F–1]

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Stampede Division, Washoe Project

Rate Schedule for Wholesale Nonfirm Power Service

Effective: The date Stampede Powerplant is placed in commercial service.

Available: In any area served by the Stampede Division.

Applicable: To wholesale nonfirm power customers for general power service supplied through one meter at one point of delivery, unless otherwise provided by contract.

Character and Conditions of Service: Alternating current, 60-hertz, three-phase, delivered and metered at the voltages and points established by contract.

Monthly Rate:

Demand Charge: None.

Energy Charge: Nonfirm energy rate: 40.45 mills per kWh. This rate will be used in the event that the Government operates and maintains the Stampede power-related facilities.

Minimum Bill: None.

Adjustments: None. Stampede power will be delivered to the customer at the Stampede Powerplant.

[Schedule SNF–2]

UNITED STATES DEPARTMENT OF ENERGY

Western Area Power Administration

Stampede Division, Washoe Project

Rate Schedule for Wholesale Nonfirm Power Service

Effective: The date Stampede Powerplant is placed in commercial service.

Available: In the area served by the Stampede Division.

Applicable: To wholesale nonfirm power customers for general power service supplied through one meter at one point of delivery, unless otherwise provided by contract.

Character and Conditions of Service: Alternating current, 60-hertz, three-phase, delivered and metered at the voltages and points established by contract.

Monthly Rate: Demand Charge: None.

Energy Charge: Nonfirm energy rate: 27.86 mills per kWh. This rate will be used in the event that the customer operates and maintains the Stampede power-related facilities at its own expense.

Minimum Bill: None.

Adjustments: None. Stampede power will be delivered to the customer at the Stampede Powerplant.

[FR Doc. 86–21659 Filed 9–23–86; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[AD–FRL–3085–7]

Confidentiality Agreement; Intent to Transfer Confidential Information to a Contractor

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to make interprogram transfer of claimed confidential information.

SUMMARY: The Environmental Protection Agency (EPA) intends to use information claimed to be proprietary collected under section 308 of the Clear Water Act to assist regulatory decision making under the Clean Air Act and the Resource Conservation and Recovery Act. Confidential information on the following subjects will be transferred to a contractor: Organic Chemicals Manufacturing; Plastics and Synthetic Fibers; Pesticide Manufacturing; Pharmaceutical Manufacturing; Pulp and Paper Mills; Textile Mills; Electrical and Electronic Components; Leather Tanning and Finishing; Paint Manufacturing and Formulation; Industrial and Commercial Laundries; Electroplating and Metal Finishing; Equipment Manufacturing and Assembly.

DATES: Comments on the notice of transfer are due 10 days after date of publication.

ADDRESSES: Send comments to James F. Durham (Industrial Wastewater Project and Hazardous Waste Treatment, Storage, and Disposal Facilities Project) or Robert E. Rosensteel (Publicly Owned Treatment Works Projects), Chemicals and Petroleum Branch, Emission Standards and Engineering Division

(MD–13), Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711 (919) 541–5671.

FOR FURTHER INFORMATION CONTACT: James F. Durham (Industrial Wastewater Project and Hazardous Waste Treatment, Storage, and Disposal Facilities Project) or Robert E. Rosensteel (Publicly Owned Treatment Works Projects), Chemicals and Petroleum Branch, Emission Standards and Engineering Division (MD–13), Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711 (919) 541–5671.

SUPPLEMENTARY INFORMATION: Under the Clean Air ACt (CAA) of 1977, the Environmental Protection Agency is required to identify hazardous air pollutants and establish national emission standards for these pollutants. The Office of Air Quality Planning and Standards is responsible for development of regulations for point source categories. The point source categories pertinent to this notice are publicly owned treatment works (POTW) and industrial wastewater treatment facilities (IWTF). The EPA is currently assessing the need for regulation of hazardous air pollutants and volatile organic compounds (VOC) emitted from these source categories. To estimate loadings and emissions, the EPA plans to use industrial discharge data collected under Section 308 of the Clean Water Act (CWA). The current strategy for estimating emissions of individual pollutants involves two major steps: (1) Estimate the loadings to individual POTW or IWTF using available data on individual industrial discharges and (2) estimate air emissions from the treatment processes using volatilization models developed by the Emission Standards and Engineering Division. The EPA has awarded a contract to Radian Corporation in Research Triangle Park, North Carolina, to provide technical support to the Office of Air Quality Planning and Standards in the development of air emission standards for point sources.

Under sections 3004 and 3007 of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA) of November 1984, EPA is required to investigate the magnitude of the area (non-combustion) source air emissions from hazardous waste treatment, storage, and disposal facilities (TSDF) and to develop standards for monitoring and control as needed. Pollutants to be considered by any such strandards would include VOC, particulate matter (PM), specific toxic substances, or a combination of these. The EPA plans to use industrial discharge data collected under section 308 of the Clean Water Act to aid in assessing potential air emission sources located at hazardous waste TSDF. Using emission models developed by ESED, the EPA plans to use data collected under authority of Section 308 of the CWA to estimate emissions of total VOC and individual compounds from the wastewater treatment at TSDF. This information will also be used to assess technologies for controlling VOC, control costs, and to assess the environmental impacts. The EPA has awarded a contract to Research Triangle Institute in Research Triangle Park, North Carolina, to provide technical support to the Office of Air Quality Planning and Standards in the development of air emission standards for TSDF.

The industrial point source categories, standard industrial classification (SIC) codes and descriptions of industries for which data are being transferred, and current location of files are listed below:

1. Organic Chemicals, Plastics, and Synthetic Fiber Manufacturing point source categories.

a. SIC codes and descriptions:

SIC 2821 Plastic materials, synthetic resins and non-vulcanizable elastomers
SIC 2823 Cellulosic man-made fibers
SIC 2824 Synthetic organic fibers, except cellulosic
SIC 2865 Cyclic (coal tar) crudes and cyclic intermediates, dyes, and organic pigments (lakes and ponds)
SIC 2869 Industrial organic chemicals, NEC

b. Location of Files: The confidential files are currently located at Science Applications International Corporation's McLean, Virginia, Office under Contract No. 68–01–6947 and will remain there.

2. Pesticide Chemicals Manufacturing point source category.

a. SIC codes and descriptions:

SIC 2879 Pesticides and agricultural chemicals, NEC

b. Location of Files: The confidential files are currently located at Science Applications International Corporation's McLean, Virginia, Office under Contract No. 68–01–6947 and will remain there.

3. Pharmaceutical Manufacturing point source category.

a. SIC codes and descriptions:

SIC 2831 Biological products
SIC 2833 Medicinal chemicals and botanical products
SIC 2834 Pharmaceutical preparations

b. Location of Files: The confidential files are currently located at EC Jordon Corporation's Portland, Maine, Office under Contract No. 68–03–6302 and will remain there.

4. Pulp and Paper Mills point source categories.

a. SIC codes and descriptions:

SIC 2611 Pulp mills
SIC 2621 Paper mills, except building paper mills
SIC 2631 Paperboard mills
SIC 264 Converted paper and paperboard products, except containers and boxes
SIC 265 Paperboard containers and boxes
SIC 2661 Building paper and building board mills

b. Location of Files: The confidential files are currently located at EC Jordon Corporation's Portland, Maine, Office under Contract No. 68–03–6302 and will remain there.

5. Textile Mills point source categories.

a. SIC codes and descriptions:

SIC 2211 Broad woven fabric mills, cotton
SIC 2221 Broad woven fabric mills, man-made fiber and silk
SIC 2231 Broad woven fabric mills, wool (including dyeing and finishing)
SIC 2241 Narrow fabrics and other smallwares mills, cotton, wool, silk, and man-made fiber
SIC 225 Knitting mills
SIC 226 Dyeing and finishing textiles, except wool fabrics and knit goods
SIC 227 Floor covering mills

b. Location of Files: The confidential files are currently located at EC Jordon Corporation's Portland, Maine, Office under Contract No. 68–03–6302 and will remain there.

6. Electrical and Electronic Components point source categories.

a. SIC codes and descriptions:

SIC 3612 Power, distribution, and specialty transformer
SIC 3624 Carbon and graphite products
SIC 3641 Electric lamps
SIC 367 Electronics components and accessories
SIC 3693 X-ray apparatus and tubes

b. Location of Files: The confidential files are currently located at Radian Corporation's McLean, Virginia, Office under Contract No. 68–01–6999 and will remain there.

7. Leather Tanning and Finishing point source categories.

a. SIC codes and descriptions:

SIC 3111 Leather tanning and finishing
SIC 3131 Boot and shoe cut stock and findings
SIC 3144 Women's footwear, except athletic

SIC 3149 Footwear, except rubber, not elsewhere classified
SIC 3171 Women's handbags and purses
SIC 3172 Personal leather goods, except handbags and purses

b. Location of Files: The confidential files are currently located at EC Jordon Corporation's Portland, Maine, Office under Contract No. 68–03–6302 and will remain there.

8. Paint Manufacturing and Formulation point source categories.

a. SIC codes and descrptions:

SIC 2851 Paints, varnishes, lacquers, enamels, and allied products

b. Location of FIles: The confidential files are currently located at EC Jordon Corporation's Portland, Maine, Office under Contract No. 68–03–6302 and will remain there.

9. Industrial and Commercial Laundries point source categories.

a. SIC codes and descriptions:

SIC 721 Laundry, cleaning, and garment services

b. Location of FIles: The confidential files are currently located at EC Jordon Corporation's Portland, Maine, Office under Contract No. 68–03–6302 and will remain there.

10. Electroplating and Metal Finishing point source categories.

a. SIC codes and descriptions:

SIC 34 Fabricated metal products, except machinery and transportation equipment
SIC 3398 Metal heat treating
SIC 3697 Electronic components, not elsewhere classified
SIC 391 Jewelry, silverware, and plated ware
SIC 3931 Musical instruments
SIC 3964 Needles, pins, and eyes, and similar notions

b. Location of FIles: The confidential files are currently located at Radian Corporation's McLean, Virginia, Office under Contract No. 68–01–6999 and will remain there.

11. Equipment Manufacturing and Assembly point source categories.

a. SIC codes and descriptions:

SIC 2522 Metal office furniture
SIC 254 Partitions, shelving, lockers, and office and store fixtures
SIC 3993 Signs and adverstising displays
SIC 34 Fabricated metal products
SIC 35 Machinery, except electrical
SIC 36 Electric and electronic equipment
SIC 37 Transportation equipment
SIC 38 Instruments and related products

b. Location of FIles: The confidential files are currently located at Radian Corporation's McLean, Virginia, Office under Contract No. 68–03–6302 and will remain there.

The EPA has determined that use of data collected under the CWA would assist in making regulatory decisions and developing regulations under the CAA and RCRA, would avoid duplication of data gathering efforts, and thereby also reduce regulatory burdens on affected industries. For these reasons, EPA proposes to transfer data from its files or grant access to Radian Corporation's Research Triangle Park, North Carolina, Office in order that they may carry out technical support work that is currently required under Contract Nos. 68–02–3816 and 68–02–3889. The EPA also proposes to transfer data or grant access to Research Triangle Institute in order that they may carry out technical support work currently required under Contract No. 68–01–6826.

This information is claimed to be proprietary information. This transfer would not affect the status of this information as information claimed to be proprietary. The relevant contracts contain all confidentiality provisions required by EPA's confidentiality regulations (40 CFR 2.302(h)(2–3)). Persons under contract to EPA to perform work for EPA may be designated authorized representatives if such designation is necessary in order for the contractor to carry out the work required by the contract. The following conditions apply when information claimed to be confidential is provided to a designated contractor:

(1) The authorized contractor representative and its employees (a) may use such confidential information only for the purposes of carrying out the work required, (b) must refrain from disclosing the information to anyone other than EPA without having received from EPA prior written approval of each affected business or of an EPA legal office, and (c) must return to EPA all copies of the information (and any abstracts or excerpts therefrom) upon request or whenever the information is no longer required for the performance of the work.

(2) The authorized contractor representative must obtain a written agreement from each of its employees who will have access to the information to honor the above-noted limitations. A copy of each such agreement must be furnished to EPA before access is permitted.

(3) The authorized contractor representative must agree that the conditions in the contract concerning the use and disclosure of confidential business information are included for the benefit of, and shall be enforceable by, both EPA and any affected business having a proprietary interest in the information.

These requirements provide reasoanble protection for the rights of owners of confidential business information.

In accordance with those regulations, sample facilities and questionnaire respondents who have submitted information claimed to be confidential have ten days from the date of this notice to comment on EPA's proposed transfer of this information to Radian Corporation, Research Triangle Park, North Carolina, and Research Triangle Institute, Research Triangle Park, North Carolina, for the purpose outlined above (40 CFR 2.302(h)(2–3)). The EPA welcomes comment on this proposed interprogram transfer to these designated EPA contractors.

Dated: September 16, 1986.

Rebecca W. Hanmer,

Acting Assistant Administrator for Water.

[FR Doc. 86–21629 Filed 9–23–86; 8:45 am]

BILLING CODE 6560–50–M

[OPP–30272; (FRL–3082–2)]

E.I. DuPont de Nemours and Co.; Application to Register a Pesticide Product

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register a pesticide product containing an active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATE: Comment by October 24, 1986.

ADDRESS: By mail submit comments identified by the document control number [OPP–30272] and the file symbol (352–UUA) to: Information Services Section (TS–757C), Program Management and Support Division, Attn: Product Manager (PM) 25, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

In person, bring comments to: Rm. 236, CM#2, Attn: PM 25, Registration Divison (TS–767C), Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information"

(CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Robert Taylor, PM 25, Rm. 245, CM#2, (703–557–1800).

SUPPLEMENTARY INFORMATION: E.I. duPont de Nemours and Co., Agricultural Products Dept., Wilmington, DE 19898, has submitted an application to EPA to register the pesticide product Du Pont Harmony Herbicide, EPA File Symbol 352–UUA, containing the active ingredient methyl 3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate at 75 percent, pursuant to the provision of section 3(c)(4) of FIFRA. The application proposes that the product be used for selective postemergence control of certain broadleaf weeds in wheat and barley. Notice of receipt of this application does not imply a decision by the Agency on the application.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

Written comments filed pursuant to this notice, will be available in the Program Management and Support Division (PMSD) office at the address provided from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. It is suggested that persons interested in reviewing the application file, telephone the PMSD office (703–557–3262), to ensure that the file is available on the date of intended visits.

Authority: 7 U.S.C. 136.

Dated: September 11, 1986.

James W. Akerman,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 86–21124 Filed 9–23–86; 8:45 am]

BILLING CODE 6560–50–M

[OPP–50662; (FRL–3083–2)]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted experimental use permits to the following applicants. These permits are in accordance with, and subject to, the provisions of 40 CFR Part 172, which defines EPA procedures with respect to the use of pesticides for experimental purposes.

FOR FURTHER INFORMATION CONTACT: By mail, the product manager cited in each experimental use permit at the address below: Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

In person or by telephone: Contact the product; manager at the following address at the office location or telephone number cited in each experimental use permit: 1921 Jefferson Davis Highway, Arlington, VA.

SUPPLEMENTARY INFORMATION: EPA has issued the following experimental use permits:

352–EUO–125. Issuance. E.I. duPont de Nemours and Co., Inc., Agricultural Chemicals Department, Wilmington, DE 19898. This experimental use permit allows the use of 120 pounds of the fungicide 1-[[bis(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole on table grapes to evaluate the control of various fungal diseases. A total of 480 acres are involved; the program is authorized only in the States of Arizona, California, Michigan, Missouri, New York, Ohio, Oregon, Pennsylvania, and Washington. The experimental use permit is effective from July 30, 1986 to April 1987. A temporary tolerance for residues of the active ingredient in or on table grapes has been established. (Henry Jacoby, PM 21, Rm. 227, CM#2, (703–557–1900))

352–EUP–136. Issuance. E.I. duPont de Nemours & Co., Inc., Agricultural Chemicals Department, Wilmington, DE 19898. This experimental use permit allows the use of 131.25 pounds of the herbicide methyl 2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-amino]carbonyl]amino] sulfonyl]benzoate on pastures and rangelands to evaluate the control of weeds. A total of 3,500 acres are involved; the program is authorized only in the States of New Mexico and Texas. The experimental use permit is effective from August 27, 1986 to August 27, 1987. A temporary tolerance for residues of the active ingredient in or on grass forage and fodder and grass hay has been established. A permanent tolerance for residues of the active ingredient in or or on barley (grain, green forage, hay, and straw) and wheat (grain, green forage, hay, and straw) (40 CFR 180.428) has been established. (Robert Taylor, PM 25, Rm. 245, CM#2, (703–557–1800))

10802–EUP–41. Issuance. ICI Americas, Inc., Concord Pike and New Murphy Road, Wilmington, DE 19897. This experimental use permit allows the use of 1,697 pounds of the insecticide (*R*+*S*)-alpha-cyano-3-phenoxybenzyl-(1*R*+1*S*)-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate on cotton, soybeans, sunflowers, sweetcorn, and winter wheat to evaluate the control of various insects. A total of 3,500 acres are involved; the program is authorized only in the States of Alabama, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Washington, West Virginia, Wisconsin, and Wyoming. The experimental use permit is effective from July 31, 1986 to July 31, 1987. This permit is issued with the limitation that all treated crops are destroyed or used for research purposes only. (George LaRocca, PM 15, Rm. 204, CM#2, (703–557–2400))

Persons wishing to review these experimental use permit are referred to the designated product managers. Inquiries concerning these permits should be directed to the persons cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136c.

Dated: September 11, 1986.

James W. Akerman,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 86-21253 Filed 9-23-86; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

[Docket No. 86-23]

Active International Shippers' Assoc., Inc. v. Korea Shipping Corp.; Filing of Complaint and Assignment

Notice is given that a complaint filed by Active International Shippers' Association (AISA) against Korean Shipping Corporation (KSC) was served September 18, 1986. AISA alleges that KSC has violated section 8(c) (by refusing to make available to AISA the essential terms of a service contract), 10(b)(6) (by refusing cargo space for AISA's cargo, despite a contract to do so, while providing cargo space for higher rated cargo), 10(b)(12) (by subjecting AISA to an unreasonable refusal to deal or to any undue or unreasonable prejudice or disadvantage), and 10(b)(13) (by refusing to negotiate with a shippers' association), Shipping Act of 1984.

This proceeding has been assigned to Administrative Law Judge Norman D. Kline. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. 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 September 18, 1987, and the final decision of the Commission shall be issued by March 18, 1988.

Joseph C. Polking,

Secretary.

[FR Doc. 86-21587 Filed 9-23-86; 8:45 am]

BILLING CODE 6730-01-M

Filing of Petition for Exemption From Self-Policing Requirements; Pacific Coast/American Samoa Rate Agreement

Notice is hereby given that the members of the Pacific Coast/American Samoa Rate Agreement (Samoa Rate Agreement) have filed a petition pursuant to section 35 of the Shipping Act, 1916 (46 U.S.C. 833a), for exemption from the self-policing requirements of section 15 of the 1916 Act (46 U.S.C. 814) as more particularly set forth in 46 CFR, Part 568 *Et seq.*

Petitioners request an order or other relief from the Federal Maritime Commission which would exempt agreements in the Pacific Coast American Samoa Trade from self-policing requirements. The request includes relief from section 15 of the Shipping Act, 1916 to the extent such section may be construed as requiring neutral body self-policing. Petitioners propose that, instead of the requirements of section 15 and 46 CFR 568, agreements in the trade would conform, in substance, to the provisions of section 5(b)(4) of the Shipping Act of 1984.

As grounds for the petition, the Samoa Rate Agreement stresses, among other reasons, the small size of the trade, the cost of complying with self-policing requirements under the Shipping Act of 1916, and the fact that while the American Samoa trade is a domestic offshore trade, "for all practical purposes the agreement concerns a trade with the economic and service characteristics of a foreign trade" and the self-policing requirements for carriers operating in the trade should be no more stringent or costly than under the provisions of the Shipping Act, 1984.

In order for the Commission to make a thorough evaluation of the petition, interested persons are requested to submit views, arguments or data on the petition no later than October 14, 1986. Responses shall be directed to the Secretary, Federal Maritime Commission, Washington, DC 20753, in an original and 15 copies. Responses shall also be served on counsel for petitioners: R. Frederic Fisher, Esquire, Lillick McHose & Charles, Two Embarcadero Center, San Francisco, California 94111.

Copies of the petition are available for examination at the Washington, DC Office of the Commission, 1100 L Street NW., Room 11101.

Joseph C. Polking,

Secretary.

[FR Doc. 86-21580 Filed 9-23-86; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

First National Bancorp et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than October 17, 1986.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street NW., Atlanta, Georgia 30303:

1. *First National Bancorp*, Gainesville, Georgia; to acquire 100 percent of the voting shares of The Citizens Bank of Toccoa, Toccoa, Georgia.

2. *LCB Corporation*, Fayetteville, Tennessee; to acquire 100 percent of the voting shares of First National Bank of Huntland, Huntland, Tennessee.

B. **Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Citizens Fidelity Corporation*, Louisville, Kentucky; to acquire 100 percent of the voting shares of Mercer County National Bank of Harrodsburg, Harrodsburg, Kentucky.

C. **Federal Reserve Bank of Minneapolis** (Bruce J. Hedblom, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Valley Holding Company*, Ronan, Montana; to become a bank holding

company by acquiring 80 percent of the voting shares of Valley Bank of Ronan, Ronan, Montana.

Board of Governors of the Federal Reserve System, September 18, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-21589 Filed 9-23-86; 8:45 am]

BILLING CODE 6210-01-M

Tripoli Bancshares, Inc.; Correction

This notice corrects a previous **Federal Register** document (FR Doc. No. 86-20697), published at page 32688 of the issue for Monday, September 15, 1986.

Under the Federal Reserve Bank of Chicago, the entry for *Tripoli Bancshares, Inc.*, is revised to read as follows:

C. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

* * * * *

2. *Tripoli Bancshares, Inc.*, Tripoli, Iowa; to become a bank holding company acquiring 93.6 percent of the voting shares of American Savings Bank, Tripoli, Iowa. Comments on this application must be received by October 6, 1986.

Board of Governors of the Federal Reserve System, September 18, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-21590 Filed 9-23-86; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

Senior Executive Service; Announcement of Membership of Performance Review Boards

The Federal Trade Commission has two Performance Review Boards. The members of the first Board are: William S. Sanger, Richard Higgins, Walter T. Winslow, and Ernest J. Isenstadt.

The members of the second Board are: Amanda Pedersen, Ronald Bond, and Barbara Clark.

For further information, please call Stephen C. Benowitz, Director of Personnel, Federal Trade Commission, (202) 523-3986.

Stephen C. Benowitz,

Director of Personnel.

[FR Doc. 86-21593 Filed 9-23-86; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 86F-0340]

Dow Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethylene-carbon monoxide copolymers as a heat-seal layer for food-contact packaging when it is sterilized with hydrogen peroxide solutions.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 6B3949) has been filed by The Dow Chemical Co., 1803 Building, Door 7, Midland, MI 48674, proposing that § 178.1005 *Hydrogen peroxide solution* (21 CFR 178.1005) be amended to provide for the safe use of ethylene-carbon monoxide copolymers as a heat-seal layer for food-contact packaging when it is sterilized with hydrogen peroxide solutions.

The potential environmental impact of this action is being reviewed. If 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: September 13, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21559 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86P-0372]

Canned Pacific Salmon Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Icicle Seafoods, Inc., to market test canned skinless and boneless chunk salmon packed in water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than December 23, 1986.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0107.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Icicle Seafoods Inc., Seattle, WA 98199.

The permit covers limited interstate marketing tests of canned skinless and boneless chunk salmon packed in water. The test product deviates from the standard of identity for canned Pacific salmon (21 CFR 161.170) in three ways: (1) The form of pack is chunk, i.e., not less than 50 percent of the fill weight of the salmon is retained on a ½-inch mesh screen; (2) the skin and backbone, i.e., vertebrae and associated bones (neural spines and ventral ribs) are removed; and (3) water, in an amount not to exceed 10 percent of the water capacity of the can, will be used as a packing medium and to aid in dispersion of salt. The test product meets all requirements of § 161.170 with the exception of these deviations. The permit provides for the temporary marketing of 15,000 cases of test product containing twenty-four 6½ ounce cans each. The test product will be distributed throughout the continental United States.

The test product is to be manufactured at the Petersburg Fisheries plant located in Petersburg, AK 99833.

Each of the ingredients used in the food is stated on the label as required by the applicable sections of 21 CFR Part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than December 23, 1986.

Dated: September 16, 1986.

Sanford A. Miller,

Director Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21569 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85P-0213]

Canned Pacific Salmon Deviating From Identity Standard; Amendment and Extension of Temporary Marketing Permit

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that (1) a tempoary permit to market test canned smoke-flavored, skinless and boneless, chunk salmon is being amended to change the test product manufacturer; and (2) the expiration date of the permit is being extended. This extension will allow the permit holder to continue experimental market testing of the product while the agency takes action on the permit holder's petition to amend the standard of identity for canned Pacific salmon.

DATE: The new expiration date of the permit will be either the effective date of a final rule based on any proposal to amend the standard of identity for canned Pacific salmon which may result from the petition, or 30 days after termination of such proposal.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF-215), Food and Drug Administration 200 C Street SW., Washington, DC 20204, 202-485-0110.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to Geo. A. Hormel and Co., Austin, MN 55912, to market test canned smoke-flavored, skinless and boneless, chunk salmon to test consumer acceptance of the new style pack. The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standard of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to Geo. A. Hormel and Co. was published in the **Federal Register** of June 12, 1985 (50 FR 24705). The expiration date of the permit is October 29, 1986.

Geo. A. Hormel and Co. has requested that the test product manufacturer be changed from Tony Downs Food Co. of Madelia, MN, to North Pacific Processors, Inc., of Cordova, AK. Accordingly, FDA is amending the temporary permit to reflect this change.

Geo. A. Hormel & Co., has also requested that the temporary permit be extended, so that the market test period can continue while agency action on a petition to amend the canned Pacific salmon standard proceeds. The company submitted the petition at the same time the application for extension was submitted. FDA has concluded that it is in the interest of consumers to issue the extension. FDA is inviting interested persons to participate in the market test under the conditions that apply to Geo. A. Hormel and Co., including the labeling requirements and the amounts of test product to be distributed, except that the designated area of distribution in the Hormel permit shall not apply.

Any interested person who wishes to participate in the market test must notify, in writing the Deputy Director, Division of Food Technology (HFF-211), Food and Drug Administration 200 C Street SW., Washington, DC 20204. The notification must include the amount of test product to be distributed, the areas of distribution, and the labeling that will be used for the test product.

Therefore, FDA is amending the permit to change the test product manufacturer to North Pacific Processors, Inc., of Cordova, AK, and, under the provisions of § 130.17(i), FDA is extending the expiration date of the permit such that the permit expires either on the effective date of a final rule based on any proposal to amend the standard of identity for canned Pacific salmon which may result from the petition, or 30 days after termination of such proposal. All other conditions and terms of this permit remain the same.

Dated: September 13, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21566 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85P-0272]

Canned Pacific Salmon Deviating From Identity Standard; Amendment And Extension of Temporary Marketing Permit

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that (1) a temporary permit to market test canned skinless and boneless chunk salmon is being amended to change the test product manufacturer; and (2) the expiration date of the permit is being extended. This extension will allow the permit holder to continue experimental market testing of the product while the agency takes action on the permit holder's petition to amend the standard of identity for canned Pacific salmon.

DATE: The new expiration date of the permit will be either the effective date of a final rule based on any proposal to amend the standard of identity for canned Pacific salmon which may result from the petition, or 30 days after termination of such proposal.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF-215), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0110.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to Geo. A. Hormel & Co., Austin, MN 55912, to market test canned skinless and boneless chunk salmon to test consumer acceptance of the new style pack. The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standard of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to Geo. A. Hormel & Co. was published in the **Federal Register** of June 12, 1985 (50 FR 24706). The expiration date of the permit is October 29, 1986.

Geo. A. Hormel & Co. has requested that the test product manufacturer be changed from Tony Downs Food Co. of Madelia, MN, to North Pacific Processors, Inc., of Cordova, AK. Accordingly, FDA is amending the temporary permit to reflect this change.

Geo. A. Hormel & Co. has also requested that the temporary permit be extended, so that the market test period can continue while agency action on a petition to amend the canned Pacific salmon standard proceeds. The company submitted the petition at the same time the application for extension was submitted. FDA has concluded that it is in the interest of consumers to issue the extension. FDA is inviting interested persons to participate in the market test under the conditions that apply to Geo. A. Hormel & Co., including the labeling requirements and the amounts of test product to be distributed, except that the designated area of distribution in the Hormel permit shall not apply.

Any interested person who wishes to participate in the market test must notify, in writing, the Deputy Director, Division of Food Technology (HFF-211), Food and Drug Administration, 200 C St.

SW., Washington, DC 20204. The notification must include the amount of test product to be distributed, the areas of distribution, and the labeling that will be used for the test product.

Therefore, FDA is amending the permit to change the test product manufacturer to North Pacific Processors, Inc., of Cordova, AK, and, under the provisions to § 130.17(i), FDA is extending the expiration date of the permit such that the permit expires either on the effective date of a final rule based on any proposal to amend the standard of identity for canned Pacific salmon which may result from the petition, or 30 days after termination of such proposal. All other conditions and terms of this permit remain the same.

Dated: September 13, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21570 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85V-0465]

Approved Variance for Digital Radiography Inspection Devices; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a variance from the performance standard for cabinet X-ray systems has been approved by FDA's Center for Devices and Radiological Health (CDRH) for the CXI-Type Automated Digital Radiography Inspection Devices manufactured by IRT Corp.

DATES: The variance became effective February 11, 1986, and terminates February 11, 1991.

ADDRESS: The application and all correspondence on the application have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tracy Donovan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: Under § 1010.4 (21 CFR 1010.4) of the regulations governing establishment of performance standards under section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f), CDRH has granted the IRT Corp., 3030 Callan Rd., San Diego, CA 92121, a variance from § 1020.40(c)(4)(i) (21 CFR 1020.40(c)(4)(i)) of the performance standard for cabinet X-ray systems for the CXI-Type Automated Digital Radiography Inspection Devices. The products are automated digital radiography devices used to inspect surface-mounted devices on printed circuit boards by using X-rays to image the device on a fluorescent screen, to digitize and enhance the image of the device, to compare the image with the standard in the computer's memory, and to accept or reject the part.

The specific requirement of the standard from which a variance has been granted pertains to the provision of § 1020.40(c)(4)(i), which requires that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and that such disconnection shall not be dependent on any moving part other than the door. All other provisions of the performance standard remain applicable to the product.

CDRH has determined that (1) the requirement of § 1020.40(c)(4)(i) is not appropriate for the product, and (2) constraints on the existing equipment design provide radiation safety equal to that required by the standard. Therefore, on February 11, 1986, CDRH approved the requested variance by a letter to the manufacturer from the Deputy Director of CDRH.

So that the product may show evidence of the variance approved for the manufacturer, the produce shall bear on the certification label required by § 1010.2(a) (21 CFR 1010.2(a)) a variance number, which is the FDA docket number appearing in the heading of this notice, and the effective date of the variance.

In accordance with § 1010.4, the application and all correspondence on the application have been placed on public display under the designated docket number in the Dockets Management Branch (address above) and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.86).

Dated: September 16, 1986.

James S. Benson,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 86-21567 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

National Cancer Institute; Cancer Research Manpower Review Committee, Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Cancer Research Manpower Review Committee, National Cancer Institute, National Institutes of Health, October 30-31, 1986, Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814. This meeting will be open to the public on October 30, from 8:30 a.m. to 10:00 a.m. to review administrative details. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on October 30 from approximately 10:00 a.m. to recess, and on October 31, from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20892 (301/496-5708) will provide summaries of the meeting and rosters of committee members, upon request.

Ms. Cynthia Sewell, Executive Secretary, Cancer Research Manpower Review Committee, National Cancer Institute, Westwood Building, Room 838, National Institutes of Health, Bethesda, Maryland 20892 (301/496-7721) will furnish substantive program information.

Dated: September 15, 1986.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 86-21618 Filed 9-23-86; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Board of Scientific Counselors, Division of Cancer Biology and Diagnosis; Meeting

Pursuant to Pub. L. 92-436, notice is hereby given of the meeting of the Board of Scientific Counselors, DCBD, National Cancer Institute, November 13, 1986, at the National Institutes of

Health, Building 31, Conference Room 4, Bethesda, Maryland 20892. This meeting will be open to the public on November 13, from 8:30 a.m. to 3:00 p.m. for concept review of proposed DCBD research projects. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, the meeting will be closed to the public on November 13, from 3:00 p.m. to adjournment, for the review, discussion, and evaluation of individual programs and projects conducted by DCBD, National Cancer Institute, including consideration of personnel qualifications and performance, the competence of individual investigators, medical files of individual research subjects, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20892 (301/496–5708) will provide summaries of the meeting and rosters of committee members, upon request.

Dr. Ihor J. Masnyk, Deputy Director, Division of Cancer Biology and Diagnosis, National Cancer Institute, Building 31, Room 3A–04, National Institutes of Health, Bethesda, Maryland 20892 (301/496–4345) will furnish substantive program information.

Dated: September 15, 1986.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 86–21619 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Board of Scientific Counselors Division of Cancer Etiology; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, Division of Cancer Etiology on October 23–24, 1986, Building 31, C Wing, Conference Room 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The meeting will be open to the public from 1:00 p.m. to recess on October 23, and from 9:00 a.m. to adjournment on October 24, for discussion and review of the Division budget and review of concepts for grants and contracts. Attendance by the public will be limited to space available.

The Board of Scientific Counselors meeting will be closed to the public from 9:00 a.m. to approximately 1:00 p.m. on October 23, 1986, in accordance ith the provisions set forth in section 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, for the review, discussion and evaluation of individual programs and projects conducted by the Division of Cancer Etiology. These programs, projects, and discussions could reveal personal information concerning individuals associated with the programs and projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20892 (301/496–5708) will provide summaries of the meeting and rosters of committee members, upon request.

Dr. David McB. Howell, Executive Secretary of the Board of Scientific Counselors, Division of Cancer Etiology, National Cancer Institute, Building 31, Room 11A06, National Institutes of Health, Bethesda, Maryland 20892 (301/496–6927) will furnish substantive program information.

Dated: September 15, 1986.

Betty J. Beveridge,

Committee Management Office, NIH.

[FR Doc. 86–21620 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Heart, Lung, and Blood Research Review Committee B; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Heart, Lung, and Blood Research Review Committee B, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892, on December 4, 1986, in Building 31, Conference Room 9.

This meeting will be open to the public on December 4, from 8:30 AM to approximately 10:00 AM to discuss administrative details and to hear reports concerning the current status of the National Heart, Lung, and Blood Institute. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and section 10(d) Pub. L. 92–463, the meeting will be closed to the public on December 4, from approximately 10:00 AM to adjournment for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Terry Bellicha, Chief, Communications and Public Information Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4A31, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–4236, will provide a summary of the meeting and a roster of the committee members.

Dr. Louis M. Ouellette, Executive Secretary, NHLBI, Westwood Building, Room 554, National Institute of Health, Bethesda, Maryland 20892, phone (301) 496–7915, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.837, Heart and Vascular Diseases Research; and 13.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: September 15, 1986.

Betty J. Beveridge

NIH Committee Management Officer.

[FR Doc. 86–21621 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Research Manpower Review Committee; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Research Manpower Review Committee, National Heart, Lung, and Blood Institute, National Institutes of Health, on October 26–28, 1986, at the Bethesda Ramada Hotel, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.

This meeting will be open to the public on October 26, from 7:00 p.m. to approximately 8:00 p.m. to discuss administrative details and to hear reports concerning the current status of the National Heart, Lung, and Blood Institute. Attendance by the public is limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and section 10(d) of Pub. L. 92–463, the meeting will be closed to the public on October 27 from approximately 8:00 a.m. until adjournment on October 28, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with

the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Terry Bellicha, Chief, Communications and Public Information Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4A21, National Institutes of Health, Bethesda, Maryland 20892, phone (301) 496–4236, will provide a summary of the meeting and a roster of the Committee members.

Dr. Robert M. Chasson, Executive Secretary, NHLBI, Westwood Building, Room 550, Bethesda, Maryland, 20892, phone (301) 496–7361, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, Heart and Vascular Diseases Research; 13.838, Lung Diseases Research; and 13.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: September 15, 1986.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 86–21622 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Allergy and Clinical Immunology Subcommittee of the Allergy, Immunology, and Transplantation Research Committee; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Allergy and Clinical Immunology Subcommittee of the Allergy, Immunology, and Transplantation Research Committee, National Institute of Allergy and Infectious Diseases, on October 14–16, 1986, in Conference Room 10, Building 31C, at the National Institutes of Health, Bethesda, Maryland 20992.

The meeting will be open to the public from 8:00 a.m. to 8:15 a.m. on October 14 and from 8:30 a.m. to 9:10 a.m. on October 15 to discuss administrative details relating to committee business and for program review. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and section 10(d) of Pub. L. 92–463, the meeting of the Allergy and Clinical Immunology Subcommitee will be closed to the public for the review, discussion, and evaluation of individual grant applications and contract proposals from 8:15 a.m. until recess on October 14, and from 9:10 a.m. on October 15 until adjournment on October 16. These applications, proposals, and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personnel information concerning individuals associated with the applications and proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Patricia Randall, Office of Research Repporting and Public Response, National Institute of Allergy and Infectious Diseases, Building 31, Room 7A–32, National Institutes of Health, Bethesda, Maryland 20892, telephone (301) 496–5717, will provide summaries of the meetings and rosters of the committees members upon request.

Dr. Nirmal K. Das, Executive Secretary, Allergy, Immunology and Transplantation Research Committee, NIAID, NIH, Westwood Building, Room 706, Bethesda, Maryland 20892, telephone (301) 496–7966, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.855, Pharmacological Sciences; 13.856, Microbiology and Infectious Diseases Research, National Institutes of Health.)

Dated: September 15, 1986.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 86–21623 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Institute of General Medical Sciences; Meetings

Pursuant to Pub. L. 92–463, notice is hereby given of the meetings of the committees of the National Institute of General Medical Sciences for October and November 1986.

These meetings will be open to the public to discuss administrative details relating to committee business for approximately two hours at the beginning of the first session of the first day of the meeting. Attendance by the public will be limited to space available. These meetings will be closed thereafter in accordance with provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, for the review, discussion, and evaluation of individual research training grant and research center grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Ann Dieffenbach, Public Information Officer, National Institute of General Medical Sciences, National Institutes of Health, Building 31, Room 4A52, Bethesda, Maryland 20892 (Telephone: 301–496–7301), will provide a summary of the meeting and a roster of committee members.

Substantive program information may be obtained from each executive secretary whose name, room number, and telephone number are listed below each committee.

Name of Committee: Pharmacological Sciencies Review Committee

Executive Secretary: Dr. Rodney Ulane, Room 952 Westwood Building, Telephone: 301–496–4772

Dates of meeting: October 30, 1986

Place of meeting: Building 31C, Conference Room 6, National Institutes of Health, Bethesda, Maryland

Open: October 30, 1986, 8:30 a.m.–10:30 a.m.

Closed: October 30, 1986, 10:30 a.m.–adjournment

Name of committee: Cellular and Molecular Basis of Disease Review Committee

Executive Secretary: Dr. Helen Sunshine, Room 950 Westwood Building, Telephone: 301–496–7125

Dates of meeting: November 3–4, 1986

Place of meeting: Building 31C, Conference Room 7, National Institutes of Health, Bethesda, Maryland

Open: November 3, 1986, 8:30 a.m.–10:30 a.m.

Closed: November 3, 1986, 10:30 a.m.–5:00 p.m. November 4, 1986, 8:30 a.m.–adjournment

Name of committee: Minority Access to Research Careers Review Committee

Executive Secretary: Dr. Agnes Donahue, Room 949 Westwood Building, Telephone: 301–495–7585

Dates of meeting: November 6–7, 1986

Place of meeting: Building 31C, Conference Room 8, National Institutes of Health, Bethesda, Maryland

Open: November 6, 1986, 8:30 a.m.–10:30 a.m.

Closed: November 6, 1986, 10:30 a.m.–5:00 p.m. November 7, 1986, 8:30 a.m.–adjournment.

Name of committee: Genetic Basis of Disease Review Committee

Executive Secretary: Ms. Linda Engel, Room 950 Westwood Building, Telephone: 301–496–7125

Date of meeting: November 13–14, 1986

Place of meeting: Building 31C, Conference Room 8, National Institutes of Health, Bethesda, Maryland

Open: November 13, 1986, 8:30 a.m.–10:30 a.m.
Closed: November 13, 1986, 10:30 a.m.–5:00 p.m. November 14, 1986, 8:30 a.m.–adjournment

(Catalog of Federal Domestic Assistance Program No. 13–859, 13–862, 13–863, 13–880, National Institute of General Medical Sciences, National Institutes of Health)
Dated: September 15, 1986.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 86–21624 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Meetings

Pursuant to Pub. L. 92–463, notice is hereby given of the meetings of the Board of Scientific counselors, National Institute on Aging, to be held at the Gerontology Research Center, 4940 Eastern Avenue, Baltimore, Maryland 21221.

The meetings will be open to the public to discuss administrative details and activities as indicated below. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S. Code and section 10(d) of Pub. L. 92–463, the meetings will be closed as indicated, for the review, discussion and evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June McCann, Committee Management Officer, National Institute on Aging, National Institutes of Health, Room 2C05, Building 31, Bethesda, Maryland 20892, (telephone 301–496–5898), will provide summaries of the meetings and rosters of committee members upon request.

Further information concerning the meetings may be obtained by contacting the office of Richard C. Greulich, Ph.D., Scientific Director, NIA, Gerontology Research Center, Room 1E07, 4940 Eastern Avenue, Baltimore, Maryland 21224.

Dates of meetings: October 14–15, 1986
Open: October 14, 8:30 a.m.–4:15 p.m.; October 15, 8:30 a.m. to adjournment
Agenda: To review the Baltimore Longitudinal Study
Closed: October 14, 4:15 p.m. to recess
Dates of meetings: October 27–29, 1986
Open: October 27, 8:30 a.m.–4:00 p.m.
Agenda: Staff of the laboratory(ies) will present and discuss their present and future research activities
Closed: October 27 4:00 p.m. to recess; October 28–29 8:30 a.m. to adjournment

(Catalog of Federal Domestic Assistance Program No. 13.866, Aging Research, National Institutes of Health).
Dated: September 15, 1986.

Betty J. Beveridge

Committee Management Officer, NIH.

[FR Doc. 86–21627 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Meetings

Pursuant to Pub. L. 92–463, notice is hereby given of meetings of the National Institute on Aging.

These meetings will be open to the public to discuss administrative details for approximately one-half hour at the beginning of the first session of the first day of the meetings. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, for the review, discussion, and evaluation of individual research grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June C. McCann, Committee Management Officer, National Institute on Aging, Building 31, Room 2C05, National Institutes of Health, Bethesda, Maryland 20892, (301/496–5898), will provide summaries of the meetings and rosters of the committee members upon request. Other information pertaining to the meetings can be obtained from the Executive Secretary indicated.

Name of Committee: Aging Review Subcommittee A
Executive Secretary: Dr. Walter Spieth, Building 31, Room 5C12, National Institutes of Health, Bethesda, Maryland 20892, Phone: 301/496–9666
Dates of Meeting: December 2–3, 1986
Place of Meeting: National Institutes of Health, Building 31C, Conference Room 4, 9000 Rockville Pike, Bethesda, Maryland 20892
Open: December 2, 8:30 a.m. to 9:00 a.m.
Closed: December 2, 9:00 a.m. to recess, December 3, 9:30 a.m. to adjournment
Closure Reason: To review grant applications
Name of Committee: Aging Review Subcommittee B
Executive Secretary: Dr. Marvin Kalt, Building 31, Room 5C12, National Institutes of Health, Bethesda, Maryland 20892, Phone: 301/496–9666
Dates of Meeting: December 4–5, 1986
Place of Meeting: National Institutes of Health, Building 31C, Conference Room 8, 9000 Rockville Pike, Bethesda, Maryland 20892
Open: December 4, 8:30 a.m. to 9:00 a.m.
Closed: December 4, 9:00 a.m. to recess, December 5, 9:30 a.m. to adjournment
Closure Reason: To review grant applications

(Catalog of Federal Domestic Assistance Program No. 13.866, Aging Research, National Institutes of Health)
Dated: September 15, 1986.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 86–21625 Filed 9–23–86; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Geriatrics Review Committee; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Geriatrics Review Committee, National Institute on Aging, on November 12–13, 1986, to be held in Building 31, Conference Room 7, National Institutes of Health, Bethesda, Maryland 20892.

The meeting will be open to the public from 8:30 a.m. to 9:00 a.m. on November 12, for introductory remarks. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, the meeting will be closed to the public on November 12, from 9:00 a.m. to adjournment on November 13 for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June C. McCann, Committee Management Officer, NIA, Building 31, Room 2C05, National Institutes of Health, Bethesda, Maryland 20892, (301/496–5898), will provide summaries of meetings and rosters of Committee members as well as substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.866, Aging Research, National Institutes of Health)

Dated: September 15, 1986.

Betty J. Beveridge,

NIH Committee Management Officer.

[FR Doc. 86-21621 Filed 9-23-86; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, as amended most recently in pertinent part at 49 FR 50114, December 26, 1984) is amended to reflect the abolishment of the Office of Consumer and Professional Affairs (OCPA), Center for Drugs and Biologics (CDB), and the transfer of those functions to the Center's Office of Managment (OM). OCPA was originally established to bring two separate functions, Freedom of information (FOI) and consumer liaison, into a location near the Office of the Director, CDB, so that visibility and priority considerations could be maintained.

The FOI program has grown over the past several years. Because it involves policy-setting and interactions with Center-wide components, relocating the FOI function into OM is reasonable because similar Center-wide management activities are performed by the Office.

External communications funtions previously located in OCPA will be transferred to the Office of Compliance (OC), CDB, and consolidated with similar function performed in OC. No change in functional statements for OC is necessary.

Section HF-B, Organization and Functions is amended as follows:

1. Delete subparagraph (n-1-i), *Office of Management (HFN-12)* and insert new subparagraph (n-1-i), *Office of Management (HFN 12).*

(n-1-i) *Office of Management (HFN-12).* Monitors the development and operation of planning systems for Center activities and resource allocations and advise the Center Director on Center administrative policies and guidlines and information systems and services.

Directs and counsels Center managers through program evaluation and technological forecasting.

Plans and directs Center operations for financial and personnel management, employee development and trainging, equal employment opportunity (EEO) activities, and Office services.

Directs Centers organization, management, and information systems, and provides library services.

Manages studies designed to improve processes and resource allocations in the Center.

Advises the Center on contract and grant proposals.

Provides coordination for receipt and distribution of initial drug and biological product applications and other related documents.

Prepares, develops, and coordinates Center and Agency responses to inquiries on drugs and biological products from health professionals, consumers, and others including requests under the Freedom of Information (FOI) Act, the Privacy Act, and other statutes.

2. Delete subparagraph (n-1-iii), *Office of Consumer and Professional Affairs (HFN 14).*

Dated: September 15, 1986.

Wilford T. Forbush,

Director, Office of Management, PHS.

[FR Doc. 86-21609 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-N

Food and Drug Administration; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, as amended most recently in pertinent parts at 49 FR 10179, March 19, 1984 and 50 FR 25328, June 18, 1985) is amended to reflect organizational changes.

FDA is establishing an Office of Beltsville Technical Operations (OBTO) within the Office of the Center Director, Center for Food Safety and Applied Nutrition. OBTO will provide centralized management and coordination of FDA's Module 1 research facility located in Beltsville, Maryland. These functions include providing for animal space, diet preparation, quality, control and veterinary support.

Section HF-B, Organization and Functions is amended as follows:

1. Insert the following new subparagraph (k-1-ii) *Office of Beltsville Technical Operations* QHFF1-5).

(k-1-ii) *Office of Beltsville Technical Operations (HFF1-5).* Provides and directs specific administrative and technical management of the Beltsville Research Complex.

Provides and coordinates the allocation of resources for the centralized support services of the entire Beltsville Research Complex.

Plans, directs, and/or coordinates centralized financial management and procurement, general services, contracts, graphic arts, printing, reproduction, and mail services for the Beltsville Research Complex.

Directs the coordination of Module 1 centralized training programs with the Center for Food Safety and Applied Nutrition (CFSAN).

Directs the coordination of overall computer support needs and assures compliance with the CFSAN Laboratory Safety Program and services.

Ensures the establishment, implementation and direction of microbial surveillance program, providing quality control for all laboratory animal operations and experiments involving animal systems.

Ensures the administration and coordination of a chemistry quality control program in support of scientific studies performed at the Beltsville Research Complex.

Effective Date: September 15, 1986.

Dated: September 15, 1986.

Wilford T. Forbush,

Director, Office of Management, PHS.

[FR Doc. 86-21610 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

September 9, 1986.

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone 202-395-7340.

Title: Special Grants for Economic Development, 25 CFR Part 278, Subpart B
Abstract: An Indian tribe supplies information required to obtain an Economic Development Grant. This information allows the Bureau to determine if the tribe meets the grant qualification standards listed in 25 CFR Part 278, Subpart B, if an adequate plan for developing a profit-making tribal enterprise has been prepared and, also, serves as a tool for the grantee and the bureau to monitor the grant. This information is required in addition to the information required on the Standard Form 424 which is used for grant applications as per OMB Circular A-102 requirements
Bureau Form Number: None
Frequency: Upon application
Description of Respondents: Indian tribes which are applying for Economic Development Grants
Annual Burden Hours: 11,700
Bureau clearance Officer: Anne Bolton 202-343-3577.

Ross O. Swimmer,

Assistant Secretary—Indian Affairs.

[FR Doc. 21597 Filed 9-23-86; 8:45 am]

BILLING CODE 4310-02-M

Bureau of Land Management

[AZ-080-06-4220-10; A-9272]

Exchange of Public and State Lands

September 17, 1986.

Notice is hereby given that the following described land has been transferred out of Federal ownership pursuant to section 206 of the Federal Land Policy and Management Act of 1976 in exchange for State-owned land. The land transferred to the State of Arizona is described as:

Gila and Salt River Meridian, Arizona

T. 27 N., R. 9E.,
Sec. 6, lots 3 to 10, incl., SE¼NW¼, E½SW¼, N½SE¼, SE¼SE¼.
Comprising 463.46 acres.

The following described land within the Grand Canyon National Park has been reconveyed to the United States and is subject to the jurisdiction of the National Park Service:

Gila and Salt River Meridian, Arizona

T. 30 N., R. 15 W.,
Sec. 16, lots 1 to 4, incl.;
T. 31 N., R. 13 W.,
Sec. 36, SW¼NW¼;
T. 31 N., R. 12 W.,
Sec. 32, all;
Sec. 36, All;
T. 32 N., R. 10 W.,
Sec. 16, S½SW¼, SE¼;
T. 36 N., R. 5 E.,
Sec. 16, all.
Comprising 2,341.40 acres.

The purpose of this notice is to inform the public and interested State and local government officials of the transfer of Federal land and acquisition of State land by the Federal government.

Inquires concerning the land should be addressed to the Chief, Branch of Lands and Minerals Operations, Arizona State Office, Bureau of Land Management, P.O. Box 16563, Phoenix, Arizona 85011.

John T. Mezes,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 86-21598 Filed 9-23-86; 8:45 am]

BILLING CODE 4310-36-M

[CO-940-86-4420-10; C-44206]

Proposed Withdrawal; Opportunity for Public Hearing

Correction

In FR Doc. 86-19897, beginning on page 31725, in the issue of Thursday, September 4, 1986, make the following corrections:

1. On page 31725, third column, in the **"SUMMARY"**, fifth line, "for" should read "from".
2. On page 31726, first column, under **"FOR FURTHER INFORMATION CONTACT"**, first line, "(301)" should read "(303)".
3. On the same page, first column, third complete paragraph from the bottom, third line, after "laws" insert "only".
4. On the same page, second column, first complete paragraph, thirteenth line, "current" should read "concurrent".

BILLING CODE 1505-01-M

[U-52625-EY]

Utah; Notice of Proposed Reinstatement of Terminated Oil and Gas Lease

In accordance with Title IV of the Federal Oil and Gas Royalty Management Act (Pub. L. 97-451), a petition for reinstatement of oil and gas lease U-52625-EY for lands in Carbon County, Utah, was timely filed and required rentals and royalties accruing from May 1, 1986, the date of termination, have been paid.

The lessee has agreed to new lease terms for rentals and royalties at rates of $5 per acre and 16-⅔ percent, respectively. The $500 administrative fee has been paid and the lessee has reimbursed the Bureau of Land Management for the cost of publishing this notice.

Having met all the requirements for reinstatement of lease U-52625-EY as set out in section 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), the Bureau of Land Management is proposing to reinstate the lease, effective May 1, 1986, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Orval L. Hadley,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 86-21605 Filed 9-23-86; 8:45 am]

BILLING CODE 4310-DQ-M

[WY-040-06-4212-11; W-96246]

Recreation and Public Purposes Lease; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Recreation and public purposes lease of public lands in Sweetwater County, Wyoming.

SUMMARY: The following public lands have been found suitable for lease to the Sweetwater County Board of Commissioners for use as an equestrian center (including a snowmobile facility) within the unincorporated area of Farson, Wyoming. The lands will be classified under the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 et seq.). They are currently under the administrative jurisdiction of the Bureau of Reclamation.

T. 25 N., R. 106 W. 6th P.M. Sweetwater County, Wyoming
Section 27: N½NE¼, N½SW¼NE¼
Containing 86.61 acres.

DATE: Interested parties must submit comments within 45 days of publication of this notice to Area Manager, Green River Resource Area, P.O. Box 1170, Rock Springs, Wyoming 82902-1170. Any adverse comments will be evaluated by the State Director, who may sustain, vacate, or modify this Realty Action. In absence of any adverse comments, the classification will become effective 60 days from the date of publication of this notice.

Upon the effective date of the classification, the lands will be open to the filing of an application under the Recreation and Public Purposes Act by any interested, qualified applicant.

FOR FURTHER INFORMATION CONTACT: The Green River Resource Area, Rock Springs District (307) 362-6422.

SUPPLEMENTARY INFORMATION: The environmental assessment process has determined that lease of these lands is in conformance with the Big Sandy

Management Framework Plan, and would not effect any BLM ongoing program and would be in the public interest.

The lease would be subject to the following conditions:

1. Provisions of the Recreation and Public Purpose Act and to all applicable regulations of the Secretary of the Interior.

2. Rights-of-way under Serial Nos. W–087346 and W–87159 road rights-of-way and W–101905 for both above ground and buried telephone cable.

These lands are segregated from disposal and mineral location under the oil shale withdrawal, Executive Order No. 5327 and Public Order No. 4522.

Dated: September 16, 1986.

Donald H. Sweep,

District Manager.

[FR Doc. 86–21596 Filed 9–23–86; 8:45 am]

BILLING CODE 4310-22-M

Bureau of Reclamation

Construction of Stagecoach Dam and Reservoir, Powerplant, and Related Facilities on the Upper Yampa River in Routt County, CO

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of final environmental impact statement.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, the Department of the Interior has prepared a final environmental impact statement for the Stagecoach Reservoir Project, Colorado (INT FES 86–30 dated September 18, 1986). The proposed development would provide water for agriculture, municipal and industrial uses, hydroelectric power generation, fish and wildlife, and recreation in the Upper Yampa River valley of Routt County in northwest Colorado.

The final statement presents a recommended plan and four alternatives. The recommended Stagecoach Reservoir Project would consist of Stagecoach Dam, Reservoir, and Powerplant and related facilities located on the Yampa River about 17 miles south of Steamboat Springs. The alternatives include a smaller and a larger reservoir at the Stagecoach Damsite, a similar reservoir at a different site on the Yampa River, and a no action alternative.

Address: Copies of the statement are available for inspection at the following locations:

Director, Office of Environmental Affairs, Bureau of Reclamation, Room 7622, Department of the Interior, Washington, DC 20240, Telephone: (202) 343–4991

Property and Services Branch, Technical Publications and Library Branch, Engineering and Research Center, Code 960, Denver Federal Center, Denver, Colorado 80225, Telephone: (303) 236–5972

Regional Director, Bureau of Reclamation, Upper Colorado Regional Office, P.O. Box 11568, Salt Lake City, Utah 84147, Telephone: (801) 524–5580.

FOR FURTHER INFORMATION CONTACT: Information or single copies of the statement may be obtained on request to the Director, Office of Environmental Affairs, or the Regional Director at the above addresses. Copies will also be available for inspection in libraries in the project vicinity.

SUPPLEMENTARY INFORMATION: The Upper Yampa Water Conservancy District would be the owner of the project and has applied for a loan and grant under provisions of the Small Reclamation Projects Act of 1956 (Pub. L. 84–984), as amended, to finance about 50 percent of the project costs. The remaining costs would be financed through a loan from the Colorado Water Conservation Board and by District funding. The District would operate the water storage and power generating facilities and is negotiating with the Colorado Division of Wildlife for management of fisheries and wildlife areas. The Colorado Division of Parks and Outdoor Recreation has committed to manage the recreation facilities. Because the Bureau of Reclamation is processing the Federal loan and grant application, it has prepared the environmental impact statement.

Dated: September 18, 1986.

Joseph B. Marcotte, Jr.,

Acting Commissioner.

[FR Doc. 86–21631 Filed 9–23–86; 8:45 am]

BILLING CODE 4310-09-M

Minerals Management Service

Development Operations Coordination Document

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed development operations coordination document (DOCD).

SUMMARY: Notice is hereby given that Mobil Oil Exploration & Producing Southeast Inc. has submitted a DOCD describing the activities it proposes to conduct on Lease OCS 0244, Block 71, West Cameron Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Cameron, Louisiana.

DATE: The subject DOCD was deemed submitted on September 15, 1986.

ADDRESS: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, MInerals Management Service, 1420 South Clearview Pkwy., Room 114, New Orleans, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Phone (504) 736–2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected States, local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: September 16, 1986.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 86–21555 Filed 9–23–86; 8:45 am]

BILLING CODE 4310-MR-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–230]

Certain Unitary Electromagnetic Flowmeters With Sealed Coil; Commission Decision to Review Initial Determination, Schedules for Filing Written Submissions on Portions of Violation, Remedy, the Public Interest, and Bonding

AGENCY: International Trade Commission.

ACTION: The U.S. International Trade Commission has determined to review portions of an initial determination (ID)

finding a violation of section 337 in the above-captioned investigation. The portions of the ID that will be reviewed are the presiding administrative law judge's (AJ's) determination regarding the effect and tendency to substantially injure the relevant domestic industry. The parties to the investigation and interested government agencies are requested to file written submissions on the issues under review and on remedy, the public interest, and bonding. Comments from other interested persons also will be accepted on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Jean A. Heck, Esq., Office of the General Counsel, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202–523–1693.

SUMMARY: On July 30, 1986, ALJ issued an ID finding that there is a violation of section 337 in the importation and sale of certain unitary electromagnetic flowmeters with sealed coils. Respondents have filed a petition for review of the ID and complainant has filed a response. No agency comments were received.

Having examined the record in this investigation, including the ID of the ALJ, the petition for review and the response thereto, the Commission has determined to review the ID. The Commission has decided that the following issues warrant review:

1. Whether the unfair acts of respondents have the effect of substantially injuring the relevant domestic industry; and

2. Whether the unfair acts of respondents have a tendency to substantially injure the relevant domestic industry.

In particular, the Commission would like the parties to address the validity of the ALJ's use of the Frost and Sullivan forecasts to determine actual market share and the validity of the ALJ's use of constructed domestic industry data in the absence of the actual data.

In addition, the parties are requested to address the issue of whether a remand to the ALJ to take additional evidence would be helpful in concluding this investigation.

No other issues will be reviewed.

SUPPLEMENTARY INFORMATION: If the Commission finds that a violation of section 337 has occurred, it may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions which address the form of relief, if any, that should be ordered.

If the Commission concludes that a violation of section 337 has occurred and contemplates some form of relief, it must consider the effect of that relief upon the public health and welfare, competitive conditions in the U.S. economy, the U.S. production of articles which are like or directly competitive with those that are subject to investigation, and U.S. consumers. The Commission is therefore interested in receiving written submissions concerning the effect, if any, that granting relief would have on the public interest.

If the Commission finds that a violation of section 337 has occurred and orders some form of relief, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond in an amount determined by the Commission and prescribed by the Secretary of the TGreasury. The Commission is therefore interested in receiving written submissions concerning the amount of the bond that should be imposed.

Written Submissions

The parties to the investigation and interested Government agencies are requested to file written submission on the issues under review and on the issues of remedy, the public interest, and bonding. Complainant and the Commission investigative attorney also are requested to submit a proposed remedial order for the Commission's consideration. Written submissions on the issues under review and the issues of remedy, the public interest, and bonding must be filed no later than the close of business on September 26, 1986. Reply submissions must be filed not later than the close of business on October 3, 1986. Persons other than the parties and Government agencies may file written submissions addressing the issues of remedy, the public interest, and bonding. Such submissions must be filed not later than the close of business on October 3, 1986. No further submissions will be permitted.

Commission Hearing

The Commission does not plan to hold a public hearing in connection with final disposition of this investigation.

Additional Information

Persons submitting written submissions must file the original document and 14 true copies thereof with the Office of the Secretary on or before the deadlines stated above. Any person desiring to submit a document (or a portion thereof) to the Commission in confidence must request confidential treatment, unless the information has already been granted such treatment by the ALJ. All such request should be directed to the Secretary to the Commission and must include a statement of the reasons why the Commission should grant such treatment. Documents containing confidential information approved by the Commission for confidential treatment will be treated accordingly. All nonconfidential written submissions will be available for public inspection in the Secretary's Office.

This action is taken under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and Commission Rule 210.55 (19 CFR 210.55)

Notice of this investigation was published in the **Federal Register** of October 30, 1985 (50 FR 45175–45176).

Copies of the nonconfidential version of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202–523–0161.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission TDD terminal on 202–724–0002.

By order of the Commission.

Issued: September 15, 1986.

Kenneth R. Mason,

Secretary.

[FR Doc. 86–21660 Filed 9–23–86; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–244]

Insulated Security Chests

AGENCY: International Trade Commission.

ACTION: Nonreview of an initial determination granting a motion for summary determination terminating the investigation as to one respondent.

SUMMARY: Notice is hereby given that the Commission has determined not to review an initial determination (ID) (Order No. 9) issued by the presiding administrative law judge (ALJ) in the above-captioned investigation granting the joint motion of complainant John D.

Brush & Co. (Brush) and respondent G.I. Joe's, Inc. (GIJ) for summary determination that GIJ is not in violation of section 337 and for termination of the investigation as to GIJ.

FOR FURTHER INFORMATION CONTACT: Edwin J. Madaj, Jr., Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–523–0148.

SUPPLEMENTARY INFORMATION: The authority for the Commission's disposition of this matter is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and in § 210.53 of the Commission's Rules of Practice and Procedure (19 CFR 210.53).

On August 8, 1986, complainant Brush and respondent GIJ jointly filed a motion for summary determination that GIJ is not in violation of section 337 and for termination of the investigation as to GIJ. On August 12, 1986, the Commission investigative attorney (IA) filed a response supporting the motion. On August 18, 1986, the administrative law judge (ALJ) issued an ID granting the motion for summary determination and terminating GIJ. The ALJ found that there was no genuine issue as to any material fact and that the moving parties were entitled to summary determination as a matter of law because it was undisputed that GIJ has neither imported nor sold any accused infringing products, and has no intent to do so in the future.

Copies of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202–523–0161.

Hearing-impaired individuals are advised that information concerning this investigation can be obtained by contacting the Commission's TDD terminal on 202–724–0002

By order of the Commission.

Issued: September 17, 1986.

Kenneth R. Mason,

Secretary.

[FR Doc. 86–21657 Filed 9–23–86; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–240]

Certain Laser Inscribed Diamonds and the Method of Inscription

AGENCY: International Trade Commission.

ACTION: Nonreview of an initial determination (ID) terminating the above-captioned investigation and to the remaining respondents on the basis of a consent order.

SUMMARY: The Commission has determined not to review an ID (Order No. 12) terminating Sears, Goodman, and Schwartz as respondents in the investigation on the basis of a consent order.

FOR FURTHER INFORMATION CONTACT: Charles Nalls, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–523–1626.

SUPPLEMENTARY INFORMATION: This action is taken under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and 19 CFR 210.53(h).

On August 8, 1986, complainant Lazare Kaplan, Inc., the remaining respondents in the investigation—Sears, Roebuck, & Co., I.B. Goodman Mfg. Co. Inc., and Aharon Schwartz & Sons—and the Commission investigative attorney jointly moved to terminate the investigation on the basis of a consent order (Motion No. 240–4). On August 19, 1986, the presiding administrative law judge issued an ID granting the joint motion to terminate the investigation with respect to the remaining respondents on the basis of the consent order. The Commission has received no petitions for review of the ID nor any comments from other Government agenices or the public.

Termination of the investigation on the basis of a consent order furthers the public interest by conserving Commission resources and those of the parties involved.

Copies of the nonconfidential version of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202–523–0161.

Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal no 202–724–0002.

By order of the Commission.

Issued: September 15, 1986.

Kenneth R. Mason,

Secretary.

[FR Doc. 86–21658 Filed 9–23–86; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–229]

Certain Nut Jewelry and Parts Thereof; Commission Decision To Review Portions of Initial Determination; Schedule for Filing Written Submissions on Issues Under Review, and on Remedy, the Public Interest, and Bonding

AGENCY: International Trade Commission.

ACTION: The U.S. International Trade Commission has determined to review portions of an initial determination (ID) finding a violation of section 337 in the above-captioned investigation. The portions of the ID that will be reviewed are the presiding administrative law judge's (ALJ's) determination regarding the definition of the domestic industry and the ALJ's denial of joint motions to terminate the investigation on the basis of consent orders. The parties to the investigation and interested government agencies are requested to file written submissions addressing the issues under review and remedy, the public interest, and bonding. Comments from other interested persons also will be accepted on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Randi S. Field, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–523–0261.

SUMMARY: On July 30, 1986, the ALJ issued an ID finding that there is a violation of section 337 in the importation and sale of certain nut jewelry and parts thereof. Respondents Blair, Ltd., and RDCO, Inc., filed petitions for review of the ID and complainant Kukui Nuts of Hawaii, Inc., filed a response to the petitions. No agency comments on the ID were received.

Having examined the record in this investigation, including the ID of the ALJ, the petitions for review and the response thereto, the Commission has determined to review portions of the ID. Specifically, the Commission has decided that the following issues warrant review:

1. The definition of the relevant domestic industry; and

2. Whether the joint motions (Motions Nos. 229–15 and 229–18) to terminate the investigation on the basis of consent orders should be granted.

In particular, the Commission would like the parties to address whether in this investigation the Commission has the power to impose a consent order upon complainant without complainant's consent and whether the

joint motions relating to respondents Blair, Ltd. and RDCO, Ltd. should be granted.

No other issues will be reviewed.

SUPPLEMENTARY INFORMATION: If the Commission finds that a violation of section 337 has occurred, it may issue (1) an order which could result in the exclusion of the subject articles from entry into the United States and/or (2) cease and desist orders which could result in respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions which address the form of relief, if any, which should be ordered.

If the Commission concludes that a violation of section 337 has occurred and contemplates that some form of relief is appropriate, it must consider the effect of that relief upon the public health and welfare, competitive conditions in the U.S. economy, the U.S. production of articles which are like or directly competitive with those that are subject to investigation, and U.S. consumers. The Commission is therefore interested in receiving written submissions concerning the effect, if any, that granting relief would have on the enumerated public interest factors.

If the Commission finds that a violation of section 337 has occurred and orders relief, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving written submissions concerning the amount of the bond which should be imposed.

Written Submissions: The parties to the investigation and interested government agencies are requested to file written submissions on the issues under review and on the issues of remedy, the public interest, and bonding. Complainant and the Commission investigative attorney are also requested to submit a proposed remedial order for the Commission's consideration. Written submissions on the issues under review and on the issues of remedy, the public interest, and bonding must be filed no later than the close of business on October 3, 1986. Reply submissions on all issues must be filed not later than the close of business on October 10, 1986. Persons other than the parties and government agencies may file written submissions addressing the issues of remedy, the public interest, and bonding. Such submissions must be filed not later than the close of business on October 3, 1986. No further submissions will be permitted.

Commission Hearing

The Commission does not plan to hold a public hearing in connection with final disposition of this investigation.

Additional Information

Persons submitting written submissions must file the original document and 14 true copies thereof with the Office of the Secretary on or before the deadlines stated above. Any person desiring to submit a document (or a portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment by the ALJ. All such requests should be directed to the Secretary of the Commission and must include a statement of the reasons why the Commission should grant such treatment. Documents containing confidential information approved by the Commission for confidential treatment will be treated accordingly. All nonconfidential submissions will be available for public inspection at the Secretary's Office.

This action is taken under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and sections 210.54–210.56 of the Commission's rules of practice and procedure (19 CFR 210.54–210.56).

Notice of this investigation was published in the **Federal Register** on October 30, 1985 (50 FR 45173).

Copies of the nonconfidential version of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington, DC 20436, telephone 202–523–0161. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–724–0002.

Issued: September 22, 1986.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 86–21787 Filed 9–23–86; 10:41 am]

BILLING CODE 7020-02-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Controlled Substances; Proposed Aggregate Production Quotas for 1987

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed aggregate production quotas for 1987.

SUMMARY: This notice proposes initial 1987 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act.

DATE: Comments or objections should be received on or before October 24, 1986.

ADDRESS: Send comments or objections to the Administrator, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Attn: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC, 20537, (202) 633–1366.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for all controlled substances listed in Schedules I and II. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration by §0.100 of Title 28 of the Code of Federal Regulations.

The quotas are to provide adequate supplies of each substance for: (1) The estimated medical, scientific, research, and industrial needs of the United States; (2) Lawful export requirements; and (3) The establishment and maintenance of reserve stocks.

The quotas are to provide adequate supplies of each substance for: (1) The estimated medical, scientific, research, and industrial needs of the United States; (2) Lawful export requirements; and (3) The establishment and maintenance of reserve stocks.

In determining the below listed proposed 1987 aggregate production quotas, the Administrator considered the following factors: (1) Total actual 1985 and estimated 1986 and 1987 net disposals of each substance by all manufacturers; (2) Estimates of inventories of each substance and of any substance manufactured from it and trends in accumulation of such inventories; and (3) Projected demand as indicated by procurment quota applications which were filed pursuant to §1303.12 of Title 21 of the Code of Federal Regulations.

Pursuant to §1303.23(c) of Title 21 of the Code of Federal Regulations, the Administrator of the Drug Enforcement Administration will in early 1987 adjust individual manufacturing quotas allocated for the year based upon 1986 year-end inventory and actual 1986 disposition data supplied by quota applicants for each basis class of Schedule I or II controlled substance.

Based upon consideration of the above factors, the Administrator of the Drug Enforcement Administration hereby proposes that aggregate production quotas for 1987 for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class	Proposed 1987 quotas
Schedule I:	
Alfentanil	10,000
2,5-Dimethoxyamphetamine	10,500,000
Lysergic Acid Diethylamide	18
3,4-Methylenedioxyamphetamine	5
3,4-Methylenedioxymethamphetamine	5
Tetrahydrocannabinols	30,000
Schedule II:	
Amobarbital	887,000
Amphetamine	325,000
Cocaine	800,000
Codeine (for sale)	58,001,000
Codeine (for conversion)	4,064,000
Desoxyephedrine	1,360,000
1,300,000 grams for the production of levodesoxyephedrine for use in a noncontrolled, nonprescription product and 60,000 grams for the production of methamphetamine.	
Dextropropoxyphene	69,637,000
Dihydrocodeine	823,000
Dihydrocodeine (for conversion)	129,000
Diphenoxylate	584,000
Ecgonine (for conversion)	650,000
Fentanyl	5,800
Hydrocodone	1,859,000
Hydromorphone	196,000
Levorphanol	22,500
Meperidine	11,282,000
Methadone	1,510,000
Methadone Intermediate (4-Cyano-2-dimethylamino-4,4-diphenylbutane)	1,888,000
Methamphetamine (for conversion)	1,938,000
Methylphenidate	1,566,000
Mixed Alkaloids of Opium	10,500
Morphine (for sale)	2,078,000
Morphine (for conversion)	62,557,000
Opium (tinctures, extracts, etc. expressed in terms of USP powdered opium	1,506,000
Oxycodone (for sale)	2,333,000
Oxycodone (for conversion)	256,000
Oxymorphone	2,500
Pentobarbital	12,000,000
Phencyclidine	47
Phenmetrazine	100,000
Phenylacetone (for conversion)	755,000
1-Piperidinocyclohexanecarbonitrile (for conversion)	54
Secobarbital	1,963,000
Sufentanil	300
Thebaine	6,954,000

All interested persons are invited to submit comments and objections in writing rearding this proposal. A person may object to or comment on the above-mentioned substances without filing comments or objections regarding the others. Comments and objections should be submitted to the Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attn: DEA Federal Register Representative, and must be received by October 24, 1986. If a person believes that one or more issues raised by him warrant a hearing, he should so state and summarize the reasons for his belief.

In the event that comments or objections to this proposal raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall cause such hearing to be convened pursuant to the provisions of Title 21 of the Code of Federal Regulations, § 1303.31(a).

Pursuant to sections (3)(c)(3) and 3(e)(2)(C) of Executive Order 12291, the Director of the Office of Management and Budget has been consulted with respect to these proceedings.

The Administrator hereby certifies this matter will have no significant impact upon small entities within the meaning of and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. The establishment of annual aggregate production quotas for Schedules I and II controlled substances is mandated by law and by international commitments of the United States. Such quotas impact predominantly upon major manufacturers of the affected controlled substances.

Dated: August 25, 1986.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 86-21582 Filed 9-23-86; 8:45 am]

BILLING CODE 4410-09-M

Quotas for Controlled Substances in Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of established 1986 aggregate production quotas.

SUMMARY: This notice establishes 1986 aggregate production quotas for Lysergic acid diethylamide and methylendioxyamphetamine.

DATE: This order is effective September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for all controlled substances in Schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of Title 28 of the Code of Federal Regulations.

On July 7, 1986, a notice proposing aggregate production quotas for lysergic acid diethylamide and methylenedioxyamphetamine was published in the **Federal Register** (51 FR 24589). All interested persons were invited to comment on or object to the proposal on or before August 6, 1986. No comments or objections were received.

Pursuant to sections 3(c)(3) and 3(e)(2)(C) of Executive Order 12291, the Director of the Office of Management and Budget has been consulted with respect to these proceedings.

The Administrator hereby certifies that this matter will have no significant impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. The establishment of annual aggregate production quotas for Schedules I and II controlled substances is mandated by law and by the international commitments of the United States. Such quotas impact predominantly upon major manufacturers of the affected controlled substances.

Therefore, under the authority vested in the Attorney General by section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826) and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that the 1986 aggregate production quotas for lysergic acid diethylamide and methylenedioxyamphetamine, expressed in grams of anhydrous base, be established as follows:

Basic class	1986 aggregate production quotas
Schedule I:	
Lysergic acid diethylamide	5
Methylenedioxyamphetamine	2

Dated: August 25, 1986.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 86-21583 Filed 9-23-86; 8:45 am]

BILLING CODE 4410-09-M

Quotas for Controlled Substances in Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of established 1986 aggregate production quotas.

SUMMARY: This notice establishes revised 1986 aggregate production quotas for controlled substances in Schedule II, as required under the Controlled Substances Act of 1970.

EFFECTIVE DATE: This order is effective upon publication.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 633–1366.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for all controlled substances in Schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of Title 28 of the Code of Federal Regulations.

On July 7, 1986, a notice of proposed revised 1986 aggregate production quotas for certain controlled substances in Schedule II was published in the **Federal Register** (51 FR 24590). All interested parties were invited to comment on or object to these proposed aggregate production quotas on or before August 6, 1986. No comments or objections were received on the proposed revised aggregate production quotas for any substance other than methylphenidate.

By letter dated July 8, 1986, the Acting Deputy Administrator requested the Administrative Law Judge to commence proceedings on the 1986 aggregate production quota for methylphenidate following a request for hearing by a manufacturer of methylphenidate. The manufacturers of methylphenidate commented on the proposed revised aggregate production quota for methylphenidate, published at 51 FR 24590. These comments have been forwarded to the Administrative Law Judge. Inasmuch as the matter of the 1986 aggregate production quota for methylphenidate is now before the Administrative Law Judge, the Administrator will not enter a final 1986 aggregate production quota for methylphenidate until completion of those proceedings. The proposed revised aggregate production quota for methylphenidate shall remain in effect pending the outcome of the proceedings before the Administrative Law Judge.

Pursuant to sections 3(c)(3) and 3(e)(2)(C) of Executive Order 12291, the Director of the Office of Management and Budget has been consulted with respect to these proceedings.

The Administrator hereby certifies that this matter will have no significant impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. The establishment of annual aggregate production quotas for Schedules I and II controlled substances is mandated by law and by the international commitments of the United States. Such quotas impact predominantly upon major manufacturers of the affected controlled substances.

Therefore, under the authority vested in the Attorney General by section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826) and delegated to the Administrator of the Drug Enforcement Administration by Section 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that the 1986 revised aggregate production quotas be established as follows:

Basic class	Established revised 1986 aggregate production quotas (expressed as grams of anhydrous acid or base)
Schedule II:	
Amobarbital	850,000
Amphetamine	389,000
Codeine (for sale)	61,228,000
Codeine (for conversion)	4,287,000
Desoxyephedrine*	1,355,000
Dihydrocodeine	959,000
Diphenoxylate	526,000
Fentanyl	6,700
Hydrocodone	1,928,000
Hydromorphone	214,000
Meperidine	11,483,000
Methadone	1,690,000
Methadone Intermediate (4-cyano-2-dimethylamino-4,4-diphenylbutane)	2,113,000
Morphine (for sale)	2,314,000
Morphine (for conversion)	61,911,000
Opium (tinctures, extracts, etc. expressed in tems of USP powdered opium)	1,592,000
Oxycodone (for sale)	2,581,000
Oxycodone (for conversion)	7,500
Oxymorphone	3,800
Pentobarbital	12,758,000
Secobarbital	1,401,000
Sufentanil	300

*1,355,000 grams for the production of levodesoxyephedrine for use in a noncontrolled, nonprescription product and 0.0 grams for the production of methamphetamine.

Dated: August 25, 1986.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 86–21584 Filed 9–23–86; 8:45 am]

BILLING CODE 4410–09–M

NUCLEAR REGULATORY COMMISSION

Bi-Weekly Notice; Applications and Amendments to Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (Pub. L.) 97–415, the Nuclear Regulatory Commission (the Commission) is publishing this regular bi-weekly notice. Pub.L. 97–415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This bi-weekly notice includes all amendments issued, or proposed to be issued, since the date of publication of the last bi-weekly notice which was published on September 10, 1986 (51 FR 32264) through September 15, 1986.

NOTICE OF CONSIDERATION OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND PROPOSED NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION AND OPPORTUNITY FOR HEARING

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination

unless it receives a request for a hearing.

Comments should be addressed to the Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice.

By October 24, 1986 the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325–6000 (in Missouri (800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to *(Project Director):* petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel-Bethesda, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Alabama Power Company, Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Unit Nos. 1 and 2, Houston County, Alabama

Date of amendments request: August 11, 1986.

Description of amendments request: The licensee proposes to change the duration of the Operating Licenses for both units to 40 years. This action would change the license expiration date on Unit 1 from August 16, 2012, to June 25, 2017, and on Unit 2 from August 16, 2012, to March 31, 2021. The original license expiration date is based on 40 years from the date the Construction Permit was issued (August 16, 1972).

Basis for proposed no significant hazards consideration determination: The licensee provides an analysis which concludes that the changes do not involve a significant hazards consideration as defined in 10 CFR 50.92.

We have reviewed the licensee's analysis and agree with its conclusion. The analysis is restated as follows:

(1) The proposed changes will not increase the probability or consequences of an accident previously evaluated because no physical changes to the plant or modifications of plant procedures are requested. The plant was originally designed for a 40-year service life as indicated in Section 2 of Attachment 3. The proposed change only amends the operating licenses to allow operation of the plant for the full 40 years. Therefore, the probability or consequences of an accident previously evaluated have not been increased.

(2) The proposed changes will not create the possibility of a new or different kind of accident from any accident previously evaluated because the plant design is not changed and the original plant design basis consisted of a 40 year service life. The proposed change only amends the operating licenses of the plant for the full 40 years. Additionally, the qualified lifetimes for equipment within the scope of 10 CFR 50.49 have been incorporated into plant equipment maintenance and replacement practices to ensure that safety-related electrical equipment remains qualified and available to perform its safety function regardless of the overall age of the plant. The plant Inservice Inspection Program ensures that the mechanical equipment within the scope of ASME Code Class 1, 2 and 3 is maintained regardless of the age of the plant. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) The proposed changes will not involve a reduction in a margin of safety because the plant design basis of a 40-year service life is not changed, the accident analyses are based upon a 40-year service life, and the safety-related equipment is maintained regardless of the overall age of the plant.

The Commission has provided certain examples (51 FR 7751) of actions likely to involve no significant hazards considerations and examples of actions likely to involve significant hazards considerations. The request involved in this case does not match any of those examples. However, the staff has reviewed the licensee's request and determined that should this request be implemented, it will not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated because plant equipment, components, and structures were designed considering a 40 year service life, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated because the physical plant design is not being changed. Also, it will not (3) involve a significant reduction in a margin of safety because surveillance and maintenance procedures are implemented into the plant operation to assure that degradation is promptly identified and corrective actions are taken.

Accordingly, the Commission proposes that this change does not involve a significant hazards consideration.

Local Public Document Room location: George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama 36303.

Attorney for licensee: Ernest L. Blake, Esquire, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: Lester S. Rubenstein.

Arkansas Power and Light Company, Docket No. 50–313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: July 18, 1986.

Description of amendment request: The proposed amendment would change Arkansas Nuclear One, Unit 1 (ANO–1) Technical Specifications (TSs) 3.1.9.3, 5.3.1.4, 3.1.9 Bases and 4.7.2 Bases to reflect the modification of the center control rod drive mechanism (CRDM) and the correct number of control rod assemblies (CRAs) after removal of the center CRA. Removal of the center CRA and modification of the center CRDM are necessary to accommodate the installation of inadequate core cooling (ICC) instrumentation per NUREG–0737, Item II.F.2. Two Radcal Gamma Thermometer Probes are scheduled to be installed during the ANO–1 seventh refueling outage (1R7) to meet the Commission's requirement for a reactor coolant inventory tracking system that improves the reliability of plant operators to diagnose the approach of ICC and to assess the adequacy of responses taken to restore core cooling.

In addition to changes to the ANO–1 TSs concerning the removal of the center CRA, one administrative change to section 5.3.1.4 is also included. The purpose of this administrative change is to reflect the correct figure number referenced in the specification.

Basis for proposed no significant hazards consideration determination: The proposed changes have been reviewed against each of the criteria in 10 CFR 50.92, namely that the proposed changes would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

With regard to: (1) Above, the administrative change to section 5.3.1.4 of the ANO–1 TSs does not increase the probability or consequences of an accident previously evaluated. Correcting the referenced figure number has no impact on the safety analyses of Chapter 14 of the ANO–1 Final Safety Analysis Report (FSAR).

The possible impact of center CRA removal was evaluated with respect to: (a) Reduction in shutdown margin, (b) its effect on the FSAR Chapter 14 analysis of a rod ejection accident, (c) degradation of reactor components due to the changes in thermal hydraulics characteristics resulting from the replacement of the existing CRA with the new ICC Radcal Gamma Thermometer Probes, (d) structural integrity of the reactor coolant system (RCS) due to the replacement of the center CRA with the ICC equipment, and (e) ICC probe interference with the center fuel assembly.

The licensee has stated that all of the accidents analyzed in the FSAR have been reviewed for Cycle 8 operation without the center CRA. Since the calculated shutdown margin for End of Cycle 8 (EOC–8) is greater than the TS required shutdown margin, removal of the center CRA will have no deleterious impact on shutdown margin.

With respect to a rod ejection accident, the presence/absence of the center CRA will have no impact. The center CRA is part of Safety Rod Group 2. This group is fully withdrawn from criticality to full power and, therefore, would not be available for ejection.

The hardware associated with the ICC probes is similar to the existing CRAs and will in fact be fitted into the center CRA guide tube. Rigorous structural and flow induced vibration analyses have been performed on the hardware to demonstrate its capability to withstand operation and accident conditions without failure. These analyses, coupled with the strict controls on materials and fabrication, provide assurance that the new hardware is no more likely to fail than the hardware it replaces.

The ICC probes which will replace the center CRA will utilize the existing reactor vessel head flange for installation. The RCS pressure boundary components, internal structures and equipment supports, meet the requirements of the applicable subsections of the American Society of Mechanical Engineers (ASME) Code, section III. Furthermore, the materials of all major components meet the material specifications of either the ASME Code or the American Society of Testing Materials (ASTM).

The hardware associated with the ICC probes will not extend into the center fuel assembly. Tolerance studies have shown that there will be no interference

between the new hardware and the center fuel assembly.

Based on the above, we conclude that the probability or consequences of a previously evaluated accident are not significantly increased.

With regard to (2) above, the administrative change to section 5.3.1.4 of the ANO–1 TSs has no impact on plant operations or the plant configuration. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The new hardware does not significantly alter operation of the plant. Nor does the hardware alter any physical limitations of the plant (i.e., lower rupture strength of vessel penetration, reduce maximum operating temperature, etc.). Therefore, the installation of the reactor vessel level probes does not create the possibility of a new or different kind of accident from any accident previously evaluated.

With regard to (3) above, the administrative change to section 5.3.1.4 does not reduce the margin of safety. The purpose of the change is to reflect the correct figure number referenced in the specification.

The licensee has stated that the required TS shutdown margin is still maintained. The fuel thermal hydraulics analysis has shown that there is adequate margin to cover the change in bypass flow caused by removal of the CRA. A structural analysis in accordance with the sections of the ASME Code applicable to each component has been performed. This analysis has shown that the hardware will withstand the stresses generated by operational and accident conditions and that the reactor vessel level probes will remain intact. Also, installation of this ICC instrumentation will enhance the ability of operators to diagnose and quantify the approach to, existence of and recovery from ICC conditions and to take actions to mitigate the consequences of ICC. Therefore, no margin of safety is significantly reduced by the installation of reactor vessel level probes at ANO–1.

On these bases, the Commission proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036.

NRC Project Director: John F. Stolz.

Arkansas Power and Light Company, Docket No. 50–313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: July 18, 1986.

Description of amendment request: The proposed amendment would change Arkansas Nuclear One, Unit 1 (ANO–1) Technical Specification Figure 2.3–1, Table 2.3–1, 2.2 Bases, and 2.3 Bases C to return the reactor coolant system (RCS) high pressure trip setpoint to the original (pre Three Mile Island, Unit 2 (TMI–2) value of 2355 psig. The current value of the high pressure trip setpoint (2300 psig) was based on changes required by the Commission, subsequent to the TMI–2 accident, to reduce challenges to and opening of the power operated relief valve (PORV). For Babcock and Wilcox (B&W) reactors these changes were: (1) Lowering the reactor high pressure trip setpoint from 2355 psig to 2300 psig, and (2) raising the PORV setpoint from 2250 psig to 2450 psig. In support of the increase in the high pressure trip setpoint while maintaining the current PORV setpoint of 2450 psig, the licensee referenced the B&W Topical Report BAW–1890 and the Commission's Safety Evaluation of BAW–1890 dated April 22, 1986.

Basis for proposed no significant hazards consideration determination: The proposed changes have been reviewed against each of the criteria in 10 CFR 50.92, namely that the proposed changes would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Invole a significant reduction in a margin of safety.

With regard to: (1) Above, since 2355 psig is the design high pressure reactor trip setpoint, the original Final Safety Analysis Report analyses remain applicable for this setpoint. Therefore, increasing the high pressure reactor trip setpoint from 2300 psig to 2355 psig does not significantly increase the probability or consequences of an accident previously evaluated.

With regard to (2) above, the function of the setpoint is not altered as a result of the changes (i.e., the setpoint still serves the purposes of assuring the integrity of the RCS as a barrier against the release of fission products, assuring that the RCS pressure safety limit is not exceeded, and reducing challenge to the PORV). Therefore, increasing the high pressure reactor trip setpoint from 2300 psig to 2355 psig does not create the possibility of a new or different kind of accident.

With regard to (3) above, the NRC Safety Evaluation of B&W Topical Report BAW–1890 concludes that this setpoint change meets the NRC requirements of NUREG–0737, Items II.K.3.2 and II.K.3.7, regarding PORV openings and PORV caused small-break loss of coolant accidents. Similarly, the requirements on this matter embodied in IE Bulletin 79–05B are also met. Also, returning the high pressure reactor trip setpoint to 2355 psig will reduce the frequency of automatic trips, and thus decrease the number of challenges to plant safety systems. Therefore, increasing the high pressure reactor trip setpoint from 2300 psig to 2355 psig does not involve a significant reduction in a margin of safety.

On these bases, the Commission proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036.

NRC Project Director: John F. Stolz.

Arkansas Power and Light Company, Docket No. 50–313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: July 31, 1986.

Description of amendment request: The proposed amendment would change Arkansas Nuclear One, Unit 1 (ANO–1) Technical Specifications (TSs) 3.5.1.9.2, 3.5.1 Bases and Table 3.5.1–1 to allow increasing the arming threshold for the turbine trip anticipatory reactor trip (ART) from its current value of 20% power to 45% power. The current value of the arming threshold for the turbine trip ART (20% power) was based on changes required by the Commission subsequent to the Three Mile Island, Unit 2 (TMI–2) accident to reduce challenges to and opening of the power operated relief valve (PORV). In support of the increase for the turbine trip ART proposed threshold power level of 45%, the licensee referenced Babcock and Wilcox (B&W) Topical Report BAW–1893 and the Commission's Safety Evaluation of BAW–1893 dated April 25, 1986.

In addition to changes to the ANO–1 TSs concerning the arming threshold for the turbine trip ART, administrative changes to sections 3.5.1.9.1 and 3.5.1.9.2 are also proposed. The purpose of these

administrative changes is to correct errors in the table referred to in the Specifications.

Basis for proposed no significant hazards consideration determination: The proposed changes have been reviewed against each of the criteria in 10 CFR 50.92, namely that the proposed changes would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

With regard to: (1) Above, the NRC Safety Evaluation of B&W Topical Report BAW–1893 concludes that the number of PORV openings per reactor-year for all events is negligibly affected by this change and that the requirements of Items II.K.3.2 and II.K.3.7 of NUREG–0737 are still satisfied at the proposed turbine trip ART power threshold of 45%. Also, the consequences of accidents analyzed at the existing turbine trip ART power threshold of 20% remain applicable at the proposed turbine trip ART power threshold of 45%. Therefore, increasing the turbine trip ART power threshold to 45% does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The administrative changes to sections 3.5.1.9.1 and 3.5.1.9.2 correct the referenced table number and have no impact on the safety analyses of Chapter 14 of the ANO–1 FSAR. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

With regard to (2) above, the function of the arming threshold for the turbine trip ART is not altered as a result of the change (i.e., the arming threshold still serves the purposes of providing a reactor trip signal in those cases where a loss of secondary heat sink would likely result in a reactor trip on some other parameter and limiting reactor heat input to the system after a loss of heat sink). Therefore, increasing the turbine trip ART power threshold to 45% does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The administrative changes to sections 3.5.1.9.1 and 3.5.1.9.2 of the ANO–1 TSs have no impact on plant operations. These changes are merely corrections to references given in the sections. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

With regard to (3) above, the NRC Safety Evaluation of B&W Topical Report BAW–1893 concludes that this threshold change meets the NRC requirements of NUREG–0737, Items II.K.3.2 and II.K.3.7, regarding PORV openings and PORV caused small-break loss of coolant accidents. Similarly, the requirements on this matter embodied in IE Bulletin 79–05B are also met. Also, increasing the turbine trip ART power threshold will reduce the frequency of automatic trips, and thus decrease the number of challenges to plant safety systems. Therefore, increasing the turbine trip ART power threshold to 45% does not involve a significant reduction in a margin of safety.

The purpose of the changes to sections 3.5.1.9.1 and 3.5.1.9.2 of the ANO–1 TSs is to reflect the correct item and table numbers referenced in the Specifications. Therefore, the proposed changes do not involve a reduction in a margin of safety.

On these bases, the Commission proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036.

NRC Project Director: John F. Stolz.

Arkansas Power & Light Company, Docket No. 50–368, Arkansas Nuclear One, Unit 2, Pope County, Arkansas

Date of amendment request: April 25, 1986.

Description of amendment request: The proposed amendment would revise the Technical Specifications (TS) to increase the Refueling Water Tank (RWT) maximum solution temperature from 100°F to 110°F.

The maximum solution temperature is specified to assure that the maximum borated water injection temperature assumed in the Final Safety Analysis Report (FSAR) emergency core colling systems (ECCS) evaluation is not exceeded. The RWT maximum solution temperature assumed in the ANO–2 FSAR is 120°F. Under the current TS, whenever the RWT solution temperature approaches 100°F due to direct solar heating, the RWT is cooled using a containment spray pump and shutdown cooling heat exchanger. The proposed change is expected to reduce frequent use an ECCS system required to cool the RWT during the summer months.

This change is one of several issues addresed in the application. The other issues will be the subject of a separate notice.

Basis for no significant hazards consideration determination: The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. A discussion of these standards as they related to this amendment follows:

Criterion 1: The proposed change is bounded by the existing accident analysis results in Chapter 15 of the ANO–2 FSAR based on the fact that the proposed RWT maximum solution temperature is within the assumptions of the FSAR accident analysis. In addition, allowing the maximum solution temperature of the RWT to be somewhat higher does not influence whether or not any transients or accidents are more or less likely to occur. Therefore, the proposed change would not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2: The proposed change would not create the possibility of a new or different kind of accident from any previously analyzed since it would not introduce new systems, modes of operation, failure modes or other perturbations.

Criterion 3: The proposed change would not involve a significant reduction in a margin of safety since there still would be sufficient margin between the RWT maximum allowable solution temperature and that assumed in the FSAR accident analysis and ECCS functional analysis.

Therefore, since the application for amendment satisfies the criteria specified in 10 CFR 50.92, the NRC staff proposes to determine that the requested change does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Esq., Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036.

NRC Project Director: George W. Knighton.

Arkansas Power & Light Company, Docket No. 50–368, Arkansas Nuclear One, Unit 2, Pope County, Arkansas

Date of amendment request: April 25, 1986.

Description of amendment request: The proposed amendment would revise the Technical Specification Surveillance Requirement pertaining to the periodic verification of moderator temperature coefficient (MTC) value. Under the proposed change to Surveillance Requirement 4.1.1.4.2, MTC measurement frequencies would be revised from within 7 EFPD after reaching a RATED THERMAL POWER equilibrium boron concentration of 800 ppm and 300 ppm to a frequency of prior to and within 14 EFPD after reaching a RATED THERMAL POWER equilibrium boron concentration of 800 ppm and 300 ppm respectively. The purpose of the proposed change is to allow greater operational flexibility in the performance of MTC measurements.

MTC can be described as the change in reactivity that results from a change in the temperature of the water in the core. The MTC limit is an input parameter in various transient and accident analyses. To ensure that the assumptions used in the transient and accident analyses remain valid throughout each fuel cycle since MTC changes slowly due principally to the reduction in reactor coolant system boron concentration associated with fuel burnup, the MTC measurements are required by Surveillance Requirement 4.1.1.4.2.

This change is one of several issues addressed in the application. The other issues will be the subject of a separate notice.

Basis for proposed no significant hazards consideration determination: The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. A discussion of these standards as they relate to this amendment follows:

Criterion 1: The proposed change would merely expand the periods during which MTC measurements have to be performed. The proposed change would not reduce the number of required MTC measurements and would not alter limiting conditions for operation. Since the MTC changes slowly, the proposed change would not significantly affect the confidence in the MTC measurements. In addition, allowing the MTC to be measured at different times does not influence whether or not any transients or accidents are more or less likely to occur. Therefore, the proposed change would not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2: The proposed change would not create the possibility of a new or different kind of accident from any previously analyzed since it would not introduce new systems, modes of operation, failure modes or other perturbations.

Criterion 3: The proposed change would not reduce the number of required MTC measurements. It would merely expand the periods during which MTC measurements have to be performed. Since the MTC changes slowly, the proposed change would not significantly affect the confidence in the MTC measurements. Therefore, the proposed change would not involve a significant reduction in the margin of safety.

Therefore, since the application for amendment satisfies the criteria specified in 10 CFR 50.92, the NRC staff proposed to determine that the requested change does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nicholas S. Reynolds, Esq., Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Suite 700, Washington, DC 20036.

NRC Project Director: George W. Knighton.

Arkansas Power & Light Company, Docket No. 50–368, Arkansas Nuclear One, Unit 2, Pope County, Arkansas

Date of amendment request: April 25, 1986.

Description of amendment request: The proposed amendment would revise Technical Specification 3.1.1.1 to increase the minimum shutdown margin for Modes 1 through 4 from 5.0% reactivity to 5.5% reactivity. The purpose of the proposed change is to assure that future operating cycles comply with accident analysis limits specified in Chapter 15 of the ANO–2 Final Safety Analysis Report (FSAR). For the current cycle, Cycle 6, the proposed change would increase the required amount of negative reactivity available to shut down the reactor when in Modes 1 through 4.

This change is one of several issues addressed in the application. The other issues will be the subject of a separate notice.

Basis for proposed no significant hazards consideration determination: The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. A discussion of these standards as they relate to this amendment follows:

Criterion 1: The proposed change, by increasing the required amount of negative reactivity available to shut the reactor down, would not reduce the reactivity control system's capability for controlling the reactivity transients associated with postulated accident conditions within acceptable limits. Further, it would not reduce the systems' capability for making the reactor subcritical from all operating conditions and for maintaining the reactor sufficiently subcritical to preclude inadvertent criticality in the shutdown condition. Therefore, the proposed change would not involve any increase in the probability or consequences of any accident previously evaluated.

Criterion 2: No new or different kind of accident can be created by increasing the capability to shut the reactor down. Therefore, the proposed changes would not create the possibility of a new or different kind of accident from any previously analyzed.

Criterion 3: The proposed change would provide additional shutdown margin and therefore, would not involve a reduction in the margin of safety.

Therefore, since the application for amendment satisfies the criteria specified in 10 CFR 50.92, the NRC staff proposes to determine that the requested change does not involve a significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Attorney for licensee: Nichols S. Reynolds, Esq., Bishop, Liberman, Cook,

Purcell and Reynolds, 1200 Seventeenth Street, NW., Washington, DC 20036.

NRC Project Director: George W. Knighton.

Carolina Power & Light Company, Docket No. 50–324, Brunswick Steam Electric Plant, Unit No. 2, Brunswick County, North Carolina

Date of application for amendment: August 22, 1986.

Description of amendment request: The proposed amendment would change Tables 2.2.2–1, 3.3.2–1 and 3.3.2–2 of the Technical Specifications (TS) by revising the Main Steam Line Radiation-High scram and isolation setpoints temporarily to allow performance of tests involving hydrogen injection into the primary coolant. This change will allow the licensee to test the feasibility of a Hydrogen Water Chemistry System as a mitigator of Intergranular Stress Corrosion Cracking (IGSCC) of stainless steel piping at Brunswick. In addition, the proposed amendment would incorporate minor administrative changes involving redesignation of footnotes on the three TS Tables noted above.

The temporary change proposed would permit the normal full power background level, associated with the main steam line radiation-high scram and isolation setpoints, to be increased only so as to compensate for the anticipated increase in the main steam radiation levels during hydrogen injection. This background radiation level increase when hydrogen injection is underway is caused by higher levels of short half-life nitrogen-16 (N–16) carryover into the main steam. The main steam radiation-high setpoint will remain at three times the background radiation level; however, the background radiation level used to determine the high radiation setpoint will be increased prior to the test based on a calculation of the anticipated background level. The change also permits the full load background radiation level to be adjusted during the test to correct for uncertainties in the initial computation. At the maximum planned hydrogen injection rate, an increase of approximately one to five times the normal main steam line background radiation level is expected. The pretest setpoints will be restored promptly following conclusion of the test and whenever power is decreased to less than 22 percent of rated thermal power. The hydrogen injection test will be discontinued whenever reactor power is reduced to less than 22 percent of rated thermal power.

A similar change was approved for the purpose of hydrogen injection tests at the Pilgrim Nuclear Plant (Amendment 86, April 5, 1985), Duane Arnold Energy Center (Amendment 131, March 27, 1986), and Hatch Nuclear Plant, Unit 1 (Amendment 125, May 21, 1986).

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The licensee evaluated the proposed amendment against the standards in 10 CFR 50.92 and has determined the following:

1. The proposed amendment does not involve a significant increase in the probability or consequences of any accident previously evaluated. The only event which takes credit for the main steam line high radiation scram and isolation setpoint is the Control Rod Drop Accident (CRDA). As stated in Bases section 2.0 of the Brunswick TS, the main steam line radiation monitors are provided for detection of gross fuel failure. The consequences of a CRDA are most severe under hot standby conditions. They are increasingly less severe above 10 percent power due to factor doppler response and lower rod worth. Above 20 percent power, the consequences are of minimal concern. Since the Main Steam Line Radiation Monitor setpoint will only be adjusted at power levels above 22 percent, there is no significant impact on the probability or consequences of the control rod drop accident. The administrative change to footnote designation has no affect on the probability or consequences of any accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated because the changes do not affect the design of any safety-related systems and as such do not affect the performance of any safety functions. Revising a setpoint does not introduce the possibility of a new or different accident. The administrative change to footnote designation does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant decrease in a margin of safety. A temporary increase in the Main Steam Line High Radiation scram and isolation setpoints does not create the possibility of a new type of accident nor does it impact any accident. The provisions of the change allow the setpoints to be altered only when reactor power is at or above 22 percent. Above 20 percent power, the consequences of CRDA are minimal and, therefore, the change in setpoint has no significant effect on the margin of safety for this accident. Due to the short half-life on N–16 (7 seconds), the increased carry over of N–16 in the main steam will not have a significant effect on the gaseous effluent release rates. Therefore, the proposed change will not present a risk to the public's health and safety. The administrative change to footnote designation does not involve a decrease in a margin of safety.

Based on the above reasoning, the licensee has determined that the proposed amendment does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Based on this review, the staff therefore proposes to determine that the proposed amendment does not involve a significant hazard consideration.

Local Public Document Room Location: Southport, Brunswick County Library, 109 W. Moore Street, southport, North Carolina 28461.

Attorney for licensee: Thomas A Baxter, Esquire, Shaw, Pittman, Potts & Trowbridge, 1800 M Street, NW., Washington DC, 20036.

NRC Project Director: Daniel R. Muller.

Carolina Power and Light Company, Docket No. 50–261, H.B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: The amendment would revise the Technical Specifications, section 5.3.1.6, to delete the maximum amount of enriched fissionable material which can be used in the core, or available on-site, in the form of fabricated neutron flux detectors for the purpose of monitoring core neutron flux. This is necessary to allow for new excore neutron flux monitoring systems to be installed pursuant to Regulatory Guide (RG) 1.97, "Instrumentation for Light-Water-Cooled Nuclear Power Plants To Assess Plant Conditions During and Following An Accident."

Basic for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of these standards by providing examples of amendments considered likely, and not likely, to involve a significant hazards consideration. These were published in the **Federal Register** on March 6, 1986 (51 FR 7751). One of the examples not likely to involve a significant hazards consideration is example (i), "a purely administrative change to the Technical

Specifications: For example, a change to achieve consistency throughout the Technical Specifications, correction of an error, or a change in nomenclature."

The deletion of the restriction on the amount of enriched fissionable material allowed on-site as fission detectors meets Example (i). Section 2.C of the Operating License specifies that the receipt, possession, and use of source byproduct and special nuclear material as authorized by the license shall be in amounts as required and in accordance with the Commission's regulations in 10 CFR Parts 30, 40 and 70. This condition was incorporated in the license by amendment, including Technical Specifications, to ensure that the byproduct, source and special nuclear materials utilized at the H.B. Robinson Unit 2 Plant were maintained in accordance with the Commission rules and regulations and used in such amounts as required for reactor operation. The limit specified in section 5 of the Technical Specifications, apparently through oversight, was not deleted at that time. The deletion of the limit specified in Section 5 will remove the restriction on the amount of fissionable material allowed on site as fission detectors consistent with the requirements specified in section 2.C of the license and will allow installation of the additional fission detectors in accordance with RG 1.97.

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29535.

Attorney for licensee: Shaw, Pittman, Potts, and Trowbridge, 1800 M Street, NW., Washington, DC 20035.

NRC Project Director: Lester S. Rubenstein.

Commonwealth Edison Company, Docket No. STN 50–454, Byron Station, Unit 1, Ogle County, Illinois

Date of application for amendment: July 30, 1986.

Description of amendment request: The amendment would revise three Technical Specification sections:

Section 3/4.5.1.4 would be revised to replace "0%" with the words "percent predicted value" at the end of cycle life for determining target flux difference. The percent predict value better reflects the actual end of cycle flux, resulting in a more accurate interpolation for determining target flux difference.

Section 3/4.2.2.2. f(3) would be revised to delete the reference to exact grid plane locations on fuel bundles and replace it with a reference to within ±2% of each grid plane region. This change would accommodate the grid strap locations for the fuel that will be used in the initial core load of Byron 2, and that may be used in the refueling of either of the units.

Section 5.3.1 would be revised to delete the words "and contain a maximum total weight of 1619 grams uranium." This would accommodate weight differences in the fuel for both units as well as the fuel used for future reloads.

It is the staff's intention to apply these three changes to Byron Station, Unit 2, when it receives its operating license if the amendment is found acceptable for Byron Station, Unit 1.

Basis for Proposed No Significant Hazards Consideration Determination: The staff has evaluated this proposed amendment in accordance with the criteria of 10 CFR 50.92 and determined that it involves no significant hazards consideration.

The first change, replacing "0%" with "percent predicted value," will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated because:

(a) A number obtained from the Nuclear Design Report is being substituted for zero into an NRC approved methodology for determining the target flux difference. This value better reflects the actual end of cycle flux, resulting in a more accurate axial flux difference when the predicted percent value is used. Therefore, using the predicted end-of-cycle flux instead of zero does not increase the probability or consequences of a previously evaluated accident.

(b) The accident of most interest in this evaluation is a loss-of-coolant accident (LOCA). There is no causal relationship between the axial flux difference and accidents. Therefore, the probability is unaffected.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated because the change being made is to a number that is used in an NRC approved method of calculating the axial flux difference. The proposed amendment does not involve any new equipment, or the manner in which the system is being operated. Hence, the possibility of a new or different kind of accident being created than was previously evaluated is unaltered.

(3) Involve a significant reduction in the margin of safety because using the predicted end of cycle flux number instead of zero will allow the licensee to calculate a more accurate target flux difference, providing greater confidence that the margin of safety has not been reduced. The second change, deleting exact grid plane locations, will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated because deleting the specific Technical Specification has no impact on the physical design of the plant. The actual location of the grid straps are appropriately modeled for accident analysis purposes using NRC approved methods. Hence, the probability and consequences of all previously evaluated accidents is not altered.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated, because:

(a) The function of the grids straps is not adversely affected by changing its location to ±2% of each of the grid plane regions. Therefore, a revision to the grid strap location will not create the possibility of a new or different kind of accident previously evaluated.

(b) This is considered to be an administrative change to take into account differences in grid strip locations for reduced rod bow and non-reduced rod bow designs.

(3) Involve a significant reduction in a margin of safety, because the information being deleted from the Technical Specifications is cycle specific in nature and is available in the nuclear design report. This change has no direct affect on operations, therefore the margin of safety has not been compromised.

The third change, deleting the total weight of uranium, will not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated because a deletion of the maximum weight of uranium per fuel rod does not increase the probability or consequences of a previously evaluated accident. The core design, and the safety analyses related to it, are based on parameters other than the weight of individual fuel rods (such as power and fuel dimensions). These parameters are either not directly affected by fuel rod weight, or are only slightly affected. A review of design parameters which may be affected indicated that a change in fuel weight does not cause other design parameters to exceed the values assumed in various safety analyses or to cause acceptance criteria to be exceeded. This is due to the fact that the safety analyses codes use fuel rod enrichment levels, not weight values. Therefore, the effects of the change are within Technical Specifications limits. Since deleting this value has no significant effect on safety analyses, it is concluded that the probability or consequences of an accident previously evaluated being significantly increased is unaltered.

(2) Create the possibility of a new or different kind of accident previously evaluated, because;

(a) The change being made is to delete the maximum total weight of uranium per fuel rod from the Technical Specifications. The proposed amendment does not involve any new equipment, or the manner in which the system is being operated. Hence, the possibility of a new or different kind of accident being created than was previously evaluated is unaltered.

(b) The change is considered to be administrative in nature.

(3) Involve a significant reduction in the margin of safety, because the margin of safety is maintained through adherence to other fuel related Technical Specifications limits and the FSAR design bases. The deletion of fuel rod weight limits in the Technical Specifications does not directly affect any safety systems, thus the plant safety margin is unaffected.

Based on the preceding assessment, the staff has determined that this proposed amendment involves no significant hazards consideration.

Local Public Document Room location: Rockford Public Library, 215 N. Wyman Street, Rockford, Illinois 61103.

Attorney for licensee: Michael Miller, Isham, Licoln & Beal, One first National Plaza, 42nd floor, Chicago, Illinois 60603.

Commonwealth Edison Company, Docket No. STN 50–454, Bryon Station, Unit 1, Ogle County, Illinois

Date of application for amendment: August 15, 1986.

Description of amendment request: The amendment would add Technical Specifications to require the availability of an essential service water (ESW) pump while the other unit is operating. This amendment is required because a Probabistic Risk Assessment done by the staff determined that the two-pump ESW system for each unit was the main contributor to a core melt frequency estimate of 10^{-3} year. Having an ESW pump available from the other unit reduces this core melt frequency.

It is the staff's intention to apply this amendment to Byron Station, Unit 2, when it receives its operating license if the amendment is found acceptable for Byron Station, Unit 1.

Basis for proposed no significant hazards consideration determination: The staff has evaluated this proposed amendment and determined that it involves no significant hazards considerations. According to 10 CFR 50.92(c), a proposed amendment to an operating license involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

This proposed amendment is a new technical specification which requires the availability of an essential service water pump and associated valves of a shutdown unit while the other unit is operating. The proposed amendment only addresses the probability and consequences of a loss of all essential service water to one of the units. This event has not been previously evaluated. The probability or consequences of accidents which have been previously evaluated are not affected by requiring the availability of additional components in the essential service water system.

As stated above, the sole purpose of this amendment is to address loss of all essential service water to one of the units. Loss of all essential service water to one of the units is a new or different kind of accident which has not been previously evaluated. Instead of creating this accident, this proposed amendment minimizes the possibility of its occurrence.

Since this proposed amendment requires additional availability of components in the essential service water system, there is no reduction in any margin of safety.

Based on the preceding assessment, the staff believes this proposed amendment involves no significant hazards considerations.

Local Public Document Room location: Rockford Public Library, 215 N. Wyman Street, Rockford, Illinois 61103.

Attorney for licensee: Michael Miller, Isham, Lincoln & Beal, One First National Plaza, 42nd Floor, Chicago, Illinois 60603.

NRC Project Director: Vincent S. Noonan.

Commonwealth Edison Company, Docket No. 50–254, Quad Cities Nuclear Power Station, Unit 1, Rock Island County, Illinois

Date of amendment request: August 26, 1986.

Description of amendment request: The amendment proposes to modify the Technical Specifications so that the actual Minimum Critical Power Ratio (MCPR) for Quad Cities Unit 1 reflects a Cycle 9 limit of 1.35, determined from results of a transient analysis.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards determination exists as stated in 10 CFR 50.92(c).

The licensee has presented its determination of no significant hazards consideration as follows:

Commonwealth Edison has performed an evaluation of the hazards consideration associated with the proposed Technical Specification amendment utilizing the criteria in 10 CFR 50.92. Our evaluation is provided below and specifically addresses the three criteria of 10 CFR 50.92(c).

The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because the change involves incorporation of an operating limit specifically calculated for Cycle 9. Adherence to this limit will assure that the core is operated within the assumed initial conditions for previous accident analyses and therefore will not increase the previously established consequences. Since the change only imposes a restriction on operating conditions, it does not directly impact any equipment or systems and therefore has no casual [causal] relationship with the probability of an accident.

The proposed amendment will not create the possibility of a new or different kind of accident than previously evaluated because it does not allow any new equipment or modes of operation (nor changes to existing equipment) which would initiate or affect an accident.

The proposed amendment does not involve a significant reduction in the margin of safety because the revised MCPR operating limit value was explicitly calculated for Cycle 9 operation, using NRC approved codes and methods, to assure the required margin to safety is maintained. Operation within the revised limit will continue to protect the MCPR safety limit against operational transients.

For the reasons stated above, Commonwealth Edison finds that the proposed amendment does not involve a significant hazards consideration based on the criteria of 10 CFR 50.92(c). We, therefore, request approval of the proposed amendment under the provisions of 10 CFR 59.91(a)(4).

The staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis.

Therefore, based on this review, the staff has made a proposed determination that the requested amendment involves no significant hazards consideration.

Local Public Document Room location: Moline Public Library, 504 17th Street, Moline, Illinois 61265.

Attorney for licensee: Mr. Michael I. Miller; Isham, Lincoln, & Beale, Three First National Plaza, Suite 5200, Chicago, Illinois 60602.

NRC Project Director: John A. Zwolinski.

Commonwealth Edison Company, Docket Nos. 50–295 and 50–304, Zion Nuclear Power Station, Unit Nos. 1 and 2, Benton County, Illinois

Date of application for amendments: April 24, 1986, supplemented June 16, 1986 and September 2, 1986.

Description of amendments request: These amendments would allow the use of the Combustion Engineering sleeving process to repair defective steam generator tubes.

The current Technical Specifications require that any steam generator tube that contains a defect of greater than 40% of nominal tube wall thickness be plugged. The act of placing a plug in both the hot and cold leg tube ends removes the tube from service by eliminating reactor coolant flow through the tube. The plugging of the tube is currently required even if the defects exists within the tube sheet region.

Sleeving is a process by which a smaller, shorter tube (sleeve) is placed inside of the existing steam generator tube. This sleeve extends throughout the tube sheet region and is sealed to the original tube, effectively forming a new barrier. Thus, if a defect were to exist in the tube sheet region, the sleeving process just described is a viable alternative to plugging the entire tube.

The advantage to sleeving is that the tube will remain in service since reactor coolant would still be permitted to flow on the inside of the sleeve and throughout the remainder of the existing steam generator tube.

Zion Station has been experiencing some defects in the tube sheet region. Thus, the existence of the sleeving option will extend the life of Zion steam generators by allowing tubes which possess defects in the tube sheet region to remain in service.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee provided the following discussion regarding the above three criteria:

Criterion 1: The creation of the option to utilize the Combustion Engineering sleeving process to repair a defective steam generator tube has no effect on either the probability or consequences of any accident previously evaluated. The integrity of the steam generator tubes will be equivalent to that of an original tube. Thus, since the structural integrity of the tubes will not be affected by this change, there is no increase in the probability of any accident previously evaluated.

In addition, the steam generator will remain capable of performing its required heat transfer function. The act of placing a sleeve in the steam generator tube actually results in a more efficient steam generator relative to plugging the affected tubes. Thus, the consequences of any accident previously evaluated is unaffected because the heat transfer capability of the steam generators will not be significantly altered.

Criterion 2: As discussed above, both the structural integrity and the heat transfer capability of Zion steam generators will not be significantly affected by the use of an NRC approved sleeving process. In addition, the steam generator tube sleeves do not interact with any of Zion's systems. Thus, there is no potential for a new or different kind of accident due to the use of a sleeving process to repair Zion steam generators.

Criterion 3: The heat transfer capabilities of Zion steam generators will be improved by utilizing the sleeving process rather than the currently required plugging procedure. The sleeving process will allow a repaired steam generator tube to remain in service, rather than completely blocking the tube's flow with plugs. Since the structural integrity of the steam generators will be unaltered the net effect of utilizing a steam generator tube sleeving process rather than the currently required plugging procedure will be an increase in the margin of safety. This increase is due to the relatively improved heat transfer characteristics of the steam generator.

The staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that the proposed changes to the Technical Specification involve no significant hazards consideration.

Local Public Document Room location: Zion-Benton Library District, 2600 Emmaus Avenue, Zion, Illinois 60099.

Attorney to licensee: P. Steptoe, Esq., Isham, Lincoln and Beale, Counselors at Law, Three First National Plaza, 51st Floor, Chicago, Illinois 60602.

NRC Project Director: Steven A. Varga.

Connecticut Yankee Atomic Power Company, Docket No. 50–213, Haddam Neck Plant, Middlesex County, Connecticut

Date of amendment request: August 29, 1986.

Description of amendment request: The proposed license amendment adds a second note of clarification to the definition of containment integrity, Technical Specification 1.8.2.b, to permit normally closed manual isolation valves SI–V–863 A, B, C, and D to be opened for periodic surveillances. In addition, the proposed amendment would permit valve SA–V–413 to be opened to allow for additional maintenance activities.

Basis for proposed no significant hazards consideration determination: The proposed license amendment will allow monthly opening of the HPSI recirculation valves, (SI–V–863 A, B, C, and D). This is important from a safety standpoint because these valves are used to ensure that safety injection check valves (SI–CV–862, A, B, C, and D) are passing flow, that there is proper boron concentration in the recirculation line and also that any precipitated boron is either flushed or redissolved into solution. The proposed amendment will also allow: (1) Periodic testing of valve SA–V–413, and (2) maintenance activities that rely on the opening of SA–V–413. SA–V–413 is used to ensure the operability of the containment continuous leak monitoring system by the introduction of service air into containment to maintain containment pressure within technical specification limits.

Using statistics on the reliability of check valves, a probabilistic risk assessment by the licensee quantitatively confirmed that monthly surveillance testing of the subject valves improves the availability of the HPSI system. The licensee also conducted a probabilistic risk assessment sensitivity study to determine the change in core melt frequency if the ECCS check valves were not tested for a period of three (3) months. The three (3) month interval was selected as a representative amendment approval interval. The evaluation indicated that the unavailability of the HPSI system increased approximately 9% assuming a three (3) month test interval (compared to a monthly interval) and, the core melt frequency increased approximately 0.4% (over the core melt frequency assuming monthly testing).

The risk (contribution to core melt frequency) associated with opening these manual containment isolation valves for monthly surveillance testing

was determined to be negligible in comparison to the risk of not allowing testing of ECCS check valves. The licensee concluded that it is beneficial in terms of reduced core melt frequency and ensuring public health and safety to open these valves as part of the HPSI system monthly surveillance tests.

CYAPCO has evaluated the proposed amendment in accordance with the standards of 10 CFR 50.92 and has concluded that the proposed amendment satisfies the three criteria of 10 CFR 50.92(c) and therefore does not involve a significant hazards consideration. In particular, the proposed amendment would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated. As presented above, the licensee has shown that *not* implementing the changes would potentially increase the unavailability of the HPSI system and increase the calculated core melt frequency.

(2) Create the possibility of a new or different kind of accident from any previously analyzed. The licensee has shown that the postulated failure modes for the affected valves cannot cause an initiating event and, therefore, cannot create the possibility for a new unanalyzed accident.

(3) Involve a significant reduction in a margin of safety. As discussed above, the licensee has shown that the margin of safety would be improved by issuance of the proposed change.

The staff has reviewed the licensee's determination that the proposed license amendment involves no significant hazards consideration and concludes that it is acceptable. Accordingly, the staff proposes to determine that the proposed changes do not involve a significant hazards consideration.

Local Public Document Room location: Russell Library, 123 Broad Street, Middletown, Connecticut 06457.

Attorney for licensee: Gerald Garfield, Esquire, Day, Berry and Howard, Counselors at Law, City Place, Hartford, Connecticut 06103–3499.

NRC Project Director: Christopher I. Grimes.

Consolidated Edison Company of New York, Docket No. 50–247, Indian Point Nuclear Generating Unit No. 2, Westchester County, New York.

Date of amendment request: June 3, 1986, as supplemented August 12, 1986.

Description of amendment request: The proposed amendment would revise the Tehnical Specifications to modify the actions required when the quadrant power tilt limits are exceeded. Specifically the actions required in Technical Specification 3.10.3, when a tilt ratio of greater than 1.09 exists, would be changed from placing the unit in Hot Shutdown with subsequent operation up to 50% of rated power to limiting the initial power reduction to 50% of rated power. In addition the required power reduction would be changed from 2 to 3 percent of rated thermal power for every percent of indicated power tilt ratio exceeding 1.0. Consolidated Edison requested the amendment to eliminate unnecessary cyclic loads on the reactor coolant system and to add a conservative limitation on reactor core power level when a tilt condition exists.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists [51 FR 7751 (March 6, 1986)]. A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in margin of safety.

The licensee provided the following discussion regarding the above three criteria:

Criteria 1: The proposed change will not significantly increase the probability or the consequences of a new or different kind of an accident from any previously evaluated since the proposed change: does not entail any physical changes in plant equipment; lessens a thermal transient by requiring a power reduction to below 50% of rated thermal power rather than initially to hot shutdown with subsequent return to 50% power; and conservatively requires a greater initial reduction in power than that currently required by increasing the power reduction requirement from 2% to 3% for every percent of indicated power tilt ratio exceeding 1.0.

Criteria 2: The proposed change will not create the possibility of a new or different kind of accident from any previously evaluated since the proposed change will require the unit to be placed in the desired condition when a tilt condition exists, in a more conservative manner with less cycling of the unit.

Criteria 3: The proposed change will not involve a significant reduction in a margin of safety since the proposed change will continue to require the unit to operate below 50% rated thermal power when a tilt condition greater than 1.02 exists.

The staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Accordingly, the Commission proposes to determine that the proposed change to the Technical Specification involves no significant hazards consideration.

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York, 10610.

Attorney for licensee: Brent L. Brandenburg, Esq., 4 Irving Place, New York, New York 10003.

NRC Project Director: Steven A. Varga.

Consumers Power Company, Docket No. 50–155, Big Rock Point Plant, Charlevoix County, Michigan

Date of amendment request: August 15, 1986.

Description of amendment request: To amend the Big Rock Point Technical Specifications (TS) to reflect the features and terminology used with the installation of new out-of-core source range nuclear instrumentation. The new instrumentation is planned to be installed during the upcoming Cycle 22 refueling outage at Big Rock Point. The licensee also requested the effective date of this amendment be coincident with the completion of the facility modification.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards determination exists as stated in 10 CFR 50.92(c).

10 CFR 50.91 requires at the time a licensee requests an amendment, it must provide to the Commission its analyses, using the standards in Section 50.92, about the issue of no significant hazards consideration. Therefore, in accordance with 10 CFR 50.91 and 10 CFR 50.92, the licensee has performed and provided the following analysis.

The facility change discussed in the licensee's submittal has been evaluated by the licensee in accordance with 10 CFR 50.59. Most of the TS changes are being requested to reflect the features and terminology used with regard to the installation of new out-of-core source range nuclear instrumentation. The new equipment is functionally equivalent to the current equipment and should exhibit improved operating characteristics. All of the proposed TS changes requested are administrative in nature and neither add new requirements nor delete existing requirements. Two of the proposed changes correct typographical errors and one proposed change clarifies the intent by more explicitly identifying when refueling procedures are required to be available.

Because all of the proposed TS changes are administrative in nature, they do not increase the previously evaluated probability of occurrence or consequences of an accident or malfunction of equipment important to safety, do not create the possibility of an accident or malfunction of a different type from those previously evaluated, and do not reduce the margin of safety as defined in any TS basis.

The staff has reviewed the licensee's no significant hazards consideration determination and agrees with the licensee's analysis. Therefore, the staff proposes to determine that the application for amendment involves no significant hazards consideration.

Local Public Document Room location: North Central Michigan College, 1515 Howard Street, Petoskey, Michigan 49770.

Attorney for licensee: Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201.

NRC Project Director: John A. Zwolinski.

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendments request: April 2, 1984 and supplemented on April 18, 1984, October 11, 1985 and February 21, 1986.

Description of amendments request: The proposed license amendments request that the current Technical Specifications relating to Inservice Inspection (ISI) be revised to assure conformance with the requirements of 10 CFR 50.55a "Codes and Standards." The licensee has submitted a revised program for ISI to the NRC staff for the Turkey Point Plant, Units 3 and 4, second Ten-year interval which has been reviewed and approved by the NRC staff. The proposed Technical Specifications are to assure the revised program for ISI is in conformance with the regulations and up date with the periodic changes in the codes specified in 10 CFR 50.55s.

The initial application dated April 2, 1984 and supplemented on April 18, 1984, which requested revised Technical Specifications relating to Inservice Testing (IST) and ISI, was notice in the **Federal Register** on May 23, 1984 (49 FR 21830). By letter dated October 11, 1985, which superseded the initial submittal, the licensee proposed to withdraw the portion of the request related to IST due to the fact that the revised program for IST was still under review by the NRC staff.

The February 21, 1986, submittal indicated that the proposed change to specification 4.4.4, Residual Heat Removal System, was IST related and should not have been included in the October 11, 1985, submittal and provided editorial comments including a corrected page proposed Technical Specification 4.1. Due to the change in scope of the initial request and the length of time since the issuance of the notice on the initial proposed amendments, the staff has determined a renotice should be issued.

Basis for proposed no significant hazards consideration determination: The standards used to arrive at a proposed determination that a request for amendments involved no significant hazards consideration are included in the Commission's regulations, 10 CFR 50.92, which state that the operation of the facilities in accordance with the proposed amendments would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of these standards by providing examples of amendments considered likely, and not likely, to involve a significant hazards consideration. These were published in the **Federal Register** on March 6, 1986 (51 FR 7751). One of the examples (vii) not likely to involve a significant hazards consideration is a change to make a license conform to changes in the regulations where the change results in very minor changes to facility operations clearly keeping with the regulations.

The current Technical Specifications reference a specific edition and addenda of the ASME Boiler and Pressure Code. In 1981, 10 CFR 50.55a was revised to incorporate a later Code edition and addenda than that referenced in the Turkey Point Technical Specifications. Subsequently, 10 CFR 50.55a was revised to require updating to the periodic changes in the Code and requirements identified in 10 CFR 50.55a for ISI and IST programs. These revisions to the regulation occurred subsequent to the NRC staff's review and approval of the initial 10 year ISI program and associated Technical Specifications for the Turkey Point Plant.

10 CFR 50.55a(g)(4) requires that components which are classified ASME Code Class 1, Class 2 and Class 3 shall meet the requirements set forth in Section XI of the edition of the ASME Boiler and Pressure Vessel Code and Addenda that are incorporated by reference in paragraph (b) of that section and shall comply with the latest edition and addenda. The proposed changes will assure updating to the periodic changes in the codes and requirements identified in 10 CFR 50.55a for ISI programs. In addition, the proposed changes are in accordance with the Standard Technical Specifications for Westinghouse Pressurized Water Reactors.

10 CFR 50.55a(g)(5)(ii) requires a technical specification change if the revised inservice inspection program conflicts with the existing Technical Specifications. This is the case for Turkey Point Units 3 and 4 for the approved revised inservice inspection program. The proposed changes will result in very minor changes to facility operations clearly keeping with the regulations.

Therefore, the staff proposes to determine that the application does not involve a significant hazards consideration since it does not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety and the proposed change falls within the Commission's example (vii) or actions not likely to involve significant hazards consideration.

Local Public Document Room location: Environmental and Urban Affairs Library, Florida International University, Miami, Florida 33199.

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzer, P.C., 1615 L Street, NW., Washington, DC 20036.

NRC Project Director: Lester S. Rubenstein.

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendments request: July 18, 1986.

Description of amendments request: The proposed amendments incorporate plant specific Technical Specifications for the Reactor Vessel Level Monitoring System (RVLMS). The RVLMS has been installed and tested on Turkey Point Units 3 and 4, and is a portion of the Inadequate Core Cooling System (ICCS). The NRC staff reviewed and approved the ICCS for Turkey Point Units 3 and 4. The details and basis for the approval

are documented in the staff's Safety Evaluation dated January 28, 1985. The RVLMS portion of the ICCS was approved for implementation subsequent to the licensee requesting technical specifications for the RVLMS. The Technical Specifications are proposed to comply with the NUREG–0737, Item II.F.2, and the staff's Safety Evaluation referenced above. The proposal is also based on the Technical Specifications approved by the NRC for the Palo Verde Nuclear Generating Station Unit 1.

Basis for proposing no significant hazards consideration determination: The proposed changes to the Turkey Point Technical Specifications are:

Table 3.5–5—Number of channels and minimum channels operable and action stations for the RVLMS are added to the accident monitoring instrumentation table.

Table 4.1–1, Sheet 4—Surveillance frequences for RVLMS are added.

Section 6.9.3, Page 6–23—The special reports referenced in the above action statements are added to the list of special reports.

Basis B3.5, Page B3.5–1—A section to describe the basis for the RVLMS is added.

The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences or an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from an accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

Operation of Turkey Point Units 3 and 4 in accordance with the proposed amendments would *not*.

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated. The Reactor Vessel Level Monitoring System (RVLMS) is neither credited nor required in the evaluated accidents, and is not relied upon for reactor trip or initiation of any plant safety systems. Therefore, operation of the facility in accordance with the proposed change does not affect the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated. Although the RVLMS has been utilized in the Emergency Procedures for corroboration of selected indications, no change to normal operating procedures is involved; thus no new path is created which may lead to a new or different kind of accident. The proposed change is intended solely to enhance the ability of the operator to manage accidents and transients by providing the operator with additional corroborative information. Therefore, operation of the facility in accordance with the proposed change does not create the possibility of a new or different accident from any accident previously evaluated.

(3) Involve a significant reduction in margin of safety. The specific purpose of the proposed amendment is to enhance accident and transient monitoring capability and, thus, to increase the margin of safety. Therefore, operation of the facility in accordance with the proposed changes does not involve a reduction in margin of safety.

The Commission has provided guidance concerning the application of the standards for determining whether a significant hazards consideration exists by providing certain examples (51 FR 7751) of amendments that are considered not likely to involve significant hazards considerations. Example (ii) related to a change that constitutes an additional limitation, restriction or control not presently included in the technical specification. The proposed changes are representative of Example (ii) in that it is an addition to the accident monitoring instrumentation required by the Nuclear Regulatory Commission's post-TMI–2 Action Plan.

Based on the above discussion, operation of the facility in accordance with the proposed amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated, or create the possibility of a new or different kind of accident from any accident previously evaluated, or involve a significant reduction in a margin of safety. Therefore, the staff proposes to determine that the proposed amendments do not involve a significant hazards consideration.

Local Public Document Room location: Environmental and Urban Affairs Library, Florida International University, Miami, Florida 33199.

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzer, P.C., 1615 L Street, NW., Washington, DC 20036.

NRC Project Director: Lester S. Rubenstein.

GPU Nuclear Corporation, Docket No. 50–219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

Date of amendment request: September 11, 1986 (TSCR 140).

Description of amendment request: The proposed amendment would make two changes to section 4.4, Emergency Cooling, of the Appendix A Technical Specification (TS). This section lists the surveillance requirements and the frequency of surveillance for the reactor emergency cooling systems. This amendment would change the stated frequency and pressure conditions for the Automatic Depressurization System (ADS) valve operability test in Item 4.4.B.1 from every refueling outage and at low pressure to after each refueling outage and at system operating pressure prior to exceeding 5 percent power. This change is to clarify the surveillance requirements of ADS valve operability in the TS.

Basis for proposed no significant hazards consideration determination: The licensee has proposed Technical Specification Change Request (TSCR), No. 140 to clarify the frequency and pressure conditions for testing ADS valve operability in the TS. The existing TS 4.4.B.1 on ADS valve operability is confusing in that the reference to "low pressure" for the tests in the Bases of Section 4.4 is not defined and that the test are run as the plant is going from the Refueling Mode into the Run Mode as the plant restarts from the refueling outage. The proposed words clearly state when and at what pressure conditions these tests are conducted.

The ADS consists of five automatically activated electromatic relief valves (EMRVs). The ADS is to depressurize the reactor coolant system during a small break LOCA to permit the low pressure core spray system to inject water into the core and provide overpressure protection for anticipated plant transients.

Specification 3.4.B.1 states that the EMRVs shall be operable when the reactor water temperature is greater than 212°F and pressurized above 110 psig. The existing specifications can be interpretated to not allow for EMRV testing at pressures representative of those at which the EMRVs would operate. Testing of the value at representative operating conditions were they would be expected to operate provides the best assurance that these valves will operate satisfactorily if called upon.

The licensee has proposed TSCR 140 to clearly state that the EMRVs may be

demonstrated operable at system operating pressures prior to exceeding 5 percent power. In addition, in order to remove a source of confusion, referene to low pressure testing of the EMRVs shall be eliminated from the basis section.

The EMRVs are tested for operability as the plant comes out of every refueling outage when there is essentially no decay heat. In the event of a leak or rupture coincident with the test and the failure of all five EMRVs, the Isolation Condensers can depressurize the reactor coolant system since there would be little stored energy or decay heat in the fuel. The depressurization capability of the Isolation Condensers is sufficient for testing the ADS following a refueling outage and as necessary during the operating cycle.

The proposed restiction that valve operability shall be demonstrated prior to exceeding 5 percent power adds a restriction to this surveillance requirement not in the existing TS.

The ADS is designed to depressurize the reactor collant system during a small break LOCA to permit the low pressure core spray system to inject water into the core. Testing the EMRVs at system pressure represents normal operating paramenters and does not expose the plant to conditions beyond which it is designed to operate. All testing of the EMRVs has been at these pressures.

Based on the above the staff has concluded that operation of the Oyster Creek plant in accordance with the proposed amendment:

(1) *Does not involve a significant increase in the probability or consequences of a previously evaluated accident because:*

Testing the EMRVs at low power levels and at pressures representative of operating conditions in TSCR 140 would not increase the probability of a small break LOCA. The proposed amendment would not increase the frequency of testing. The testing is at pressure conditions to best assure that these valves will operate as designed. In the unlikely event of a small break LOCA during testing of the EMRVs and the coincident failure of all five EMRVs, the Isolation Condensers and containment isolation would be available to depressurize the reactor coolant system only into containment and initiate core spray as the ADS is designed to operate. Therefore, the proposed amendment does not significantly change the consequences of an accident previously evaluated.

(2) *Does not create the possibility of a new or different kind of accident from any accident previously analyzed because:*

The Isolation condensers will be available to depressurize the reactor coolant system and initiate core spray as the ADS is designed to operate in the unlikely event of a small break LOCA during EMRV testing coincident with the failure of all five EMRVs.

(3) *Does not involve a significant reduction in a margin of safety because:*

The EMRVs are tested at low power and with little stored energy in the fuel and with alternate depressurization means available in the unlikely event of a small break LOCA coincident with the failure of all five EMRVs.

Therefore, because the licensee's request meets the above three criteria in 10 CFR 50.92(c), the staff proposes to determine that the licensee's proposed change does not involve a significant hazards consideration.

Local Public Document Room location: Ocean County Library, 101 Washington Street, Toms River, New Jersey 08753.

Attorney for licensee: Ernest L. Blake, Jr.; Shaw, Pittman, Potts, and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: John A. Zwolinski.

Indiana and Michigan Electric Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: August 19, 1986.

Description of amendment request: The proposed amendment would change the Technical Specifications on snubbers to correct a number of errors, to allow surveillance inspections to be performed sooner, and to clarify that the fluid observation port at the entrance to the valve operator must be checked and full to have an operable snubber.

Basis for proposed no significant hazards consideration determination: The Commission has provided guidance concerning the application of the standards for making a no significant hazards determination by providing certain examples (51 FR 7744). One of these examples (i) is a purely administrative change to technical specifications: for example, a change to achieve consistency throughout the technical specifications, correction of an error or a change in nomenclature. The proposed corrections of errors are directly related to this example. These changes include grammatical corrections, snubber designation corrections, location changes, and accessibility corrections. None of these changes will alter the snubber inspection program or frequency.

The licensee also proposes to change the frequency of testing to allow surveillance intervals at less than the prescribed times and to clarify that the fluid observation port closest to the value operator must be full or the snubber is inoperable. Under the Commission's regulations in 10 CFR 50.92, a no significant hazards consideration can be determined if the proposed amendments would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously analyzed; or (3) involve a significant reduction in a margin of safety. Testing the snubbers at intervals less than prescribed should reveal any failures sooner than the prescribed interval so that repairs can be made before further operation. The fluid port nearest the valve operator, if full, indicates that the snubber is not air-bound and the valve operator and snubber should be operable. The port at the fluid reservoir, away from the operator, may be full but gives less indication that fluid is available at the operator. Therefore, the changes do not increase the probability or consequences of a previously evaluated accident. These changes in frequency and fluid available at the operator do not represent a significant change in plant operation or testing, therefore they do not create the possibility of a new or different kind of accident. These changes should increase the possibility or finding failed snubbers sooner, thus, there is no decrease in a margin of safety.

Based on the above, the Commission proposes to determine that the changed do not invlve a significant hazards consideration.

Local Public Document Room location: Maude Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Attorney for licensee: Gerald Charnoff, Esquire, Shaw, Pittman, Potts and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: B.J. Youngblood.

Kansas Gas and Electric Company, Kansas City Power and Light Company, Kansas Electric Power Cooperative, Inc., Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: August 25, 1986.

Description of amendment request: The purpose of the proposed

amendment request is for deletion of the requirements for resistance testing of certain fuses whose function is to provide containment penetration conductor overcurrent protection, and deletion of the list of containment penetration conductor overcurrent protective devices (circuit breakers and fuses) from the technical specifications.

Basis for proposed no significant hazards consideration determination: The technical specifications currently require that among other things, all containment penetration conductor overcurrent protection fuses shall be demonstrated operable at least once per 18 months by selecting and functionally testing a representative sample (10%) of each type of fuse on a rotating basis. The license amendment application addresses the fact that resistance checking of fuses does not provide a meaningful assurance of the fault interrupting capability of the fuse, and that periodic removal of fuses for testing can compromise the integrity of the fuse holder and contact points. Based on these considerations, and the fact that resistence verification is performed by the vendor during the manufacturing process, the deletion of the requirements for resistance checking of these fuses will not involve a significant increase in the probability of fuse failure. Since the proposed deletion of field testing by resistance will not impact fuse integrity, will not affect the method of plant operation, and will not affect equipment important to safe operation, the proposed amendment does not create the possibility of a new and different accident from any previously evaluated. Since the resistance checking of fuses only generates data that is not indicative of performance, and the fact that resistance checking will be replaced by an inspection and maintenance program, the deletion of the requirements for resistance checking of these fuses will not significantly reduce any margins of safety.

The technical specifications also list the containment penetration conductor overcurrent protective devices (circuit breakers and fuses). The license amendment application also addresses the fact that the deletion of this list from the technical specifications shall in no way degrade compliance with the operability of the containment penetration conductor overcurrent protective devices since it is proposed that the list of these devices will be maintained in the appropriate plant procedures. However, maintaining the list in the procedures instead of in the technical specifications will allow the licensee to have the flexibility in the future to change the list as needed without requesting a technical specification change. Examples of such changes are the addition or deletion of circuits (and breakers) or the changing of a circuit to require a larger or smaller breaker, as a result of a design change in the plant. On March 6, 1986, the NRC published guidance in the **Federal Regiser** (51 FR 7744) concerning examples of amendments that are not likely to involve a significant hazards considerations. This part of the amendment request is similar to the example of a purely administrative change to the technical specifications. The list of containment electrical penetration protective devices will be administratively maintained at the plant rather than in the technical specifications, and this will in no way degrade the operability requirements of these devices.

Based on the foregoing, the requested amendment does not present a significant hazard.

Local Public Document Room location: The William Allen White Library, Emporia State University, Emporia Kansas; and the Washburn University School of Law, Topeka, Kansas.

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: B.J. Youngblood.

Louisiana Power and Light Company, Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of Amendment Request: July 15, 1986.

Description of Amendment Request: The proposed changes would revise the Moderator Temperature Coefficient (MTC) limits of Technical Specification 3.1.1.3. MTC can be described as the change in reactivity that results from a change in the temperature of the water in the core. The MTC limit is an input parameter in various transient and accident analyses. To ensure that the assumptions used in the transient and accident analyses remain valid throughout each fuel cycle (since MTC changes slowly due, principally, to the reduction in reactor coolant system boron concentration associated with fuel burnup), TS 3.1.1.3 imposes limitations on MTC. The proposed changes are needed to accommodate the change in core characteristics from Cycle 1, to accommodate a longer fuel cycle beginning with Cycle 2.

Technical Specification 3.1.1.3 currently states that the MTC shall be less negative than -2.5×10^{-4} delta k over k at rated thermal power, and less positive than $+0.2\times10^{-4}$ delta k over k at or below 70% thermal power, and less positive than 0.0×10^{-4} delta k over k above 70% thermal power. The proposed change will extend the most negative limit to -3.3×10^{-4} delta k over k at all levels of thermal power and will extend the most positive limit to 0.5×10^{-4} delta k over k at or below 70% thermal power. The current positive limit of 0.0×10^{-4} delta k over k above 70% thermal power is not modified by this change.

The above changes are needed for Cycle 2 to accommodate the MTC associated with higher fuel burnup at the end of the fuel cycle and higher boron concentration at the beginning of the fuel cycle. However, the proposed negative limit is more negative than is required for Cycle 2 to accommodate anticipated future cycles.

Basis for Proposed No Significant Hazards Consideration Determination: As part of the Cycle 2 reload analysis, the Waterford 3 FSAR Chapter 15 accident analyses are reviewed for potential impact caused by this change. An example of a potential impact is for the main steam line break event which results in a rapid cooldown of the reactor coolant system. When a more negative MTC is used in the analysis, a more positive reactivity addition occurs due to the cooldown. For the steam line break event, a greater return to power (although not necessarily worse consequences) could result. The accident analyses will utilize the applicable MTC values specified in the proposed change depending upon the power level assumed for each accident or transient analyzed. The acceptance criteria of the Standard Review Plan is used to determine the acceptability of the Cycle 2 results.

The NRC staff proposes to determine that this change does not involve a significant hazards consideration because, as required by the criteria of 10 CFR 50.92(c), operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in the margin of safety. The basis for this proposed finding is given below.

(a) These changes are proposed to accommodate the wider range in MTC values necessary to support an increased cycle length for Cycle 2. As such, they are normal and expected changes. FSAR Chapter 15 events that

are limiting with respect to MTC will be analyzed using the proposed MTC values for Cycle 2. The results of the revised analyses will not show a significant increase in the probability or consequences of any accident previously evaluated since the standard acceptance criteria for each event must be met to allow plant startup following shutdown for refueling.

(b) The proposed revisions address the changes in core characteristics from Cycle 1 to Cycle 2. No new failure modes, accident paths, modes of operation or other plant perturbations are introduced. Therefore, this change does not create the possibility of any new or different kind of accident.

(c) The proposed changes impose limits on the MTC value to ensure that the assumptions used in the FSAR Chapter 15 accident analyses remain valid throughout the cycle. The accident analyses using the more negative MTC limits will be bounded by and will yield acceptable Chapter 15 accident analysis results in the Waterford 3 FSAR. Therefore, this change will not involve a significant reduction in a margin of safety.

As the change requested by the licensee's June 24, 1986 submittal satisfies the criteria of 50.92, it is concluded that: (1) The proposed changes does not constitute a significant hazards consideration as defined by 10 CFR 50.92; (2) there is reasonable assurance that the health and safety of the public will not be endangered by the proposed change; and (3) this action will not result in a condition which significantly alters the impact of the station on the environment as described in the NRC Final Environmental Statement.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Attorney for Licensee: Mr. Bruce W. Churchill, Esq., Shaw, Pittman, Potts and Trowbridge, 1800 M St., NW., Washington, DC 10036.

NRC Project Director: George W. Knighton.

Louisiana Power and Light Company, Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish Louisiana

Date of Amendment Request: August 29, 1986.

Description of Amendment Request: Table 3.6–1 of Technical Specification 3.6.1.2 lists those containment penetrations considered to be potential containment leakage paths, and identifies the type of leakage test to be performed on each listed penetration in accordance with 10 CFR Part 50 Appendix J. The proposed change would add two containment penetrations to Table 3.6–1. These penetrations are presently designated as spares (i.e., they are welded shut), but are to be modified for use during refueling outages in order to provide temporary auxiliary air, water and electrical services inside containment.

Following their modification and following their later use during refueling outages, each affected penetration will be sealed using blind flanges to maintain containment integrity during power operation. These penetrations, however, are presently excluded from the Waterford 3 Appendix J test program and Table 3.6–1 because they are welded shut.

Upon modification, these penetrations will be given a Type "B" leak rate test to establish the integrity of the blind flange seals. They will also be added to the Waterford 3 local leak rate test program to ensure continued periodic monitoring in the future. This proposed Technical Specification change is submitted to maintain consistency between the Technical Specification and the pending revision to the local leak rate test program. The change involves no exceptions or deviations from the existing level of compliance of Waterford 3 to 10 CFR Part 50 Appendix J or plant Technical Specifications.

Basis for Proposed No Significant Hazards Consideration Determination: The NRC staff proposes to determine that the proposed change does not involve a significant hazards consideration because, as required by the criteria of 10 CFR 50.92(c), operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident previously evaluated; or (3) Involve a significant reduction in the margin of safety. The basis for this proposed finding is given below.

(1) Conversion of two spare penetrations to active use would add two new points of potential leakage from containment during an accident. However, the Waterford 3 local leak rate test program has been established to ensure that all active penetrations are periodically tested at accident pressure for leakage in accordance with plant Technical Specifications and 10 CFR Part 50 Appendix J. The allowable leakage rates set forth are based on accident conditions and account for the combined leakage through all containment penetrations. Thus, inclusion of the converted penetrations in the Waterford 3 local leak rate test program will ensure that any leakage through these penetrations is accounted for in calculations used to demonstrate that overall containment integrity will be maintained within acceptable leakage limits under accident conditions.

The affected penetrations were originally designated to maintain containment integrity under accident conditions. Their modification to accept blind flinge seals when not in service will not result in any degradation of the penetration structural adequacy or sealing ability. A type "B" leakage test at accident pressure will be performed upon installation of the blind flanges to ensure initial seal integrity prior to power ascension.

Based on the above, the proposed change will not involve a significant increase in the probability or consequences of any accident previously evaluated.

(2) The proposed change introduces no new systems, modes of operation, failure modes or other plant perturbations. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) As noted above, margin of safety with respect to allowable leakage from containment during an accident is established in accordance with 10 CFR 50 Appendix J and plant Technical Specification limits. Although the subject penetrations constitute two more points of potential leakage, their inclusion of the Waterford 3 leak rate test program will ensure that the overall margin of safety is not reduced below the established acceptable limits.

As the change requested by the licensee's June 24, 1986 submittal satisfies the criteria of 50.92, it is concluded that: (1) The proposed changes does not constitute a significant hazards consideration as defined by 10 CFR 50.92; (2) there is reasonable assurance that the health and safety of the public will not be endangered by the proposed change; and (3) this action will not result in a condition which significantly alters the impact of the station on the environment as described in the NRC Final Environmental Statement.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Attorney for Licensee: Mr. Bruce W. Churchill, Esq., Shaw, Pittman, Potts and Trowbridge, 1800 M St., NW., Washington, DC 20036.

NRC Project Director: George W. Knighton.

Louisiana Power and Light Company, Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of Amendment Request: August 29, 1986.

Description of Amendment Request: Technical Specification 3.3.3.8 addresses fire protection instrumentation. In Table 3.3–11, a summary of the fire detection instruments is given. The proposed change of this table reflects the installation of battery powered smoke detectors in control room panels CP–1, 2, 3, 4, 6, 7, 8, 18, 35 and 36. The installation of these smoke detectors is made as an enhancement to satisfy paragraph 2.C.9.d. of the Waterford 3 operating license.

Basis for Proposed No Significant Hazards Consideration Determination: The NRC staff proposes that the proposed change does not involve a significant hazards consideration because, as required by the criteria of 10 CFR 50.92(c), operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in the margin of safety. The basis for this proposed finding is given below.

(1) The proposed change indicates the installation of these battery powered smoke detectors to control room panels. This is an enhancement and as such, will not increase the probability or consequences of any previously evaluated accident.

(2) The installation of the battery powered smoke detectors is performed in response to License Condition 2.C.9.d. By providing extra smoke detection ability in the control room, this enhancement will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) The detectors are powered from a IE power supply. These detectors provide for increased safety against control room fires. Therefore, the operation of the facility with these detectors will not involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of standards for determining whether a significant hazards consideration exists by providing certain examples (51 FR 7751) of amendments that are considered not likely to involve significant hazards considerations. Example (ii) relates to a change that constitutes an additional limitation, restriction, or control not presently included in the Technical Specifications, (i.e., a more stringent surveillance requirement).

In this case, the proposed change is similar to Example (ii) in that the additional smoke detectors constitute additional restrictions not presently included in the Technical Specifications.

As the change requested by the licensee's August 29, 1986 submittal fits the example provided, as well as satisfies the criteria of 50.92, it is concluded that: (1) The proposed change does not constitute a significant hazards consideration as defined by 10 CFR 50.92; (2) there is a reasonable assurance that the health and safety of the public will not be endangered by the proposed change; and (3) this action will not result in a condition which significantly alters the impact of the station on the environment as described in the NRC Final Environmental Statement.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Attorney for Licensee: Mr. Bruce W. Churchill, Esq., Shaw, Pittman, Potts and Trowbridge, 1800 M St., NW., Washington, DC 20036.

NRC Project Director: George W. Kinghton.

Louisiana Power and Light Company, Docket No. 50–382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of Amendment Request: August 29, 1986.

Description of Amendment Request: During the first cycle of Waterford 3, a seismic monitor suffered heat damage effects incurred at its present location. This was reported in Special Report SR–85–0001–00 pursuant to Technical Specification action statement 3.3.3.3.a The seismic monitor is a passive device which serves no safety related function. It allows evaluation of Reactor Coolant System (RCS) movement following a seismic event. During the first refueling outage, a proposed relocation of this seismic monitor is planned, removing it from its present location on the Pressurizer, where it is subjected to high temperatures, to Safety Injection Tank 1B where it will be in a lower temperature environment. The planned relocation will employ a mount virtually identical to the original mount and thereby will perform the identical function.

Tables 3.3–7, and 4.3–4 of the Waterford 3 Technical Specifications identify Seismic Monitoring Instrumentation and Seismic Monitoring Instrumentation Surveillance Requirements, respectively. Changes are made to indicate the new location of YR–SM 6020. In reviewing the Technical Specifications to identify the pages affected by this change, the location for monitor YR–SM 6021 was identified as incorrect. The correction of this elevation involves the same tables as the above change for YR–SM 6020. Therefore, both changes are included in the notice.

Basis for Proposed No Significant Hazards Consideration Determination: The NRC staff proposes that the proposed changes do not involve a significant hazards consideration because, as required by the criteria of 10 CFR 50.92(c), operator of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in the margin of safety. The basis for this proposed finding is given below.

(1) These seismic monitors are not credited for any safety related function in any of the accidents previously evaluated. Therefore, these changes will not involve a significant increase in the probability or consequences of any accident previously evaluated.

(2) The monitors provide no safety function. Therefore, the relocation for one and the correction of the location for the other in the Technical Specifications will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) As stated, the monitor only provides information to be used in evaluation of RCS movement following a seismic event. The relocation does not effect any accident analysis and as such, will not involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of standards for determining whether a significant hazards consideration exists by providing certain examples (51 FR 7751) of amendments that are considered not likely to involve significant hazards considerations. Example (i) relates to a purely administrative change to technical specifications; i.e, a change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature.

For the change involving monitor YR-SM 6021, the proposed change fits this example since it is merely a correction of an error.

As one change requested by the licensee's August 29, 1986 submittal fits the example provided and both satisfy the criteria of 50.92, it is concluded that: (1) The proposed changes do not constitute a significant hazards consideration as defined by 10 CFR 50.92; (2) there is a reasonable assurance that the health and safety of the public will not be endangered by the proposed changes; and (3) this action will not result in a condition which significantly alters the impact of the station on the environment as described in the NRC Final Environmental Statement.

Local Public Document Room Location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Attorney for licensee: Mr. Bruce W. Churchill, Esq., Shaw, Pitman, Potts and Trowbridge, 1800 M St., NW., Washington, DC 20036.

NCR Project Director: George W. Knighton.

Mississippi Power & Light Company, Middle South Energy, Inc., South Mississippi Electric Power Association, Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of amendment request: July 14, 1986, as amended August 15, September 4 and September 5, 1986.

Description of amendment request: The amendment would make changes to the Technical Specifications needed for fuel cycle 2 operation with new (reload) fuel assemblies replacing spent fuel assemblies. The reload fuel assemblies are supplied by Exxon Nuclear Company, Inc. (ENC) and the present fuel assemblies in the core, including the spent fuel to be removed in the first refueling outage, was supplied by General Electric Company (GE). The proposed changes to the Technical Specifications reflect the replacement of GE fuel assemblies with ENC fuel assemblies in the core and the use of ENC methods of analysis of fuel protection limits. Changes would be made to: Definition 1.8, "Critical Power Ratio"; Bases 2.1, "Safety Limits"; Specification 3/4.1.2 and associated Bases, "Reactivity Anomalies"; Specification 3/4.2.1 and associated Bases, "Average Planar Linear Heat Generation Rate"; Specification 3/4.2.4, "Linear Heat Generation Rate"; Bases 3/4.2.3 and associated References, "Minimun Critical Power Ratio"; Bases 3/4.3.10 "Neutron Flux Monitoring Instrumentation"; and, Specification 3/4.4.1 and associated Bases, "Recirculation System."

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR 50.92 A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with a proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The licensee has provided an analysis of significant hazards considerations in its July 14, 1986 request for a license amendment as amended August 15, September 4, and September 5, 1986. The licensee has concluded, with appropriate bases, that the proposed amendment meets the three standards in 10 CFR 50.92 and, therefore, involves no significant hazards considerations.

The Commission has also provided guidance concerning the application of these standards by providing examples of amendments considered likely, and not likely, to involve a significant hazards consideration. These were published in the **Federal Register** on March 6, 1986 (51 FR 7744). The NRC staff has made a preliminary review of the licensee's submittal. A discussion of these examples as they relate to the proposed amendment follows.

One of the examples of actions involving no significant hazards consideration (iii) is a change resulting from a reactor core reloading, if no fuel assemblies significantly different from those found previously acceptable to the NRC for a previous core at the facility in question are involved. This example assumes that no significant changes are made to the acceptance criteria for Technical Specifications or to analytical methods previously found acceptable by the NRC. The proposed changes to the Technical Specifications requested for this reload are similar to this example. The ENC reload fuel assemblies are a square bundle of 8x8 fuel rods like the GE spent fuel assemblies they replace. Dimensions and design of the ENC fuel are very similar to those for the GE fuel. The fuel safety limits remain the same for the ENC fuel as for the GE fuel. Criteria for determining reactivity anomalies remain the same. The calculated peak cladding temperature for ENC fuel following a loss of coolant accident is significantly below the 10 CFR 50.46 limit as it is for the GE fuel. The ENC methods of analysis of loss of coolant accidents and transients have been previously approved by the NRC staff either on a generic basis or a plant-specific basis. Technical Specifications established for power distribution limits of GE fuel during fuel cycle 1 provide adequate protection of cladding strain and cladding temperature limits for the ENC and GE fuel during fuel cycle 2 and will not be changed. Limits developed for fuel cycle 1 single loop operation, increased core flow region, and extended load region will remain the same for fuel cycle 2.

Accordingly, for the reasons cited above, the Commission proposes to determine that these changes to the Technical Specification do not involve significant hazards considerations.

Local Public Document Room location: Hinds Junior College, McLendon Library, Raymond, Mississippi 39154.

Attorney for licensee: Nicholas S. Reynolds, Esquire, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 17th Street, NW., Washington, DC 20036.

NRC Project Director: Walter R. Butler.

Northern States Power Company, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2, Goodhue County, Minnesota

Date of amendments request: July 15, 1986.

Description of amendments request: The licensee proposes a revision to the existing reactor coolant system heatup and cooldown curves which are valid for ten effective full power years (EFPY). The proposed revised curves would provide reactor coolant system heatup and cooldown limitations up to 15 EFPY.

In addition, the licensee proposed a number of minor changes that fall into four categories consisting of (1) of the Radiation Environmental Monitoring Program, (2) design features (Section 5 of the technical specifications), (3) Security Plan Implementing Procedures, and (4) administrative changes (Section 6 of the technical specification (TI)).

The Radiation Environmental Monitoring Program changes involve correcting errors regarding references, corn environmental sampling, iodine monitoring, and sample locations. The design features appearing in section 55 of the TS were corrected and updated to agree with the current Code of Federal Regulations. The changes involving the Security Plan Implementing Procedures deal with clarifying the scope of review of the operations committee. Changes to

the administrative section of the TS deal with correcting errors and updating administrative requirements to meet recent changes to 10 CFR Part 50, §50.49.

Basis for proposed no significant hazards consideration determination: The major change requested in this proposed license amendment consists of revisions to the heatup and cooldown limit curves due to the existing curves being valid for 10 EFPY.

This proposed change does not involve a significant hazards consideration because operation of the Prairie Island Nuclear Generating Plan Unit Nos. 1 and 2 in accordance with this change would not:

(1) Significantly increase the probability or consequences of an accident previously evaluated. The revised heatup and cooldown limit curves meet the applicable regulatory requirements that ensure the conservatism of the curves. The proposed curves were calculated using techniques that conform to the requirements of 10 CFR Part 50, Appendix G and the guidance set forth in Draft Regulatory Guide 1.99, Revision 2 (current version). Since the proposed heatup and cooldown curves conform to the requirements of 10 CFR Part 50, Appendix G and are more restrictive than the existing curves, they will provide an adequate safety margin for the reactor coolant system pressure boundary during normal operating conditions; including transients resulting from postulated design basis accidents for a service period up to 15 EFPY.

(2) Create the possibility of a new or different type of accident from any previously analyzed. The proposed heatup and cooldown curves were developed by the recalculation of the existing curves to reflect the reactor vessel fluence anticipated to 15 EFPY and the Capsule R radiation surveillance program and guidance set forth in the Draft Regulatory Guide 1.99, Revision 2. Therefore, the revised heatup and cooldown curves do not create the possibility of a new or different type of accident. On this basis, the staff proposes to conclude that no new or different type of accident has been created.

(3) Significantly reduce the margin of safety as defined in the basis for any TS. The safety factors and margins used in the preparation of the proposed limit curves meet the requirements of ASME Code and the guidance of Draft Regulatory Guide 1.99, Revision 2. The safety factor which was applied to the thermal stress intensity factor meets the requirements of the ASME Code and the criteria in the Standard Review Plan. In addition, the margins added to the material reference temperature were consistent with Draft Regulatory Guide 1.99, Revision 2. Regarding the number of minor proposed changes, they fall under the four categories described above. The Commission has provided guidance for the application of standards for determining whether a significant hazards consideration exists by providing examples of amendments that are considered not likely to involve significant hazards considerations (51 FR 7744). One of these examples (i) is a purely administrative change to technical specifications: For example, a change to achieve consistency throughout the technical specifications correction of an error, or a change in nomenclature. All the minor changes falling under the four categories described above consists of clarifications, correction of errors due to changes in regulations, corrections to monitoring program stemming from implementation of the programs, and administrative changes. These changes whether considered separately or collectively in no way relaxes that intent of the technical specifications or reduces the margin of safety.

Based on our evaluation of the first change involving revised heatup and cooldown limit curves, we have determined that this change does not involve a significant hazards consideration. The remaining minor proposed changes are similar to an example for which no significant hazards consideration exists. As a consequence of the above, the staff has made a proposed determination that the application for amendment involves no significant hazards consideration.

Local Public Document Room location: Environmental Conservation Library, Minneapolis Public Library, 300 Nicollet Mall, Minneapolis, Minnesota

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts, and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: George E. Lear.

Pennsylvania Power & Light Company, Docket No. 50–387 and 50–388, Suequehanna Steam Electric Station, Units 1 and 2, Luzerne County, Pennsylvania

Date of amendment request: February 10, 1986, as supplemented on March 4, June 24, and August 29, 1986.

Description of amendment request: The licensee has requested modifications to Technical Specifications (TS) 3.3.7.9, 3.7.6.2, 3.7.6.5, 3.8.1.1, 3.8.1.2, 3.8.2.1, 3.8.2.2, 3.8.3.1, 3.8.3.2, 3.8.4.2. All of the above TS modifications are requested to provide operational control for the newly installed 5th diesel generator. This fifth diesel will function as a manual swing spare capable of replacing any one of the four existing diesels.

Technical Specifications 3.3.7.9, 3.7.6.2, and 3.7.6.5 have all been modified to incorporate the appropriate fire protection requirements for the new diesel generator housed in its own separate newly constructed building. These fire protection controls are commensurate with those found acceptable for the four existing diesels. Technical Speification 3.8.1.1 has been moified to include (1) operational controls for the fifth diesel when being aligned, and (2) surveillance controls for the fifth diesel at all times in order to maintain diesel reliability. Technical Speifications 3.8.1.2, 3.8.2.1, 3.8.2.2, 3.8.3.1, 3.8.3.2, and 3.8.4.2 have all been changed to include operation control for all support systems necessary for the reliable functioning of the fifth diesel. All of the support systems included for the fifth diesel are the same as those previously included for each of the four existing diesels.

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A proposed amendment to an operating license for a facility involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from an accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The changes proposed by the licensee do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed changes support the use of a fifth diesel generator as a manual swing spare capable of replacing any one of the four existing diesels. Any accidents relating to the loss of one diesel generator or the associated Emergency Service Water (ESW) loop have already been analyzed in the Final Safety Analysis Report (FSAR). The proposed operability requirements are the same for the fifth diesel when aligned as part of the plant. Additionally, when the fifth diesel is not aligned to the plant it wil not impact the operation of the nuclear units in any way. The testing requirements imposed on the fifth diesel are commensurate with those presently imposed on the four existing diesels.

Based on the above the staff finds that there is no significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated. When the fifth diesel generator is not aligned to the 1E electrical system it does not impact the existing plant systems. When the fifth diesel is being aligned or is aligned to the 1E electrical system it can only result in the loss of a diesel generator which is a previously analyzed event. During testing of the fifth diesel generator the fifth diesel relies on cooling water from the ESW system. The design is such that the worst case would be the loss of an ESW loop and a diesel generator. This accident has already been analyzed.

The proposed changes do not involve a significant reduction in the margin of safety. The purpose of installing a fifth diesel generator is to have an additional diesel available should one of the existing diesels fail. Having an additional diesel available doesnot not reduce the margin of safety and will likely increase the reliability of the diesel generators as a source of AC power.

Based on the foregoing discussion, the NRC staff proposes to find that the amendment request does not involve a significant hazards consideration.

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Attorney for the licensee: Jay Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 1800 M Street, NW., Washington, DC 20036.

NRC Project Director: E. Adensam.

Power Authority of the State of New York, Docket No. 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of Amendment request: April 10, 1986.

Description of amendment request: The proposed amendment would revise Section 3.9.A.3 of the Technical Specifications (TS) to eliminate the requirement to disconnect an emergency bus from the normal power source and connect it to the reserve power source, when its associated Emergency Diesel Generator (EDG) system is inoperable. This manual transfer destabilizes the power supply and has already led to a loss of power with subsequent plant scram.

Basis for proposed no significant hazards consideration determination: In accordance with the Commission's Regulations in 10 CFR 50.92, the Commission has made a determination that the proposed amendment involves no significant hazards considerations. To make this determination the staff must establish that operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the posibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

As described in the FitzPatrick Final Safety Analysis Report, Section 8.5, automatic transfer of power supply is provided for equipment required for a safeguard function. The transfer equipment is designed so that the normal source breaker or contactor must open before the alternate source breaker or contactor can close, and the alternate source breaker or contactor will not close if an overload condition exists. The power transfer equipment is designed to meet single failure criteria. Automatic fast transfer of power supply is provided from the normal to the reserve source. Automatic residual transfer takes place either after an unsuccessful fast transfer, or when the nature of the disturbance will not allow a fast transfer. In the unlikely event that neither automatic fast transfer not automatic residual transfer takes place, a manual transfer can still be made. The proposed amendment does not change the total number of power sources available. The requirement that the two incoming power sources be available and that the remaining EDG system be operable is sufficient to ensure that power is available in the event that one of the EDG systems is declared inoperable. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated. On the same basis, the proposed amendment also will not create the possibility of a new or different kind of accident from any previously analyzed. Therefore, criteria (1) and (2) above are satisfied.

The existing TS requires manual transfer to reserve power when one EDG system is declared inoperable, even when the normal power source is available. In addition, if the EDG system is made operable within 7 days, another manual transfer is then required to return to the normal power source. During the evolution of manually transferring power, it is necessary to "parallel" the two sources of power for a period of time. During this period, the large phase angle which frequently occurs, results in high currents which may cause a breaker trip and result in loss of power and reactor scram. The elimination of this unnecessary operator action would not reduce the margin of safety but, rather, would enhance the safe operation of the plant by decreasing the possibility of an inadvertent scram. Therefore, criteria (3) above is satisfied.

Because it has been established that plant operation in accordance with the proposed amendment would satisfy the three above stated criteria, the staff has, therefore, made a proposed determination that the proposed amendment involves no significant hazards consideration.

Local Public Document Room location: Pennfield Library, State University College of Oswego, Oswego, New York.

Attorney for licensee: Mr. Charles M. Pratt, Assistant General Counsel, Power Authority of the State of New York, 10 Columbus Circle, New York, New York, 10019.

NRC Project Director: Daniel R. Muller.

Power Authority of the State of New York, Docket No 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of amendment request: July 11, 1986.

Description of amendment request: The proposed amendment would revise the Technical Specifications (TS) to reflect changes in the organizational structure of the licensee's headquarters staff. The specific revisions proposed are as follows and are intended to provide focused functional area management and efficiency.

A. Proposed changes to Figure 6.1–1

1. The Department of Quality Assurance and Reliability has been changed to the Department of Appraisal & Compliance Services. In addition, the title of the Vice President of Quality Assurance & Reliability has been changed to Senior Vice President—Appraisal & Compliance Services.

2. The Director of Safety and Fire Protection who previously reported to the Vice President—Quality Assurance & Reliability, now reports to the new position of Director of Security, Safety, and Fire Protection.

3. The Executive Vice President & Chief Engineer—Engineer & Design now reports to the First Executive Vice President—Operations. The position of First Executive Vice President & Chief Development Officer has been eliminated.

B. Proposed Changes to Figure 6.2.–1

The proposed changes to Figure 6.2–1 reflect the change in title of the Senior Vice President—Quality Assurance & Reliability. In addition, a new position has been added. The Director—QA will report to the Senior Vice President—Appraisal and Compliance Services. Consequently, the QA Superintendent & Staff will now report to the Director—QA.

C. Proposed Changes to Subsection 6.5.2.2

The proposed changes to subsection 6.5.2.2 of the Technical Specifications consists of the following changes:

1. The title of Vice President Nuclear Support—BWR has been changed to Vice President—Nuclear Operation:

2. The title of Vice President Nuclear Support—PWR has been changed to Vice President—Nuclear Engineering:

3. The title of Vice President—Generic Nuclear Support has been changed to Vice President—Nuclear Support.

Basis for proposed no significant hazards consideration determination: In accordance with the Commission's Regulations in 10 CFR 50.92 , the Commission has made a determination that the proposed amendment involves no significant hazards considerations. To make this determination the staff must establish that operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

The proposed amended in this instance does not involve a physical modification of the plant, a change in operating procedures, or a change in any limiting conditions of operation. Rather, the change is administrative, concerning changes in management organization, position titles, position responsibilities, and other administrative corrections. In view of the administrative nature of the proposed amendment, none of the criteria enumerated above apply.

Based on the foregoing, the Commission proposes to determine that the proposed amendment does not involve a significant hazards consideration. *Local Public Document Room Location:* Pennfield Library, State University College of Oswego, Oswego, New York.

Attorney for licensee: Mr. Charles M. Pratt, Assistant General Counsel, Power Authority of the State of New York, 10 Columbus Circle, New York, New York, 10019.

NRC Project Director: Daniel R. Muller.

Sacramento Municipal Utility District, Docket No. 50–312, Rancho Seco Nuclear Generating Station, Sacramento County, California

Date of amendment request: August 1, 1985, as supplemented November 25, 1985, and February 20, 1986.

Description of amendment request: This proposed change would revise existing fire protection Technical Specifications (TSs) to include additional fire protection components in the auxiliary building, turbine building, and Nuclear Service Electrical Building, and clarify requirements on fire barriers. The minimum operable requirements for heat, flame, and smoke detectors have been increased from appromixately 50 percent of those available to 100 percent of the available detectors being operable.

These revisions will upgrade the existing TSs to be in compliance with the applicable requirements of 10 CFR Part 50, Appendix R, based on the 1985 Rancho Seco Fire Hazard Analysis Report (FHAR) update.

In addition, Specifications 3.14.3.1, 3.14.4.1 and 3.14.5.1 would be reformatted to a table format. The system location titles and zone designations would be revised to be consistent with the titles and zone designations used on the control room displays. The fire protection TS bases and definition of the areas protected by fire barriers would be revised to be consistent with the 1985 Rancho Seco FHAR update. The reporting requirements of Specification 6.9.5.E would be modified to be consistent with Specification 3.14.

Basis for proposed no significant hazards consideration determination: One type of change proposed involves additional detectors, water suppression systems, carbon dioxide systems, and hose stations to be added to the TS tables to reflect the 1985 Rancho Seco FHAR update which defines the safety related fire areas or areas containing redundant systems important to safe shutdown.

The Commission has provided guidance concerning the application of standards considered not likely to involve a significant hazards consideration by providing certain examples (51 FR 7751).

Example (ii) involves a change that constitutes an additional limitation, restriction, or control not presently included in the technical specifications; for example, a more stringent surveillance requirement. The proposed addition of fire protection TSs clearly fits this example.

A second group of proposed changes involves minor typographical corrections, reformatting, and clarification to gain consistency and is therefore deemed administrative in nature. These changes fit example (i) which involves a purely administrative change to technical specifiations: For example, a change to achieve consistency throughout the technical specifications, correction of an error, or a change in nomenclature.

Thus, based on the example presented, the Commission proposes to determine that the amendment request involves no significant hazards considerations.

Local Public Document Room location: Sacramento City-County Library, 828 I Street, Sacramento, California 95814.

Attorney for licensee: David S. Kaplan, Sacramento Municipal Utility District, 6201 S Street, P.O. Box 15830, Sacramento, California 95813.

NRC Project Director: John F. Stolz.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: August 8, 1986.

Description of amendment request: The proposed amendments would reduce the minimum flow requirements for the safety injection pumps and centrifugal charging pumps given in surveillance requirements 4.5.2.h.1.2 and 5.4.2.h.2.a.

Basis for proposed no significant hazards consideration determination: The NRC published guidance in the **Federal Register** (51 FR 7744) concerning examples of amendments that are not likely to involve a significant hazards consideration.

Example (vi) provided in 51 FR 7744 identifies a proposed amendment to an operating license likely to involve no significant hazard if it is a change which either may result in some increase to the probability or consequences of a previously-analyzed accident or may reduce in some way a safety margin, but where the results of the change are clearly within all acceptable criteria with respect to the system or component specified in the Standard Review Plan: For example, a change resulting from the application of a small refinement of a previously used calculational model or design method.

The proposed changes would reduce a safety margin since the reduced pump flow would increase the peak clad

temperature (PCT) resulting during a six-inch (the most limiting size), small-break, loss-of-coolant accident. However, the increase in the PCT would still be within the 2200°F limit specified in section 15.0 of NUREG–0800, "The Standard Review Plan."

Accordingly, the Commission proposes to determine that these proposed amendments involve no significant hazards considerations.

Local Public Document Room location: Chattanooga-Hamilton County Bicentennial Library, 1001 Broad Street, Chattanooga, Tennessee 37401.

Attorney for licensee: Mr. Herbert S. Sanger, Jr., Esquire, General Counsel, Tennessee Valley Authority, 400 Commerce Avenue, E11B33, Knoxville, Tennessee 37902.

NRC Project Director: B.J. Youngblood.

Vermont Yankee Atomic Power Corporation, Docket No. 50–271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of amendment request: August 28, 1986.

Description of amendment request: By letter dated August 28, 1986, the licensee, Vermont Yankee Nuclear Power Corporation, submitted a proposed license amendment for NRC review and approval which would revise the Vermont Yankee Technical Specifications to permit one RHR pump to be out of service for up to 14 days, rather than the 7 days presently permitted, in order to perform inspection or repair of impeller wear rings during the 1986–87 operating cycle. During the period the RHR pump is out of service, the requirement for daily testing of the operable RHR pumps is removed, in order to avoid causing the loss of total system function.

Basis for proposed no significant hazards consideration determination: This case is in fact an example likely to involve significant hazards consideration except that in this case it does not because the Commission has provided criteria for determining whether a significant hazards determination exists as stated in 10 CFR 50.92(c). A proposed amendment to an operating license involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety.

(1) The proposed amendment does not involve a significant increase in the consequences of an accident previously evaluated because the Vermont Yankee FSAR addresses the consequences of any postulated accidents with only one RHR pump available. There is not a significant increase in the probability of an accident because the remaining three RHR pumps, which are required to be operable, provide full cooling capacity.

(2) The proposed amendment does not create a new or different kind of accident from any accident previously evaluated because the Vermont Yankee FSAR addresses accidents with only one RHR pump available.

(3) The proposed amendment does not involve a significant reduction in a margin of safety because operation with one RHR pump out of service is presently permitted, therefore, the margin of safety is not signficantly affected.

Accordingly, the Commission proposes to determine that the proposed amendment does not involve a significant hazards consideration.

Local Public Document Room location: Brooks Memorial Library, 224 Main Street, Brattleboro, Vermont 05301.

Attorney for licensee: John A. Ritscher, Esquire, Ropes and Gray, 225 Franklin Street, Boston, Massachusetts 02110.

NRC Project Director: Daniel R. Muller.

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: August 22, 1986.

Description of amendment request: The proposed changes would extend the duration of the NA–1&2 full power Operating Licenses (NPF–4 and NPF–7, respectively) to 40 years from the date of issuance of the operating licenses. The current operating licenses for NA–1&2 expire 40 years from the date of issuance of the construction permit. Because of the time required for construction, fuel loading and startup testing, the effective periods of Operating Licenses NPF–4 (NA–1) and NPF–7 (NA–2) are approximately 33 years and 30½ years, respectively. Current NRC policy is to issue operating licenses for a 40 year period beginning with the date of issuance, consistent with the guidelines of 10 CFR 50.51 and section 103.C of the Atomic Energy Act of 1954 (42 U.S.C. 2133.C), as amended. The North Anna Power station is currently licensed for a period of 40 years commencing with the issuance of the construction permit, which was issued for both units on February 19, 1971. The current licenses will therefore expire at midnight on February 18, 2011, and February 19, 2011, for NA–1&2, respectively. This request would allow for 40 full years of operation by changing the license expiration dates to April 1, 2018, for NA–1 (NPF–4) and to August 21, 2020, for NA–2 (NPF–7).

The request for the extension of the operating licenses is based on the fact that a 40 year operating life (Reference UFSAR Table 5.1–1) was considered by the NSSS Vendor (Westinghouse Electric Corporation) and Architect Engineer (Stone and Webster Engineering Corporation) during the design and construction of the plant. A 40 year design life, however, does not preclude that some equipment may require repair and/or replacement during the lifetime of the station. Design features have been incorporated which provide for the inspectability of structures, systems and equipment. The surveillance, inspection, testing and maintenance practices which have been implemented in accordance with applicable codes, standards and the facility Technical Specifications, provide assurance that degradation in plant equipment will be identified and corrected.

In accordance with 10 CFR 50.49, "Environmental Qualification of Electrical Equipment Important to Safety for Nuclear Power Plants," aging anlayses have been performed for safety-related electrical equipment identifying qualified lifetimes for this equipment. These lifetimes are incorporated into plant equipment maintenance and replacement practices to ensure that safety-related electrical equipment remains qualified and available to perform its safety function regardless of the overall age of the plant.

Reactor vessel material analyses have shown that the expected cumulative neutron fluence on the reactor vessel will not be a limiting consideration for a 40 year operating life. Periodic anlaysis of the surveillance specimens inside the reactor also allows for monitoring the actual cumulative effects of neutron fluence. Periodic vessel inservice inspection and testing requirements provide additional assurance that any degradation will be identified.

On-site storage of spent nuclear fuel will be available through the year 1999. Additional onsite storage through the use of fuel rod consolidation or dry cask storage, will be added as necessary. Also, the U.S. Department of Energy should make available off-site storage and disposal, under the Nuclear Waste Policy Act of 1982, before 2011.

Therefore, storage of spent fuel generated after 2011 is not a concern.

No new safety concerns are introduced by this proposed amendment since (1) a 40 year life was considered in the design of the plant, and since (2) new or revised accident analyses, plant modifications, procedure changes UFSAR revisions and Technical Specification revisions are not required. However, it is noted that since the issuance of the operating licenses, numerous modifications have been implemented to enhance safety and to address issues such as Appendix R, Regulatory Guide 1.97, ALARA, Equipment Qualification, and the TMI-2 Lessons Learned (NUREG-0737).

Basis for proposed no significant hazards consideration determination: The Commission has provided standards for determining whether a significant hazards consideration exists as stated in 10 CFR Part 50.92(c). A proposed amendment to an operating license for a facility involves no significant hazards considerations if operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety.

The proposed license amendment to permit a 40 year operating life does not constitute a significant hazards consideration as defined in 10 CFR 50.92 since:

1. The proposed amendment does not involve a significant increase in the probability or consequences of any accident previously evaluated since no changes are required to the design or operation of the station. This amendment does not involve new or revised safety analyses, physical plant modifications, procedure changes, UFSAR revisions or Technical Specification revisions. The proposed license extensions are within the original design considerations for the station and the current surveillance, inspection, testing and maintenance practices provide assurance that degradation in plant equipment will be identified and corrected throughout the lifetime of the facility.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated since no changes are required to the design or operation of the station.

3. The proposed amendment does not involve a significant reduction in a margin of safety since no changes are required to the design or operation of the station and since the amendment does not involve new or revised safety analyses, procedure changes, UFSAR revisions or Technical Specification revisions. The current surveillance, inspection, testing and maintenance practices provide assurance that degradation in plant equipment will be identified and corrected throughout the life time of the facility.

Therefore, the NRC staff proposes to determine that the standards for determining that the proposed changes involve no significant hazards consideration are met, and that the extension of the NA-1&2 operating licenses in accordance with the proposed changes would not involve a significant hazards consideration.

Local Public Document Room location: Board of Supervisors Office, Louisa County Courthouse, Louisa, Virginia 23093 and the Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Attorney for licensee: Michael W. Maupin, Esq., Hunton, Williams, Gay and Gibson, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Lester S. Rubenstein.

Washington Public Power Supply System, Docket No. 50-397, WNP-2, Richland, Washington

Date of amendment request: August 18, 1986.

Description of amendment request: This proposed amendment, if approved, would revise the WNP-2 Technical Specifications by modifying Section 3/4.3.8, Turbine Overspeed Protection System, to change the turbine valve surveillance test interval from seven days to thirty-one days.

The seven day test schedule currently required by the Technical Specifications was based on a previous recommendation of the turbine vendor (Westinghouse) to ensure reliability of operation of the model BB296 turbine, the turbine in use of WNP-2. Westinghouse has now informed the Supply System of additional evaluations that are applicable to plants with BB296 turbines. These evaluations provide a justification for reducing the frequency of turbine valve surveillance testing without a significant increase in accident probability. For BB296 turbines, the vendor recommendation for turbine valve surveillance test interval was revised from weekly to monthly.

The turbine valve test interval stipulated in the WNP-2 Technical Specification was derived from the historic Westinghouse recommended test interval. This test interval was developed for fossil units and carried over to early nuclear units due to similarity in design. Fossil units produced steam with much greater particulate (impurities) content than is permitted in nuclear units. These impurities required more frequent valve surveillance to insure reliable operation. Improved valve design and an increase in the body of knowledge concerning turbine valve reliability mitigated the original reasons for frequent valve testing. For these reasons an evaluation of the importance of turbine valve testing interval was undertaken by Westinghouse, and it was shown that acceptance criteria were met less frequent testing.

This vendor recommendation for a revised surveillance test interval is based on the high reliability of the turbine overspeed and trip system which also has been demonstrated by plant experience. Specifically, it has been demonstrated that there is no significant difference in the valve failure rate between valves tested weekly and those tested monthly.

These studies also demonstrated, however, that there is an increase in the total yearly hypothetical turbine missile generation probability from 7.6×10^{-6} to 9.0×10^{-6} when the test interval is changed from weekly to monthly. This increase in probability is small, not statistically less than the NRC guideline of 1×10^{-4} per year. The value is also less than the more recently proposed requirement of 1×10^{-5} per year.

Basis for proposed no significant hazards consideration determination:

The Commission has provided standards for determining whether a significant hazards consideration exists (10 CFR 50.92(c)). A propsoed amendment to an operating license for a facility involves no significant hazards consideration if operating of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from an accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has determined, and the staff agrees, that the requested amendment per 10 CFR 50.92 does not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated because the increase in accident probability has

been demonstrated to be minimal—not significant—and the accident consequences are unchanged; or (2) create the possibility of a new or different kind of an accident from an accident previously evaluated because no change in configuration or design is associated with a change in surveillance test frequency only, so the accidents previously evaluated are still appropriate and no new or different ones are introduced; or (3) involve a significant reduction in a margin of safety because the margin of safety was demonstrated by Westinghouse to be only minimally and insignificantly increased.

Based on or review of the proposed modification, the staff finds that there exists reasonable assurance that this proposed change will have little or no impact on the public health and safety. Accordingly, the Commission proposes to determine that the requested change to the WNP–2 Operating License involves no significant hazards considerations.

Local Public Document Room Location: Richland Public Library, Swift and Northgate Streets, Richland, Washington 99352.

Attorney for the Licensee: Nicholas Reynolds, Esquire; Bishop, Liberman, Cook, Purcell and Reynolds, 1200 Seventeenth Street NW., Washington, DC 20036

NRC Project Director: E. Adensam.

PREVIOUSLY PUBLISHED NOTICES OF CONSIDERATION OF ISSUANCE OF AMENDMENTS TO OPERATING LICENSES AND PROPOSED NO SIGNIFICANT HAZARDS CONSIDERATION DETERMINATION AND OPPORTUNITY FOR HEARING

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices because time did not allow the Commission to wait for this bi-weekly notice. They are repeated here because the bi-weekly notice lists all amendments proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Arizona Public Service Company, et al., Docket Nos. 50–528 and 50–529, Palo Verde Nuclear Generating Station, Units 1 and 2, Maricopa County, Arizona

Date of Amendment Request: July 23, 1986, and supplemental letter dated August 26, 1986.

Brief Description of Amendment: Technical Specification changes to setpoints involved with the Low Reactor Coolant Flow reactor trip function.

Date of Publication of Individual Notice in Federal Register: September 2, 1986 (51 FR 31179).

Expiration Date of Individual Notice: October 2, 1986.

Local Public Document Room Location: Phoenix Public Library, Business, Science and Technology Department, 12 East McDowell Road, Phoenix, Arizona 85007.

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE

During the period since publication of the last bi-weekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with these actions was published in the **Federal Register** as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and the local public documents rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555; Attention: Director, Division of Licensing.

Arizona Public Service Company, et al. Docket No. STN 50–528, Palo Verde Nuclear Generating Station, Unit 1, Maricopa County, Arizona

Date of Application for Amendment: May 29, 1986.

Brief Description of Amendment: The amendment revised the organizational structure in the Technical Specifications to be consistent with the organizational structure for Palo Verde Unit 2.

Date of Issuance: September 3, 1986.

Effective Date: September 3, 1986.

Amendment No.: 8.

Facility Operating License No.: NPF–41: Amendment revised the Technical Specifications.

Dates of Initial Notice in Federal Register: July 2, 1986 (51 FR 24249). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 3, 1986.

No significant hazards consideration comments were received: No.

Local Public Document Room Location: Phoenix Public Library, Business, Science and Technology Department, 12 East McDowell Road, Phoenix, Arizona 85007.

Arizona Public Service Company, et al. Docket No. STN 50–528, Palo Verde Nuclear Generating Station, Unit 1, Maricopa County, Arizona

Date of Application for Amendment: May 14, 1986.

Brief Description of Amendment: The amendment revised the Technical Specifications by changing the testing requirements for the emergency diesel generators to be consistent with regulatory guidance and identical to the testing requirements for Palo Verde Unit 2.

Date of Issuance: September 3, 1986.

Effective Date: September 3, 1986.

Amendment No.: 9.

Facility Operating License No.: NPF–41: Amendment revised the Technical Specifications.

Dates of Initial Notice in Federal Register: June 18, 1986 (51 FR 22227). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 3, 1986.

No significant hazards consideration comments were received: No.

Local Public Document Room Location: Phoenix Public Library, Business, Science and Technology Department, 12 East McDowell Road, Phoenix, Arizona 85004.

Arkansas Power & Light Company, Docket No. 50–368, Arkansas Nuclear One, Unit 2, Pope County, Arkansas

Date of Application for Amendment: April 25, 1986 as supplemented May 23, 1986.

Brief Description of Amendment: The amendment revised Technical Specification 3.1.1.4 pertaining to moderator temperature coefficient.

Date of Issuance: September 10, 1986.

Effective Date: September 10, 1986.

Amendment No.: 80.

Facility Operating License No.: NPF–6: Amendment revised the Technical Specifications.

Dates of Initial Notice in Federal Register: July 2, 1986 (51 FR 24249) The Commission's related evaluation of the amendment is contained in a Safety Evaluated dated September 10, 1986.

No significant hazards consideration comments were received: No.

Local Public Document Room Location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801.

Carolina Power and Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: September 12, 1985.

Brief description of amendment: The amendment revises the Technical Specification to increase the total steam flow rate to reflect the as-built conditions of the new steam generators and deletes section 3.J. of the Operating License imposed during the steam generator replacement program.

Date of issuance: August 25, 1986.

Effective date: August 25, 1986.

Amendment No. 102.

Facility Operating License No. DPR–23. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 2, 1986 (51 FR 24250) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 25, 1986.

No significant hazards consideration comments received: No

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29535.

Commonwealth Edison Company, Docket No. 50–249, Dresden Nuclear Power Station, Unit No. 3, Grundy County, Illinois

Date of application for amendment: June 18, 1986.

Brief description of amendment: The changes to the Technical Specifications (TS) involve modifications to the surveillance requirements for certain Reactor Protection System and Emergency Core Cooling System instruments due to the replacement of these instrument channels with an Analog Trip System.

The changes affects TS tables, notes and bases that pertain to the instruments.

Date of issuance: September 2, 1986.

Effective date: September 2, 1986.

Amendment No. 89.

Facility Operating License No. DPR–25. The amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27279). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 2, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Morris Public Library, 604 Liberty Street, Morris, Illinois 60450.

Commonwealth Edison Company, Docket No. 50–374, La Salle County Station, Unit 2, La Salle County, Illinois

Date of amendment request: June 11, 1986.

Brief description of amendment: This amendment revised the La Salle Unit 2 Technical Specifications to reflect the replacement of eight 26-inch and two 8-inch vent and purge isolation valves with valves manufactured by Clow Corporation. These new valves meet all the requirements for containment vent and purge isolation valves. Since the new valves are qualified to close from any position, including the full open (90°) position, the Technical Specifications 3.6.1.8, 4.6.1.8.1, and associated basis 3/4.6.1.8 are revised to remove the 50° limit on valve opening. This limit was required until the original valves were replaced by new valves capable of closing during a loss-of-coolant accident or a steam line break. In addition, the new Clow valves do not contain resilient seals; and therefore, the once per 92 days leakage surveillance is no longer required. Technical Specification 4.6.1.8.2 is deleted. The purpose of the accelerated leakage rate testing (every 92 days) was to provide an early indication of material seal degradation. Finally, since these Clow valves are air operated, no thermal overload bypass functions are required. Technical Specification 3.8.3.3 is revised to delete these valves from Table 3.8.3.3–1.

The above items addressed in this amendment will be completed prior to startup after the first refueling, as required by License Condition 2.C.(8).

Date of issuance: August 29, 1986.

Effective date: Upon startup following the first refueling.

Amendment No: 25.

Facility Operating License No. NPF–18. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27279) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 29, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Commonwealth Edison Company, Docket No. 50–374, La Salle County Station, Unit 2, La Salle County, Illinois

Date of amendment request: July 3, 1986.

Brief description of amendment: This amendment adds requirements in the La Salle, Unit 2 Technical Specification for new suppression poll level and water temperature instruments for the remote shutdown monitoring instrumentation to be added at the first refueling outage. This satisfies License Condition 2.C.(15)(j).

Date of issuance: August 29, 1986.

Effective date: Startup following first refueling.

Amendment No: 26.

Facility Operating License No. NPF–18. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27279) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 29, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Commonwealth Edison Company, Docket No. 50–374, La Salle County Station, Unit 2, La Salle County, Illinois

Date of amendment request: July 3, 1986.

Brief description of amendment: This amendment would add requirements to the La Salle, Unit 2 Technical Specifications for the modification of the automatic depressurization system logic to be added at the first refueling outage. This is in accordance with License Condition 2.C.(18)(d)(i).

Date of issuance: August 29, 1986.

Effective date: Upon startup following the first refueling outage.

Amendment No.: 27.

Facility Operating License No. NPF–18: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27280).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 29, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Connecticut Yankee Atomic Power Company, Docket No. 50–213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: April 15, 1986 as modified June 4, 1986.

Brief description of amendment: This amendment revises the technical specifications to permit plant operation given that four steam generator tubes in steam generator #4 were not inspected as required per Technical Specification Table 4.10.1–2. Haddam Neck Plant operation in this condition is limited to the present cycle (cycle 14) only and the licensee has agreed to inspect these steam generator tubes during the next outage.

Date of issuance: September 3, 1986.

Effective date: September 3, 1986.

Amendment No.: 82.

Facility Operating License No. DPR–61: Amendment revised the technical specifications.

Date of initial notice in Federal Register: July 2, 1986 (51 FR 24251).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 3, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Russell Library, 124 Broad Street, Middletown, Connecticut 06457.

Connecticut Yankee Atomic Power Company, Docket No. 50–213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: May 30, 1986.

Brief description of amendment: This amendment revises the technical specifications on fire protection and loss prevention audits to conform with the guidance of Generic Letter 82–21. More specifically, the triennial fire protection program audit for the Haddam Neck plant will be performed by a qualified fire protection consultant independent of Northeast Utilities.

Date of issuance: September 9, 1986.

Effective date: September 9, 1986.

Amendment No.: 83.

Facility Operating License No. DPR–61: Amendment revised the technical specifications.

Date of initial notice in Federal Register: July 16, 1986 (51 FR 25768).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 1986.

No significant hzards consideration comments received: No.

Local Public Document Room Location: Russell Library, 124 Broad Street, Middletown, Connecticut 06457.

Dairyland Power Cooperative, Docket No. 50–409, La Crosse Boiling Water Reactor, Vernon County, Wisconsin

Date of application for amendment: February 21, 1986 as clarified July 29, 1986.

Brief description of amendment: The license amendment deletes section 2.6, description of the electrical power system design, and adds this information to the bases to section 4.2.3. The new bases alters section 4.2.3 to conform more closely with boiling water reactor Standard Technical Specifications.

Date of issuance: September 2, 1986.

Effective date: September 2, 1986.

Amendment No.: 52.

Provisional Operating License No. DPR–45: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 7, 1986 (51 FR 16926).

The Commission's related evaluation for the license amendment is contained in a Safety Evaluation dated September 2, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room Location: La Crosse Public Library, 800 Main Street, La Crosse, Wisconsin 54601.

Dairyland Power Cooperative, Docket No. 50–409, La Crosse Boiling Water Reactor, Vernon County, Wisconsin

Date of application for amendment: July 11, 1983, as amended September 17, 1985.

Brief description of amendment: The amendment changes the Technical Specifications by adding operational requirements on the Containment Building ventilation isolation inlet and exhaust dampers.

Date of issuance: September 5, 1986.

Effective date: September 5, 1986.

Amendment No.: 53.

Provisional Operating License No. DPR–45: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 3, 1985 (50 FR 27505); December 30, 1985 (50 FR 53231).

The Commission's related evaluation for the license amendment is contained in a Safety Evaluation dated September 5, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: La Crosse Public Library, 800 Main Street, La Crosse, Wisconsin 54601.

Dairyland Power Cooperative, Docket No. 50–409, La Crosse Boiling Water Reactor, Vernon County, Wisconsin

Date of application for amendment: February 21, 1986.

Brief description of amendment: The amendment updates the La Crosse Boiling Water Reactor Facility Organizational Chart, Figure 6.2.2–1 of the Technical Specifications.

Date of Issuance: September 10, 1986.

Effective date: September 10, 1986.

Amendment No.: 54.

Provisional Operating License No. DPR–45: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 7, 1986 (51 FR 16926). The Commission's related evaluation for the license amendment is contained in a Safety Evaluation dated September 10, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: La Crosse Public Library, 800 Main Street, La Crosse, Wisconsin 54601.

Duke Power Company, et al., Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of application for amendment: July 22, 1985, as supplemented September 11, 1985, March 7, 1986, and June 12, 1986.

Brief description of amendments: The amendments change the Technical Specifications to increase the allowed out-of-service times for Reactor Trip System analog channels.

Date of Issuance: September 8, 1986.

Effective date: September 8, 1986.

Amendment Nos.: 9 and 2.

Facility Operating License Nos. NPF–35 and NPF–52. Amendments revised the Technical Specifications.

Date of initial notices in Federal Register: December 18, 1985 (50 FR 51620) and March 26, 1986 (51 FR 10456).

The Commission's related evaluation of the amendments is contained in a

Safety Evaluation dated September 8, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730.

GPU Nuclear Corporation, et al., Docket No. 50–289, Three Mile Island Nuclear Station, Unit No. 1, Dauphin County, Pennsylvania

Date of application for amendment: July 16, 1986.

Brief description of amendment: The amendment allows the withdrawal of axial power shaping rods under end of cycle core conditions. The overall result of this amendment allows continued operation until about November 1, 1986 before beginning the Cycle 6 refueling outage.

Date of Issuance: September 2, 1986.

Effective date: September 2, 1986.

Amendment No.: 120

Facility Operating License No. DPR–50: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27284). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 2, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126

Iowa Electric Light and Power Company, Docket No. 50–331, Duane Arnold Energy Center, Linn County, Iowa

Date of application for amendment: September 24, 1985 as clarified by letter dated June 26, 1986.

Brief description of amendment: The amendment revises the Technical Specifications to incorporate plant staffing changes and some administrative changes.

Date of Issuance: September 4, 1986.

Effective date: September 4, 1986.

Amendment No.: 136.

Facility Operating License No. DPR–49. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: November 20, 1985 (50 FR 47864). The June 20, 1986 submittal provided clarifying information only and, therefore, did not change the determination of the initial **Federal Register** notice. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 4, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Cedar Rapids Public Library, 500 First Street, S.E., Cedar Rapids, Iowa 52401.

Northeast Nuclear Energy Company, et al., Docket No. 50–245, Millstone Nuclear Power Station, Unit No. 1, New London County, Connecticut

Date of application for amendment: May 30, 1986.

Brief description of amendment: This amendment revises the technical specifications on fire protection and loss prevention audits to conform with the guidance of Generic Letter 82–21. More specifically, the triennial fire protection program audit for Millstone Unit 1 will be performed by a qualified fire protection consultant independent of Northeast Utilities.

Date of Issuance: September 9, 1986.

Effective date: September 9, 1986.

Amendment No.: 111

Provisional Operating License No. DPR–21: This amendment revised the technical specifications.

Date of initial notice in Federal Register: July 16, 1986 (51 FR 25768). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

Northeast Nuclear Energy Company, et al., Docket No. 50–336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: May 30, 1986.

Brief description of amendment: This amendment revises the technical specifications on fire protection and loss prevention audits to conform with the guidance of Generic Letter 82–21. More specifically, the triennial fire protection program audit for Millstone Unit 2 will be performed by a qualified fire protection consultant independent of Northeast Utilities.

Date of issuance: September 9, 1986.

Effective date: September 9, 1986.

Amendment No: 112.

Facility Operating License No. DPR–64: This amendment revised the technical specifications.

Date of initial notice in Federal Register: July 16, 1986 (51 FR 25768). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

Northeast Nuclear Energy Company, et al., Docket No. 50–423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of application for amendment: May 30, 1986.

Brief description of amendment: This amendment revises the technical specifications on fire protection and loss prevention audits to conform with the guidance of Generic Letter 82–21. More specifically, the triennial fire protection program audit for Millstone Unit 3 will be performed by a qualified fire protection consultant independent of Northeast Utilities.

Date of issuance: September 9, 1986.

Effective date: September 9, 1986.

Amendment No: 1.

Facility Operating License No. NPF–49: This amendment revised the technical specifications.

Date of initial notice in Federal Register: July 16, 1986 (51 FR 25768). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Waterford Public Library, 49 Rope Ferry Road, Waterford, Connecticut 06385.

Northern States Power Company, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2, Goodhue County, Minnesota

Date of application for amendments: June 6, 1986.

Brief description of amendments: The amendments incorporate operability and testing requirements related to the inadequate core cooling instrumentation systems (ICCI) associated with the subcooling margin monitors, core-exit thermocouples and the reactor vessel level instrumentation systems (RVLIS) at the Prairie Island Nuclear Generating Plant Unit Nos. 1 and 2. The licensee was requested by our Generic Letters 82–28 and 83–37 to install ICCI systems and propose technical specifications to assure adequate operability and testing of these instrumentation systems.

Date of issuance: August 28, 1986.

Effective date: August 28, 1986.

Amendment Nos: 78 and 71.

Facility Operating License Nos. DPR-42 and DPR-60: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 16, 1986 (51 FR 25770). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 28, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Environmental Conservation Library, Minneapolis Public Library, 300 Nicollet Mall, Minneapolis, Minnesota.

NRC Project Director: George E. Lear, Director.

Omaha Public Power District, Docket 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of application for amendment: April 25, 1986 as revised by letter dated July 10, 1986.

Brief description of amendment: This amendment changed the reactor coolant system pressure-temperature limits for heatup and cooldown to provide for operation through 15 effective full power years.

Date of issuance: September 8, 1986.

Effective date: September 8, 1986.

Amendment No. 53.

Facility Operating License No. NPF-12. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: April 9, 1986 (51 FR 12239). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Fairfield County Library, Garden and Washington Steets, Winnsboro, South Carolina 29180.

Southern California Edison Company, et al., Docket Nos. 50-361 and 50-362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Dates of Application of Amendments: April 27 and August 29, 1985.

Brief Description of Amendments: The amendments revise Technical Specifications to allow incineration of radioactively contaminated oil.

Date of Issuance: August 20, 1986.

Effective Date: August 20, 1986, to be implemented within 30 days of issuance.

Amendment Nos.: 52 and 41.

Facility Operating License Nos. NPF-10 and NPF-15: Amendments revised the Technical Specifications.

Date of Initial Notice in Federal Register: July 16, 1986 (51 FR 25771). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 20, 1986.

No significant hazards considered comments were received: No.

Local Public Document Location: General Library, University of California at Irvine, California 92713.

Southern California Edison Company, et al., Docket Nos. 50-361 and 50-362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Dates of Application of Amendments: April 2, and 27, 1984 and March 18 and July 1, 1985.

Brief Description of Amendments: The amendments revise Technical Specifications (T.S.) 3/4.2.3 "Azimuthal Power Tilt-Tq" and its Bases, T.S. 3/4.2.3, "Engineered Safety Features Actuation System Instrumentation," and the Bases of T.S. 2.2.1, "Reactor Trip Setpoints".

Date of Issuance: September 9, 1986.

Effective Date: September 9, 1986, to be implemented within 30 days of issuance.

Amendment Nos.: 54 and 43.

Facility Operating License Nos. NPF-10 and NPF-15: Amendments revised the Technical Specifications.

Date of Initial Notice in Federal Register: April 23, 1985 and July 3, 1985 (50 FR 16015 and 50 FR 27510). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 9, 1986.

No significant hazards considered comments were received: No.

Local Public Document Room Location: General Library, University of California at Irvine, California 92713.

Southern California Edison Company, et al., Docket Nos. 50-361 and 50-362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Dates of Application of Amendments: April 2, 1984 and July 1, 1985.

Brief Description of Amendments: The amendments revise Technical. Specifications ¾.5.2, "Emergency Core Cooling Systems (ECCS) Subsystems—Tavg Greater Than or Equal to 350°F" and the related Table 3.3.5, "Engineered Safety Features Actuation System Instrumentation Response Times."

Date of Issuance: September 9, 1986.

Effective Date: September 9, 1986, to be implemented within 30 days of issuance.

Amendment Nos.: 55 and 44.

Facility Operating License Nos. NPF-10 and NPF-15: Amendments revised the Technical Specifications.

Date of Initial Notice in Federal Register: June 19, 1985 and November 20, 1985 (50 FR 25486 and 50 FR 47875). The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 9, 1986.

No significant hazards considered comments were received: No.

Local Public Document Room Location: General Library, University of California at Irvine, Irvine, California 92713.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: January 3, 1986.

Brief description of amendment: The amendment modifies the Technical Specifications to reflect administrative and organizational changes.

Date of issuance: September 8, 1986.

Effective date: September 8, 1986.

Amendment No.: 16.

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27291). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 8, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Fulton City Library, 709 Market Street, Fulton, Missouri 65251 and the Olin Library of Washington University, Skinker and Lindell Boulevards, St. Louis, Missouri 63130.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: October 16, 1985.

Brief description of amendment: The amendment modifies the surveillance interval for analog channel operational tests and the allowable out-of-service time of reactor trip system instrumentation.

Date of issuance: September 8, 1986.

Effective date: September 8, 1986.

Amendment No.: 17.

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 30, 1986 (51 FR 27290) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 8, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Fulton City Library, 709 Market Street, Fulton, Missouri 65251 and the Olin Library of Washington University,

Skinker and Lindell Boulevards, St. Louis, Missouri 63130.

Virginia Electric and Power Company, et al., Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of application for amendments: January 3, 1986.

Brief description of amendments: The amendments revise the negative end-of-cycle (EOC) moderator temperature coefficient (MTC) limit from the current vale of -4.0×10^{-4} delta k/k/°F to -4.4×10^{-4} delta k/k/°F. In addition, the amendments revise the corresponding 300 ppm equilbrium boron concentration value from -3.1×10^{-4} delta k/k/°F to -3.3×10^{-4} delta k/k/°F. Finally because of the difficulty of performing MTC measurements near the end of hot full power reactivity, the amendments eliminate MTC testing at EOC provided the 60 ppm measurement is greater than -4.0×10^{-4} delta k/k/°F.

Date of issuance: September 8, 1986.

Effective date: September 8, 1986.

Amendment Nos.: 85 and 72.

Facility Operating License Nos. NPF-4 and NPF-7. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: April 23, 1986 (51 FR 15412) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 8, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room locations: Board of Supervisors Office, Louisa County Courthouse, Louisa, Virginia 23093, and the Alderman Library, Manuscripts Department, University of Virginia, Charlottesville, Virginia 22901.

Wisconsin Electric Power Company, Docket Nos. 50-266 and 50-301, Point Beach Nuclear Plant, Unit Nos. 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of application for amendments: October 25, 1983 as revised February 7, and April 18, 1984.

Brief description of amendments: The amendments revise the requirements for conducting containment integrated leak rate testing to allow for reduced duration testing (less than 24 hours); to allow inclusion of purge supply and exhaust valves under Type "B" testing; to allow one of two in-series purge supply and exhaust valves to be open for repairs; and to make minor editorial changes.

Date of issuance: August 27, 1986.

Effective date: 30 days from issuance.

Amendment No.: 104 and 107.

Facility Operating License Nos. DPR-24 and DPR-27. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: January 26, 1984 (49 FR 3344, 3358) renoticed June 20, 1984 (49 FR 25350, 25382). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 27, 1986.

No significant hazards consideration comments received: No.

Local Public Document Room location: Joseph P. Mann Library, 1516 Sixteenth Street, Two Rivers, Wisconsin.

NOTICE OF ISSUANCE OF AMENDMENT TO FACILITY OPERATING LICENSE AND FINAL DETERMINATION OF NO SIGNIFICANT HAZARDS CONSIDERATION AND OPPORTUNITY FOR HEARING (EXIGENT OR EMERGENCY CIRCUMSTANCES)

During the period since publication of the last bi-weekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commision to publish, for public comment before issuance, its usual 30-day Notice of Consideration of Issuance of Amendment and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing. For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License, and (3) the Commission's related latter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission,

Washington, DC 20555, Attention: Director, Division of Licensing.

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendments. By October 24, 1986, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Cmmission's Public Department Room, 1717 H Street, NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325–6000 (in Missouri (800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to (*Project Director*): petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel-Bethesda, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

Baltimore Gas & Electric Company, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of application for amendments: August 1, 1986 supplemented by August 25, 1986.

Brief description of amendments: The amendments temporarily change Technical Specification (TS) 3/4.8.1, "A.C. Sources," to permit, for one time only, continued at-power dual-unit operation of up to 240 hours with the swing diesel generator (No. 12) out of service. This extension of the allowed period of diesel generator inoperability has been made contingent in the Action Statements of T.S. 3/4.8.1 upon the continued operability of each unit's dedicated diesel generator and of all three offsite A.C. power supplies. The amendments shall be used only to determine and correct the cause of the carbon monoxide leakage into the No. 12 diesel generator jacket water coolant system. This extension shall expire upon completion of repairs to the No. 12 diesel generator.

Date of issuance: September 8, 1986.

Effective date: This amendment is temporary and shall be used only once. This amendment is effective upon issuance and shall be implemented when No. 12 diesel generator is taken out of service to determine and repair the causes of the leakage of carbon monoxide or other combustion products into the jacket water cooling system of No. 12 diesel generator. Upon completion of these repairs, this amendment is cancelled and the previous TS are reinstated.

Amendment Nos.: 121 and 103.

Facility Operating License Nos. DPR–53 and DPR–69. Amendments revised the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration. Yes. Requested in a Public Notice printed in *The Baltimore Sun* on August 15, 1986. Comments received: No.

The commission's related evaluation is contained in a Safety Evaluation date September 8, 1986.

Attorney for licensee: D. A. Brune, Esq., Shaw, Pittman, Potts and Trowbridge, 1800 M. Street, NW., Washington, DC 20036.

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland.

Dated at Bethesda, Maryland this 17th day of September, 1986.

For the Nuclear Regulatory Commission.

Thomas M. Novak,

Acting Director, Division of PWR Licensing-A, Office of Nuclear Reactor Regulation.

[FR Doc. 86-21528 Filed 9-23-86; 8:45 am]

BILLING CODE 7590-01-M

POSTAL RATE COMMISSION

Visit: New Washington, DC, Post Office

September 18, 1986.

Notice is hereby given that the Chairman and Commissioners of the Postal Rate Commission will visit the new Washington, DC Post Office, 900 Brentwood Road, NE., on October 7, 1986, at 10:30 a.m. A report of the visit will be on file in the Commission's Docket Room.

Charles L. Clapp,

Secretary.

[FR Doc. 86-21556 Filed 9-23-86; 8:45 am]

BILLING CODE 7715-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-23619; File No. SR-NASD-86-21]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change

The National Association of Securities Dealers, Inc., submitted on July 22, 1986, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to exempt secondary offerings of or secondary market transactions in a direct participation program security for which quotations are displayed on he NASDAQ System or listed on a registered national securities exchange from the suitability requirement of section 3 and 4(d) of Appendix F to Article III of the NASD's Rules of Fair Practice. The proposed rule change would also exempt from the suitability requirement primary offerings of direct participation programs for which an application for inclusion on the NASDAQ System or listing on a registered national securities exchange has been approved.

Notice of the proposed rule change, together with terms of substance of the proposed rule change, was given by the issuance of a Commission release (Securities Exchange Act Release No. 23515) and by publication in the **Federal Register** (51 FR 19176, August 14, 1986).[1]

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of section 15A and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Jonathan G. Katz,

Secretary.

September 15, 1986.

[FR Doc. 86-21650 Filed 9-23-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23620; SR-Phlx-86-30]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Filing of and Order Granting Accelerated Approval to Proposed Rule Change.

On September 2, 1986, the Philadelphia Stock Exchange, Inc. ("Phlx") submitted a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b-4 thereunder [2] to increase from 599 to 1099 the number of shares eligible for the Phlx Automated Communication and Execution System ("PACE") and to amend certain standards contained in Phlx Rule 229 for execution of orders on the PACE system. Specifically, market orders, including round-lots, odd-lots and combined round-lot and odd-lot orders (partial round-lots) ("PRL's") up to 1099 shares entered prior to the opening will be executed at the New York market opening. Market orders of round lots up to 500 shares and of PRL's to 599 entered after the opening will continue to be executed on the PACE quote (the best-bid ask quote among the American, Boston, Cincinnati, Midwest, New York, Pacific or Phlx, or the Intermarket Trading System/Computer Assisted Execution System quote, as appropriate). Market orders of round-lots of 600 to 1000 shares and PRL's greater than 600 shares entered after the opening will not be subject to the execution parameters of Rule 229. Also, the proposed rule change specifies that paragraph .10 of the Supplementary Material to Rule 229 shall apply to round-lot limit orders up to 500 shares and combined PRL limit orders up to 599 shares.

Interested persons are invited to submit comments on this proposal within 21 days of the date of this publication. Six copies of such comments should be submitted to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Reference should be made to File No. SR-Phlx-86-30. Copies of the proposed rule change and related documents, other than those that may be withheld from the public pursuant to 5 U.S.C. 552, are available for inspection and copying at the Commission's Public Reference Room and at the Phlx.

The Commission finds that the Phlx's proposal to amend Rule 229 is consistent with the provisions of the Act applicable to national securities exchanges and, in particular, with section 6(b)(5) of the Act, in that the proposed rule change will help perfect the mechanism of a free and open market and a national market system.

The Commission finds good cause for approving the proposed rule change contained in File No. SR-Phlx-86-30 prior to the thirtieth day after publication of notice thereof in the **Federal Register** in that the proposed increase is routing and execution size is consistent with limits the Commission previously has approved for automatic routing and execution systems of other exchanges.[3] Further, the proposed rule change is not a substantive change.

The Commission therefore orders that the proposed rule change be approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: September 16, 1986.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-21647 Filed 9-23-86; 8:45 am]

BILLING CODE 8010-01-M

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[1] It may have appeared from the **Federal Register** insert published on August 14, 1986 that current subsection 3(c) of Appendix F to Article III, Section 34 of the Rules of Fair Practice was inended to be deleted by proposed rule change SR-NASD-86-21. Instead, the provision is to be retained, but is propsoed to be demoninated subsection 3(d) as a result of the proposal to adopt new subsection 3(c).

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1985).

[3] *See* Securities Exchange Act Release No. 21730 (February 8, 1985) 50 FR 6300 (Cincinnati Stock Exchange); Securities Exchange Act Release No. 21673 (January 18, 1985) 50 FR 3858 (Midwest Stock Exchange); Securities Exchange Act Release No. 21206 (August 3, 1984) 49 FR 31971.

[Release No. IC-15318; File No. 812-6429]

Drexel Series Trust; Application For Amended Order

September 18, 1986.

Notice is hereby given that Drexel Series Trust (the "Trust"), 60 Broad Street, New York, New York 10004, registered under the Investment Company Act of 1940, as amended (the "Act"), as an open-end, diversified, management investment company, filed an application on July 3, 1986, pursuant to section 6(c) of the Act, for an order of the Commission, amending a prior Commission order (the "Prior Order") (Release No. IC-14343) granted to the Trust on January 30, 1985, so as to exempt the Trust, in addition to all exemptions granted in the Prior Order, from the Provisions of sections 2(a)(32), 2(a)(35), 22(c) and 22(d) of the Act and Rules 22c-1 and 22d-1 thereunder, to the extent necessary or appropriate to permit the Trust (i) to waive the contingent deferred sales load permitted by the Prior Order in certain additional situations, and (ii) to provide a pro rata credit for any contingent deferred sales load paid in connection with redemptions of shares of any series of the Trust followed by a reinvestment effected within thirty days of such redemption. All interested person are referred to the application on file with the Commission for a statement of the representations contained therein and to the Act and the rules thereunder for the text of all applicable provisions.

According to the application, the Trust was organized as a business trust under Massachusetts law on September 24, 1984. The Trust presently consists of seven series—Money Market Series, Government Securities Series, Bond-Debenture Series, Growth Series, Emerging Growth Series, Option Income Series and Convertible Securities Series. Although the Trust has no current intention to create and issue any additional series, the Trust requests that the propsed exemptive relief with respect to the waiver of the contingent deferred sales load and pro rata credit extend to the Trust's initial series of shares and any additional series or classes of shares that may at any time hereafter be offered on substantially the same basis.

The Trust states that it currently offers its shares without an initial sales load so that investors have the entire amount of their purchase payments fully invested when made. The Trust pays to its distributor a contingent deferred sales load from the proceeds of certain redemptions of the Trust's shares. The Trust states that in no event will the aggregate amount of such load exceed 5% of the aggregate purchase payments made by an investor.

The Trust represents that its contingent deferred sales load is imposed if an investor redeems an amount which causes the current value of the investor's account with the Trust to fall below the total dollar amount of purchase payments made by the investor during the preceding five years. The Trust states that no sales load is imposed if the amount redeemed is derived from (1) increases in the value of the investor's account above the amount of purchase payments during the preceding five years, or (2) purchase payments made more than five years, prior to the redemption. The Trust currently waives the imposition of the contingent deferred sales load on the following redemptions, pursuant to the Prior Order: (i) Redemptions following the death or disability, as defined in section 72(m)(7) of the Internal Revenue Code of 1954, as amended (the "Code"), of a shareholder (including one who owns the shares as joint tenant with his or her spouse), provided the redemption is requested within one year of the death or initial determination of disability; (ii) Any partial or complete redemption in connection with certain distributions from Individual Retirement Accounts ("IRAs") or other qualified retirement plans; and (iii) Involuntary redemptions pursuant to the Trust's right to liquidate shareholder accounts if the aggregate net asset value of the shares held in the account is less than an amount specified from time to time by its board (currently, $100).

The Trust states that where a contingent deferred sales load is presently imposed, the rate of the load will decline from 5% to 1% depending on the number of years since the investor made the purchase payment from which an amount is being redeemed. Such load would be 5% in the first year and decrease by 1% per year. For purposes of applying the load, it is assumed that the redemption is made from the earliest purchase payment from which a redemption has not already been effected.

The Trust states that it is seeking an amendment to the Prior Order to permit the Trust to waive the contingent deferred sales loan on redemptions by employee benefit plans for the benefit of employees of Drexel Burnham Lambert Incorporated, the Trust's principal underwriter, and its affiliates. The Trust also proposes to waive the contingent deferred sales load in two additional circumstances. The trust intends to offer automatic investment in shares of the Government Securities Series of the Trust for monthly distributions of principal and interest on shares of any current or future series of Drexel Burnham Lambert Unit Trusts High Income Trust Securities ("HITS"), a unit investment trust with a diversified portfolio of high yield corporate bonds selected by Drexel Burnham Lambert Incorporated. The Trust submits that investment of monthly distributions from shares of HITS will be made at the net asset value of shares of the Government Securities Series of the Trust next calculated after the receipt of the distributions by the Trust. The Trust proposes to waive the contingent deferred sales load on redemptions of shares of the Government Securities Series purchased by the automatic investment of monthly distributions from shares of HITS. The Trust states that redemptions of shares of any other series of the Trust which are acquired by the exchange of shares of the Government Securities Series will be subject to the contingent deferred sales load. The Trust also states that for purposes of calculating such contingent deferred sales load, shares will be deemed to have been acquired as of the date such shares were exchanged out of the Government Securities Series of the Trust and into another series of the Trust.

The Trust also proposes to provide a pro rata credit for any contingent deferred sales load paid in connection with redemptions of shares of any series of the Trust, followed by a reinvestment effected within thirty days of such redemption. The Trust states that a redeemed shareholder may exercise this privilege only once.

The Trust assets that the exemptions requested are appropriate and in the public interest, consistent with the protection of investors and consistent with the purposes fairly intended by the Act. The Trust further submits that waiver of the contingent deferred sales load under the above-described circumstances will not harm the Trust or its remaining shareholders or unfairly discriminate among shareholders or purchasers. The Trust submits that the waiver of the contingent deferred sales load with respect to redemptions of shares of the Government Securities Series of the Trust, purchased by the automatic investment of monthly distributions from shares of HITS, is fully consistent with the scope of reduced or waived sales loads permitted under Rule 22d-1 and is justified on basic considerations of fairness. The Trust submits that it is also justified because the additional expense of

marketing and selling shares of the Government Securities Series through such an automatic investment program is minimal.

The Trust submits that a one time pro rata credit for any contingent deferred sales load paid in connection with redemptions of shares of any series of the Trust, followed by reinvestment effected within thirty days of such redemption, is fully consistant with the scope of reduced or waived sales loads permitted under Rule 22d–1. The Trust submits that this permits investors, who erroneously redeemed or otherwise had second thoughts about having redeemed their shares, to reinvest the proceeds without reincurring the sales load. Additionally, the Trust represents that it will disclose the waiver provisions in the Post-Effective Amendment to its Registration Statement on Form N–1A.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than October 14, 1986, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, DC 20549. A copy of the request should be served personally or by mail upon Applicants at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed this the request. After said date an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86–21648 Filed 9–23–86; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–24194]

Filings Under the Public Utility Holding Company Act; Consolidated Natural Gas Co. et al.

September 18, 1986.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by October 14, 1986 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the addresses specified below. Proof of service (by affidavit, or in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Consolidated Natural Gas Company et al. [70–6680]

Consolidated Natural Gas Company ("Consolidated"), a registered holding company, and its subsidiary, CNG Energy Company ("CNG Energy"), Four Gateway Center, Pittsburgh, Pennsylvania 15222, have filed post-effective amendments to their application-declaration pursuant to sections 6(b), 9(a), 10, 12(b), and 13(b) of the Act and Rules 45, 50(a)(5), 87, 90, and 91 promulgated thereunder.

CNG Energy proposes to increase the par value of its common stock from $100 to $1,000 and to increase its authorized capitalization by $100 million from $12,500,000 to $112,500,000. It further proposes $100 million of financing through December 31, 1991, through the issuance and sale of common stock and/or unsecured notes to Consolidated and/or open account advances from Consolidated. Also included in the $100 million of financing will be notes proposed to be issued to nonassociated third parties. If issued to third parties, the notes may be guaranteed by Consolidated. CNG Energy proposes to use the proceeds to invest in qualifying cogeneration facilities ("Qualifying Facilities") as defined pursuant to the Public Utility Regulatory Policies Act of 1978 and the rules and regulations promulgated thereunder by the Federal Energy Regulatory Commission and as permitted by Pub. L. 99–186, December 18, 1985, 99 Stat. 1180, authorizing registered gas utility holding-company systems to acquire interests in Qualifying Facilities. CNG Energy's investments in Qualifying Facilities may be in the form of the acquisition of stock, participation in partnerships, joint ventures, project financings, and other business entities, the making and/or guaranteeing of loans, and involvement in other contractual arrangements. In order to gain freedom and flexibility, CNG Energy requests authorization to proceed in acquiring interests in Qualifying Facilities subject to the $100 million limitation on investment without further Commission authorization. Any cogeneration corporation, partnership, joint venture, or other business entity in which CNG Energy acquires interests may itself engage in financing through project financing, short-term and long-term borrowings from third parties or from the project's owners or sponsors, capital contributions from the project's owner or sponsors, or any other means and in such amounts as may be deemed appropriate by the project managers. Authorization for all such financings and investments is requested without further filings with the Commission.

The interest rate on the notes proposed to be issued to Consolidated will be substantially the same interest as that charged Consolidated and for the same term required by outside lenders at the date of issuance of such CNG Energy notes. Short-term borrowings from nonassociated third parties will not exceed three years, and the interest rates thereon will not exceed 2% over the base or prime rate. Permanent financing from nonassociated third parties may be for a term of from 3 to 20 years, but in no event will any term loan exceed 20 years. The long-term rate will be no greater than 300 basis points over the rate for U.S. Treasury securities of a comparable term.

CNG Energy further proposes to perform feasibility studies and engineering or other services for a fee for owners of cogeneration facilities or for its co-venturers. Finally, it is proposed that CNG Energy will obtain a variety of management, technical, financial, and legal services from Consolidated Natural Gas Service Company, Consolidated's service subsidiary, and that, on occasion, employees of other Consolidated subsidiaries may provide services to CNG Energy.

The Connecticut Light and Power Company and Western Massachusetts Electric Company

[70–6961; 70–7086; 70–7144; and 70–7186]

The Connecticut Light and Power Company ("CL&P"), Selden Street, Berlin, Connecticut 06037, and Western Massachusetts Electric Company

("WMECO"), 174 Brush Hill Avenue, West Springfield, Massachusetts 01089, subsidiaries ("Companies") of Northeast Utilities, a registered holding company, have filed post-effective amendments to four declarations as previously filed and amended (S.E.C. File Nos. 70–6961; 70–7086; 70–7144; and 70–7186) pursuant to sections 6(a) and 7 of the Act and Rule 50(a)(5) thereunder.

By prior orders in these matters (HCAR Nos. 23366; 23636; 23829; and 23954, on July 12, 1984; March 21, 1985; September 13, 1985; and December 19, 1985, respectively), the Commission authorized transactions in each of the declcarations which were substantially similar, and related to the financing of each of the Companies' portion of the cost of acquiring, constructing, and installing certain pollution control facilities, and sewage or solid waste disposal facilities at the Millstone 1, Millstone 2, and Millstone 3 nuclear electric generating facilities. In connection with each of these transations, CL&P and WMECO, pursuant to certain loan agreements, each incurred certain repayment obligations to the Connecticut Development Authority ("CDA"), as evidenced by promissory notes issued by each of the Companies, and, pursuant to certain reimbursement and letter of credit agreements, certain reimbursement obligations to various banks ("Letters of Credit Banks") (such repayment and reimbursement obligations together the "Obligations"). The Companies now propose to secure the Obligations, equally and ratably, by granting to the CDA and the Letter of Credit Banks a second mortgage on the Companies' interests in Millstone 1.

New England Energy Incorporated

[70–7055]

New England Energy Incorporated ("NEEI"), 25 Research Drive, Westborough, Massachusetts 01582, a subsidiary of New England Electric System ("NEES"), a registered holding company, has filed a post-effective amendment to its previously filed application pursuant to sections 9(a) and 10 of the Act.

By order dated October 28, 1985 (HCAR No. 23882), NEEI was authorized to invest up to $105 million in its Partnership Agreement ("Agreement") with Samedan Oil Corporation ("Samedan"). The NEEI-Samedan Agreement provides, in relevant part, for the acquisition of interests in properties that have been determined to contain hydrocarbon reserves if such properties are part of or associated with an existing Partnership prospect. NEEI now proposes to amend its Agreement with Samedan to include acquisition of interests in producing properties that are not part of or associated with a Partnership prospect. All production of oil and gas from such producings properties will be used to serve the fuel needs of NEES companies either by delivery of such production for use as fuel purchased or by delivery of a like amount of fuel by NEEI with proceeds from sale of such production to non-affiliates. Such producing properties will not exceed in the aggregate 30 million equivalent barrels without further order of the Commission. Any investments in producing properties made by NEEI during 1986 would be within the $105 million investment previously authorized by the Commission.

The Connecticut Light and Power Company and Western Massachusetts Electric Company

[70–7275]

The Connecticut Light and Power Company ("CL&P"), Selden Street, Berlin, Connecticut 06037, and Western Massachusetts Electric Company ("WMECO"), 174 Brush Hill Avenue, West Springfield, Massachusetts 01089, subsidiaries ("Companies") of Northeast Utilities, a registered holding company, have filed an amendment to their declaration as amended pursuant to sections 6(a) and 7 of the Act and Rule 50(a)(5) thereunder.

This matter was previously noticed on July 24, 1986 (HCAR No. 24156) and relates to the financing of each of the Companies' portion of the cost of acquiring, constructing, and installing certain pollution control facilities, and sewage or solid waste disposal facilities at the Millstone 1, Millstone 2, and Millstone 3 nuclear electric generating facilities. In connection with each of these transactions, CL&P and WMECO, pursuant to certain loan agreements, each incurred certain repayment obligations to the Connecticut Development Authority ("CDA"), as evidenced by promissory notes issued by each of the Companies, and, pursuant to certain reimbursement and letter of credit agreements, certain reimbursement obligations to various banks ("Letters of Credit Banks") (such repayment and reimbursement obligations together the "Obligations"). The Companies now propose to secure the Obligations, equally and ratably, by granting to the CDA and the Letter of Credit Banks a second mortgage on the Companies' interests in Millstone 1.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86–21649 Filed 9–23–86; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Advisory Committee on Veterans Business Affairs; Public Meeting

The U.S. Small Business Administration, Advisory Committee on Veterans Business Affairs will hold a public meeting at 10:00 a.m., on Tuesday, September 30, 1986, at the U.S. Small Business Headquarters, 1441 L Street, NW 2nd Floor Conference Room, Washington, DC 20416, to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Vincent B. Pagano, Director, Office of Veterans Affairs, U.S. Small Business Administration, 1441 L Street, NW, Room 414, Washington, DC 20416, (202) 653–8220.

Jean M. Nowak,

Director, Office of Advisory Councils.

September 18, 1986.

[FR Doc. 86–21636 Filed 9–23–86; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF STATE

[CM–811006]

Shipping Coordinating Committee; Subcommittee on Safety of Life at Sea Working Group on the Carriage of Dangerous Goods; Meeting

The Working Group on the Carriage of Dangerous Goods of the Subcommittee on Safety of life at Sea (SOLAS) will conduct an open meeting on October 23, 1986 at 9:30 A.M. in Room 2415 at Coast Guard Headquarters, 2100 2nd Street SW., Washington, DC 20593.

The purpose of this meeting is to discuss—

—Results of the 38th Session of the IMO Subcommittee on the Carriage of Dangerous of Goods held April 21–25, 1986;

—Revision of the IMDG Code stowage and segregation requirements; and

—Possible United States proposals to be made to the 39th Session of the IMO Subcommittee of the Carriage of Dangerous Goods;

—Revision of the International Maritime Dangerous Goods (IMDG) Code

requirements for the shipment of explosives;
—Inclusion of additional shipping requirements in the IMDG Code for marine pollutants;
—Medical and emergency response for accidents involving hazardous materials.
—IMO activities of a continuing nature.

Members of the public may attend up to the seating capacity of the room. For further informaiton contact Lieutenant Commander Phillip C. Olenik, U.S. Coast Guard Headquarters (G-MTH-1), 2100 2nd Street SW., Washington, DC 20593. Telephone: (202) 267-1577.

Dated: September 17, 1986.

Richard C. Scissors,

Chairman, Shipping Coordinating Committee.

[FR Doc. 86-21633 Filed 9-23-86; 8:45 am]

BILLING CODE 4710-07-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Notice 86-10]

Senior Executive Service Performance Review Board; Addition of Members

AGENCY: Department of Transportation (DOT).

ACTION: Addition to Members to Performance Review Board (PRB).

SUMMARY: Notice is hereby given of the names of additional members to the Federal Aviation Administration (FAA) PRB.[1]

FOR FURTHER INFORMATION CONTACT: Ms. Diana L. Zeidel, Director, Office of Personnel; and Executive Secretary, DOT, Executive Resources Board, (202) 366-4088.

SUPPLEMENTARY INFORMATION: The following persons are added to the FAA-PRB:

Albert W. Blackburn, Associate Administrator for Policy and International Aviation,
and
Dale E. McDaniel, Deputy Associate Administrator for Policy and International Aviation.

Issued in Washington, DC, on September 19, 1986.

Diana L. Zeidel,

Director of Personnel.

[FR Doc. 86-21608 Filed 9-23-86; 8:45 am]

BILLING CODE 4910-62-M

[1] 51 FR 26328, July 22, 1986.

Federal Aviation Administration

Advisory Circular 25.994-1; Design Considerations to Protect Fuel Systems During a Wheels-Up Landing

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of issuance of advisory circular.

SUMMARY: This notice announces the issuance of Advisory Circular (AC) 25.994-1, Design Considerations to Protect Fuel Systems During a Wheels-Up Landing, which presents guidelines and methods for complying with the requirements of § 25.994 of the Federal Aviation Regulations (FAR). The guidelines pertain to protecting fuel system components located in the engine nacelles and the fuselage from damage which could result in spillage of enough fuel to constitute a fire hazard as a consequence on a wheels-up landing on a paved runway.

DATE: Advisory Circular 25.994-1 was issued by the Transport Airplane Certification Directorate in Seattle, Washington, on July 24, 1986.

How to obtain copies: A copy of AC 25.994-1 may be obtained by writing to the U.S. Department of Transportation, M-494.3, Subsequent Distribution Unit, Washington, DC 20590.

Issued in Seattle, Washington, on September 12, 1986.

Leroy A. Keith,

Manager, Aircraft Certification Division, ANM-100.

[FR Doc. 86-21551 Filed 9-23-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: September 18, 1986.

The Department of Treasury has submitted the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of these submissions may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding these information collections should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Room 7221, 1201 Constitution Avenue NW., Washington, DC 20220.

Bureau of Alcohol, Tobacco and Firearms

OMB Number: 1512-0207
Form Number: ATF REC 5110/04-ATF F 5110.43
Type of Review: Extension
Title: Distilled Spirits Plan (DSP) Denaturation Records and Reports

OMB Number: 1512-0216
Form Number: ATF F 5120.17(702)
Type of Review: Extension
Title: Monthly Report of Wine Cellar Operations

Clearance Officer: Robert G. Masarsky, (202) 566-7077, Bureau of Alcohol, Tobacco and Firearms, Room 7202, Federal Building, 1200 Pennsylvania Avenue NW., Washington, DC 20226
OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503.

Douglas J. Colley,

Departmental Reports Management Office.

[FR Doc. 86-21654 Filed 9-23-86; 8:45 am]

BILLING CODE 4810-25-M

VETERANS ADMINISTRATION

Advisory Committee on Native-American Veterans, Meeting

The Veterans Administration gives notice under Pub. L. 92-463 that the first meeting of the Advisory Committee on Native-American Veterans will be held on October 21, 22 and 23, 1986 at the Veterans Administration Central Office, 810 Vermont Avenue, NW, Washington, DC 20420, in the Omar Bradley Conference Room. The October 21 and 22 meetings will begin at 8:30 a.m. and run until 4:30 p.m. The October 23 meeting will begin at 8:30 a.m. and adjourn at 12:30 p.m.

The Committee will examine and evaluate programs and other activities of the Veterans Administration with respect to the needs of veterans who are Native-Americans, including American Indians and Alaska Natives.

All meetings will be open to the public up to the seating capacity of the room. Anyone having questions concerning the meetings may contact the Committee Manager, Mr. John Fulton, M.S.W., Veterans Administration Central Office (122) at phone number 202/389-2614.

Dated: September 15, 1986.

By direction of the Administrator:

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 86-21630 Filed 9-23-86; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 51, No. 185
Wednesday, September 24, 1986

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

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COMMISSION ON CIVIL RIGHTS

September 19, 1986.

DATE AND TIME: Friday, September 26, 1986.

STATUS OF THE MEETING: Special meeting. Open to the public.

MATTERS TO BE CONSIDERED:

I. Commission Appropriation for Fiscal Year 1987—Proposed Reorganization

PERSON TO CONTACT FOR FURTHER INFORMATION: Barbara Brooks, Press and Communications Division (202) 376–8312.

William H. Gillers,

Solicitor, 376–8339.

[FR Doc. 86–21651 Filed 9–19–86; 4:22 pm]

BILLING CODE 6335-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 3:45 p.m. on Thursday, September 18, 1986, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to: (1) Receive bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in Texas Independence Bank, Pasadena, Texas, which was closed by the Banking Commissioner for the State of Texas on Thursday, September 18, 1986; (2) accept the bid for the transaction submitted by The Texas Independence Bank, Pasadena, Texas, a newly-chartered State nonmember bank; (3) approve the applications of The Texas Independence Bank, Pasadena, Texas, for Federal deposit insurance and for consent to purchase certain assets of and assume the liability to pay deposits made in Texas Independence Bank, Pasadena, Texas; and (4) provide such financial assistance, pursuant to section 13(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)(2)), as was necessary to facilitate the purchase and assumption transaction.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: September 19, 1986.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 86–21722 Filed 9–22–86; 2:47 pm]

BILLING CODE 6714-01-M

3

FEDERAL RESERVE SYSTEM, BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, September 29, 1986.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Implementation of the Board's Program Improvement Project. (This item was originally announed for a closed meeting on September 15, 1986.)

2. Federal Reserve Bank and Branch director appointments. (This item was originally announced for a closed meeting on September 10, 1986.)

3. Proposed Federal Reserve Bank custody control standards.

4. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

5. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: September 19, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86–21656 Filed 9–23–86; 4:35 pm]

BILLING CODE 6210-01-M

4

NATIONAL TRANSPORTATION SAFETY BOARD

TIME AND DATE: 9:00 a.m., Tuesday, September 30, 1986.

PLACE: NTSB Board Room, Eighth Floor, 800 Independence Avenue, SW., Washington, DC 20594.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. *Aircraft Accident Report:* Bar Harbor Airlines Flight 1808, Beech 99, NE00WP, Auburn-Lewiston Airport, Auburn, Maine, August 25, 1985.

2. *Aircraft Accident Report:* Henson Airlines, Beech B99, N339HA, Grottoes, Virginia, September 23, 1985.

3. *Recommendations* to the Federal Aviation Administration and to the Regional Airline Association regarding the Henson, Bar Harbor and Simmons Commuter Airlines Accidents.

FOR MORE INFORMATION, CONTACT: H. Ray Smith (202) 382–6525.

Monica Revelle,

Alternate Federal Register Liaison Officer.

September 19, 1986.

[FR Doc. 86–21655 Filed 9–19–86; 4:35 pm]

BILLING CODE 7533-01-M

federal register

Wednesday
September 24, 1986

Part II

Environmental Protection Agency

Guidelines for Carcinogen Risk Assessment

ENVIRONMENTAL PROTECTION AGENCY

[FRL-2984-1]

Guidelines for Carcinogen Risk Assessment

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final guidelines for carcinogen risk assessment.

SUMMARY: The U.S. Environmental Protection Agency is today issuing five guidelines for assessing the health risks of environmental pollutants. These are:

Guidelines for Carcinogen Risk Assessment
Guidelines for Estimating Exposures
Guidelines for Mutagenicity Risk Assessment
Guidelines for the Health Assessment of Suspect Developmental Toxicants
Guidelines for the Health Risk Assessment of Chemical Mixtures

This notice contains the Guidelines for Carcinogen Risk Assessment; the other guidelines appear elsewhere in today's **Federal Register.**

The Guidelines for Carcinogen Risk Assessment (hereafter "Guidelines") are intended to guide Agency evaluation of suspect carcinogens in line with the policies and procedures established in the statutes administered by the EPA. These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Office of Health and Environmental Assessment (OHEA) in the Agency's Office of Research and Development. They reflect Agency consideration of public and Science Advisory Board (SAB) comments on the Proposed Guidelines for Carcinogen Risk Assessment published November 23, 1984 (49 FR 46294).

This publication completes the first round of risk assessment guidelines development. These Guidelines will be revised, and new guidelines will be developed, as appropriate.

EFFECTIVE DATE: The Guidelines will be effective September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Dr. Robert E. McGaughy, Carcinogen Assessment Group, Office of Health and Environmental Assessment (RD–689), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, 202–382–5898.

SUPPLEMENTARY INFORMATION: In 1983, the National Academy of Sciences (NAS) published its book entitled *Risk Assessment in the Federal Government: Managing the Process.* In that book, the NAS 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. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

General

The guidelines published today are products of a two-year Agencywide effort, which has included many scientists from the larger scientific community. These guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments, and to inform Agency decision makers and the public about these procedures. In particular, the guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific information on each agent and use the most scientifically appropriate interpretation to assess risk. The guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Finally, the guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Guidelines for Carcinogen Risk Assessment

Work on the Guidelines for Carcinogen Risk Assessment began in January 1984. Draft guidelines were developed by Agency work groups composed of expert scientists from throughout the Agency. The drafts were peer-reviewed by expert scientists in the field of carcinogenesis from universities, environmental groups, industry, labor, and other governmental agencies. They were then proposed for public comment in the **Federal Register** (49 FR 46294). On November 9, 1984, the Administrator directed that Agency offices use the proposed guidelines in performing risk assessments until final guidelines become available.

After the close of the public comment period, Agency staff prepared summaries of the comments and analyses of the major issues presented by the commentors, and proposed changes in the language of the guidelines to deal with the issues raised. These analyses were presented to review panels of the SAB on March 4 and April 22–23, 1985, and to the Executive Committee of the SAB on April 25–26, 1985. The SAB meetings were announced in the **Federal Register** as follows: February 12, 1985 (50 FR 5811) and April 4, 1985 (50 FR 13420 and 13421).

In a letter to the Administrator dated June 19, 1985, the Executive Committee generally concurred on all five of the guidelines, but recommended certain revisions, and requested that any revised guidelines be submitted to the appropriate SAB review panel chairman for review and concurrence on behalf of the Executive Committee. As described in the responses to comments (see Part B: Response to the Public and Science Advisory Board Comments), each guidelines document was revised, where appropriate, consistent with the SAB recommendations, and revised draft guidelines were submitted to the panel chairmen. Revised draft Guidelines for Carcinogen Risk Assessment were concurred on in a letter dated February 7, 1986. Copies of the letters are available at the Public Information Reference Unit, EPA Headquarters Library, as indicated elsewhere in this notice.

Following this Preamble are two parts: Part A contains the Guidelines and Part B, the Response to the Public and Science Advisory Board Comments (a summary of the major public comments, SAB comments, and Agency responses to those comments).

The Agency is continuing to study the risk assessment issues raised in the guidelines and will revise these guidelines in line with new information as appropriate.

References, supporting documents, and comments received on the proposed guidelines, as well as copies of the final guidelines, are available for inspection and copying at the Public Information Reference Unit (202–382–5926), EPA Headquarters Library, 401 M Street, SW., Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m.

I certify that these Guidelines are not major rules as defined by Executive Order 12291, because they are nonbinding policy statements and have no direct effect on the regulated community. Therefore, they will have no effect on costs or prices, and they will

have no other significant adverse effects on the economy. These Guidelines were reviewed by the Office of Management and Budget under Executive Order 12291.

Dated: August 22, 1986.

Lee M. Thomas,

Administrator.

Contents

Part A: Guidelines for Carcinogen Risk Assessment

I. Introduction

This is the first revision of the 1976 Interim Procedures and Guidelines for Health Risk Assessments of Suspected Carcinogens (U.S. EPA, 1976; Albert et al., 1977). The impetus for this revision is the need to incorporate into these Guidelines the concepts and approaches to carcinogen risk assessment that have been developed during the last ten years. The purpose of these Guidelines is to promote quality and consistency of carcinogen risk assessments within the EPA and to inform those outside the EPA about its approach to carcinogen risk assessment. These Guidelines emphasize the broad but essential aspects of risk assessment that are needed by experts in the various disciplines required (e.g., toxicology, pathology, pharmacology, and statistics) for carcinogen risk assessment. Guidance is given in general terms since the science of carcinogenesis is in a state of rapid advancement, and overly specific approaches may rapidly become obsolete.

These Guidelines describe the general framework to be followed in developing an analysis of carcinogenic risk and some salient principles to be used in evaluating the quality of data and in formulating judgments concerning the nature and magnitude of the cancer hazard from suspect carcinogens. It is the intent of these Guidelines to permit sufficient flexibility to accommodate new knowledge and new assessment methods as they emerge. It is also recognized that there is a need for new methodology that has not been addressed in this document in a number of areas, e.g., the characterization of uncertainty. As this knowledge and assessment methodology are developed, these Guidelines will be revised whenever appropriate.

A summary of the current state of knowledge in the field of carcinogenesis and a statement of broad scientific principles of carcinogen risk assessment, which was developed by the Office of Science and Technology Policy (OSTP, 1985), forms an important basis for these Guidelines; the format of these Guidelines is similar to that proposed by the National Research Council (NRC) of the National Academy of Sciences in a book entitled *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983).

These Guidelines are to be used within the policy framework already provided by applicable EPA statutes and do not alter such policies. These Guidelines provide general directions for analyzing and organizing available data. They do not imply that one kind of data or another is prerequisite for regulatory action to control, prohibit, or allow the use of a carcinogen.

Regulatory decision making involves two components: risk assessment and risk management. Risk assessment defines the adverse health consequences of exposure to toxic agents. The risk assessments will be carried out independently from considerations of the consequences of regulatory action. Risk management combines the risk assessment with the directives of regulatory legislation, together with socioeconomic, technical, political, and other considerations, to reach a decision as to whether or how much to control future exposure to the suspected toxic agents.

Risk assessment includes one or more of the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization (NRC, 1983).

Hazard identification is a qualitative risk assessment, dealing with the process of determining whether exposure to an agent has the potential to increase the incidence of cancer. For purposes of these Guidelines, both malignant and benign tumors are used in the evaluation of the carcinogenic hazard. The hazard identification component qualitatively answers the question of how likely an agent is to be a human carcinogen.

Traditionally, quantitative risk assessment has been used as an inclusive term to describe all or parts of dose-response assessment, exposure assessment, and risk characterization. Quantitative risk assessment can be a useful general term in some circumstances, but the more explicit terminology developed by the NRC (1983) is usually preferred. The dose-response assessment defines the relationship between the dose of an agent and the probability of induction of a carcinogenic effect. This component usually entails an extrapolation from the generally high doses administered to experimental animals or exposures noted in epidemiologic studies to the exposure levels expected from human contact with the agent in the environment; it also includes considerations of the validity of these extrapolations.

The exposure assessment identifies populations exposed to the agent, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the agent.

In risk characterization, the results of the exposure assessment and the dose-response assessment are combined to estimate quantitatively the carcinogenic risk. As part of risk characterization, a summary of the strengths and weaknesses in the hazard identification, dose-response assessment, exposure assessment, and the public health risk estimates are presented. Major assumptions, scientific judgments, and, to the extent possible, estimates of the uncertainties embodied in the assessment are also presented, distinguishing clearly between fact, assumption, and science policy.

The National Research Council (NRC, 1983) pointed out that there are many questions encountered in the risk assessment process that are unanswerable given current scientific knowledge. To bridge the uncertainty that exists in these areas where there is no scientific consensus, inferences must be made to ensure that progress continues in the assessment process. The OSTP (1985) reaffirmed this position, and generally left to the regulatory agencies the job of articulating these inferences. Accordingly, the Guidelines incorporate judgmental positions (science policies) based on evaluation of the presently available information and on the regulatory mission of the Agency. The Guidelines are consistent with the principles developed by the OSTP (1985), although in many instances are necessarily more specific.

II. Hazard Identification

A. Overview

The qualitative assessment or hazard identification part of risk assessment contains a review of the relevant biological and chemical information bearing on whether or not an agent may pose a carcinogenic hazard. Since chemical agents seldom occur in a pure state and are often transformed in the body, the review should include available information on contaminants, degradation products, and metabolites.

Studies are evaluated according to sound biological and statistical considerations and procedures. These have been described in several publications (Interagency Regulatory Liaison Group, 1979; OSTP, 1985; Peto et al., 1980; Mantel, 1980; Mantel and Haenszel, 1959; Interdisciplinary Panel on Carcinogenicity, 1984; National Center for Toxicological Research, 1981; National Toxicology Program, 1984; U.S. EPA, 1983a, 1983b, 1983c; Haseman, 1984). Results and conclusions concerning the agent, derived from different types of information, whether indicating positive or negative responses, are melded together into a weight-of-evidence determination. The strength of the evidence supporting a potential human carcinogenicity judgment is developed in a weight-of-evidence stratification scheme.

B. Elements of Hazard Identification

Hazard identification should include a review of the following information to the extent that it is available.

1. *Physical-Chemical Properties and Routes and Patterns of Exposure.* Parameters relevant to carcinogenesis, including physical state, physical-chemical properties, and exposure pathways in the environment should be described where possible.

2. *Structure-Activity Relationships.* This section should summarize relevant structure-activity correlations that support or argue against the prediction of potential carcinogenicity.

3. *Metabolic and Pharmacokinetic Properties.* This section should summarize relevant metabolic information. Information such as whether the agent is direct-acting or requires conversion to a reactive carcinogenic (e.g., an electrophilic) species, metabolic pathways for such conversions, macromolecular interactions, and fate (e.g., transport, storage, and excretion), as well as species differences, should be discussed and critically evaluated. Pharmacokinetic properties determine the biologically effective dose and may be relevant to hazard identification and other components of risk assessment.

4. *Toxicologic Effects.* Toxicologic effects other than carcinogenicity (e.g., suppression of the immune system, endocrine disturbances, organ damage) that are relevant to the evaluation of carcinogenicity should be summarized. Interactions with other chemicals or agents and with lifestyle factors should be discussed. Prechronic and chronic toxicity evaluations, as well as other test results, may yield information on target organ effects, pathophysiological reactions, and preneoplastic lesions that bear on the evaluation of carcinogenicity. Dose-response and time-to-response analyses of these reactions may also be helpful.

5. *Short-Term Tests.* Tests for point mutations, numerical and structural chromosome aberrations, DNA damage/repair, and *in vitro* transformation provide supportive evidence of carcinogenicity and may give information on potential carcinogenic mechanisms. A range of tests from each of the above end points helps to characterize an agent's response spectrum.

Short-term *in vivo* and *in vitro* tests that can give indication of initiation and promotion activity may also provide supportive evidence for carcinogenicity. Lack of positive results in short-term tests for genetic toxicity does not provide a basis for discounting positive results in long-term animal studies.

6. *Long-Term Animal Studies.* Criteria for the technical adequacy of animal carcinogenicity studies have been published (e.g., U.S. Food and Drug Administration, 1982; Interagency Regulatory Liaison Group, 1979; National Toxicology Program, 1984; OSTP, 1985; U.S. EPA, 1983a, 1983b, 1983c; Feron et al., 1980; Mantel, 1980) and should be used to judge the acceptability of individual studies. Transplacental and multigenerational carcinogenesis studies, in addition to more conventional long-term animal studies, can yield useful information about the carcinogenicity of agents.

It is recognized that chemicals that induce benign tumors frequently also induce malignant tumors, and that benign tumors often progress to malignant tumors (Interdisciplinary Panel on Carcinogenicity, 1984). The incidence of benign and malignant tumors will be combined when scientifically defensible (OSTP, 1985; Principle 8). For example, the Agency will, in general, consider the combination of benign and malignant tumors to be scientifically defensible unless the benign tumors are not considered to have the potential to progress to the associated malignancies of the same histogenic origin. If an increased incidence of benign tumors is observed in the absence of malignant tumors, in most cases the evidence will be considered as limited evidence of carcinogenicity.

The weight of evidence that an agent is potentially carcinogenic for humans increases (1) with the increase in number of tissue sites affected by the agent; (2) with the increase in number of animal species, strains, sexes, and number of experiments and doses showing a carcinogenic response; (3) with the occurrence of clear-cut dose-response relationships as well as a high level of statistical significance of the increased tumor incidence in treated compared to control groups; (4) when there is a dose-related shortening of the time-to-tumor occurrence or time to death with tumor; and (5) when there is a dose-related increase in the proportion of tumors that are malignant.

Long-term animal studies at or near the maximum tolerated dose level (MTD) are used to ensure an adequate power for the detection of carcinogenic

activity (NTP, 1984; IARC, 1982). Negative long-term animal studies at exposure levels above the MTD may not be acceptable if animal survival is so impaired that the sensitivity of the study is significantly reduced below that of a conventional chronic animal study at the MTD. The OSTP (1985; Principle 4) has stated that,

> The carcinogenic effects of agents may be influenced by non-physiological responses (such as extensive organ damage, radical disruption of hormonal function, saturation of metabolic pathways, formation of stones in the urinary tract, saturation of DNA repair with a functional loss of the system) induced in the model systems. Testing regimes inducing these responses should be evaluated for their relevance to the human response to an agent and evidence from such a study, whether positive or negative, must be carefully reviewed.

Positive studies at levels above the MTD should be carefully reviewed to ensure that the responses are not due to factors which do not operate at exposure levels below the MTD. Evidence indicating that high exposures alter tumor responses by indirect mechanisms that may be unrelated to effects at lower exposures should be dealt with on an individual basis. As noted by the OSTP (1985), "Normal metabolic activation of carcinogens may possibly also be altered and carcinogenic potential reduced as a consequence [of high-dose testing]."

Carcinogenic responses under conditions of the experiment should be reviewed carefully as they relate to the relevance of the evidence to human carcinogenic risks (e.g., the occurrence of bladder tumors in the presence of bladder stones and implantation site sarcomas). Interpretation of animal studies is aided by the review of target organ toxicity and other effects (e.g., changes in the immune and endocrine systems) that may be noted in prechronic or other toxicological studies. Time and dose-related changes in the incidence of preneoplastic lesions may also be helpful in interpreting animal studies.

Agents that are positive in long-term animal experiments and also show evidence of promoting or cocarcinogenic activity in specialized tests should be considered as complete carcinogens unless there is evidence to the contrary because it is, at present, difficult to determine whether an agent is only a promoting or cocarcinogenic agent. Agents that show positive results in special tests for initiation, promotion, or cocarcinogenicity and no indication of tumor response in well-conducted and well-designed long-term animal studies should be dealt with on an individual basis.

To evaluate carcinogenicity, the primary comparison is tumor response in dosed animals as compared with that in contemporary matched control animals. Historical control data are often valuable, however, and could be used along with concurrent control data in the evaluation of carcinogenic responses (Haseman et al., 1984). For the evaluation of rare tumors, even small tumor responses may be significant compared to historical data. The review of tumor data at sites with high spontaneous background requires special consideration (OSTP, 1985; Principle 9). For instance, a response that is significant with respect to the experimental control group may become questionable if the historical control data indicate that the experimental control group had an unusually low background incidence (NTP, 1984).

For a number of reasons, there are widely diverging scientific views (OSTP, 1985; Ward et al., 1979a, b; Tomatis, 1977; Nutrition Foundation, 1983) about the validity of mouse liver tumors as an indication of potential carcinogenicity in humans when such tumors occur in strains with high spontaneous background incidence and when they constitute the only tumor response to an agent. These Guidelines take the position that when the only tumor response is in the mouse liver and when other conditions for a classification of "sufficient" evidence in animal studies are met (e.g., replicate studies, malignancy; see section IV), the data should be considered as "sufficient" evidence of carcinogenicity. It is understood that this classification could be changed on a case-by-case basis to "limited," if warranted, when factors such as the following, are observed: an increased incidence of tumors only in the highest dose group and/or only at the end of the study; no substantial dose-related increase in the proportion of tumors that are malignant; the occurrence of tumors that are predominantly benign; no dose-related shortening of the time to the appearance of tumors; negative or inconclusive results from a spectrum of short-term tests for mutagenic activity; the occurrence of excess tumors only in a single sex.

Data from all long-term animal studies are to be considered in the evaluation of carcinogenicity. A positive carcinogenic response in one species/strain/sex is not generally negated by negative results in other species/strain/sex. Replicate negative studies that are essentially identical in all other respects to a positive study may indicate that the positive results are spurious.

Evidence for carcinogenic action should be based on the observation of statistically significant tumor responses in specific organs or tissues. Appropriate statistical analysis should be performed on data from long-term studies to help determine whether the effects are treatment-related or possibly due to chance. These should at least include a statistical test for trend, including appropriate correction for differences in survival. The weight to be given to the level of statistical significance (the p-value) and to other available pieces of information is a matter of overall scientific judgment. A statistically significant excess of tumors of all types in the aggregate, in the absence of a statistically significant increase of any individual tumor type, should be regarded as minimal evidence of carcinogenic action unless there are persuasive reasons to the contrary.

7. *Human Studies.* Epidemiologic studies provide unique information about the response of humans who have been exposed to suspect carcinogens. Descriptive epidemiologic studies are useful in generating hypotheses and providing supporting data, but can rarely be used to make a causal inference. Analytical epidemiologic studies of the case-control or cohort variety, on the other hand, are especially useful in assessing risks to exposed humans.

Criteria for the adequacy of epidemiologic studies are well recognized. They include factors such as the proper selection and characterization of exposed and control groups, the adequacy of duration and quality of follow-up, the proper identification and characterization of confounding factors and bias, the appropriate consideration of latency effects, the valid ascertainment of the causes of morbidity and death, and the ability to detect specific effects. Where it can be calculated, the statistical power to detect an appropriate outcome should be included in the assessment.

The strength of the epidemiologic evidence for carcinogenicity depends, among other things, on the type of analysis and on the magnitude and specificity of the response. The weight of evidence increases rapidly with the number of adequate studies that show comparable results on populations exposed to the same agent under different conditions.

It should be recognized that epidemiologic studies are inherently capable of detecting only comparatively large increases in the relative risk of

cancer. Negative results from such studies cannot prove the absence of carcinogenic action; however, negative results from a well-designed and well-conducted epidemiologic study that contains usable exposure data can serve to define upper limits of risk; these are useful if animal evidence indicates that the agent is potentially carcinogenic in humans.

C. Weight of Evidence

Evidence of possible carcinogenicity in humans comes primarily from two sources: long-term animal tests and epidemiologic investigations. Results from these studies are supplemented with available information from short-term tests, pharmacokinetic studies, comparative metabolism studies, structure-activity relationships, and other relevant toxicologic studies. The question of how likely an agent is to be a human carcinogen should be answered in the framework of a weight-of-evidence judgment. Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds and consistency of responses induced by a suspect carcinogen. There are three major steps to characterizing the weight of evidence for carcinogenicity in humans: (1) Characterization of the evidence from human studies and from animal studies individually, (2) combination of the characterizations of these two types of data into an indication of the overall weight of evidence for human carcinogenicity, and (3) evaluation of all supporting information to determine if the overall weight of evidence should be modified.

EPA has developed a system for stratifying the weight of evidence (see section IV). This classification is not meant to be applied rigidly or mechanically. At various points in the above discussion, EPA has emphasized the need for an overall, balanced judgment of the totality of the available evidence. Particularly for well-studied substances, the scientific data base will have a complexity that cannot be captured by any classification scheme. Therefore, the hazard identification section should include a narrative summary of the strengths and weaknesses of the evidence as well as its categorization in the EPA scheme.

The EPA classification system is, in general, an adaptation of the International Agency for Research on Cancer (IARC, 1982) approach for classifying the weight of evidence for human data and animal data. The EPA classification system for the characterization of the overall weight of evidence for carcinogenicity (animal, human, and other supportive data) includes: Group A—Carcinogenic to Humans; Group B—Probably Carcinogenic to Humans; Group C—Possibly Carcinogenic to Humans; Group D—Not Classifiable as to Human Carcinogenicity; and Group E—Evidence of Non-Carcinogenicity for Humans.

The following modifications of the IARC approach have been made for classifying human and animal studies.

For human studies:

(1) The observation of a statistically significant association between an agent and life-threatening benign tumors in humans is included in the evaluation of risks to humans.

(2) A "no data available" classification is added.

(3) A "no evidence of carcinogenicity" classification is added. This classificaton indicates that no association was found between exposure and increased risk of cancer in well-conducted, well-designed, independent analytical epidemiologic studies.

For animal studies:

(1) An increased incidence of combined benign and malignant tumors will be considered to provide sufficient evidence of carcinogenicity if the other criteria defining the "sufficient" classification of evidence are met (e.g., replicate studies, malignancy; see section IV). Benign and malignant tumors will be combined when scientifically defensible.

(2) An increased incidence of benign tumors alone generally constitutes "limited" evidence of carcinogenicity.

(3) An increased incidence of neoplasms that occur with high spontaneous background incidence (e.g., mouse liver tumors and rat pituitary tumors in certain strains) generally constitutes "sufficient" evidence of carcinogenicity, but may be changed to "limited" when warranted by the specific information available on the agent.

(4) A "no data available" classification has been added.

(5) A "no evidence of carcinogenicity" classification is also added. This operational classification would include substances for which there is no increased incidence of neoplasms in at least two well-designed and well-conducted animal studies of adequate power and dose in different species.

D. Guidance for Dose-Response Assessment

The qualitative evidence for carcinogenesis should be discussed for purposes of guiding the dose-response assessment. The guidance should be given in terms of the appropriateness and limitations of specific studies as well as pharmacokinetic considerations that should be factored into the dose-response assessment. The appropriate method of extrapolation should be factored in when the experimental route of exposure differs from that occurring in humans.

Agents that are judged to be in the EPA weight-of-evidence stratification Groups A and B would be regarded as suitable for quantitative risk assessments. Agents that are judged to be in Group C will generally be regarded as suitable for quantitative risk assessment, but judgments in this regard may be made on a case-by-case basis. Agents that are judged to be in Groups D and E would not have quantitative risk assessments.

E. Summary and Conclusion

The summary should present all of the key findings in all of the sections of the qualitative assessment and the interpretive rationale that forms the basis for the conclusion. Assumptions, uncertainties in the evidence, and other factors that may affect the relevance of the evidence to humans should be discussed. The conclusion should present both the weight-of-evidence ranking and a description that brings out the more subtle aspects of the evidence that may not be evident from the ranking alone.

III. Dose-Response Assessment, Exposure Assessment, and Risk Characterization

After data concerning the carcinogenic properties of a substance have been collected, evaluated, and categorized, it is frequently desirable to estimate the likely range of excess cancer risk associated with given levels and conditions of human exposure. The first step of the analysis needed to make such estimations is the development of the likely relationship between dose and response (cancer incidence) in the region of human exposure. This information on dose-response relationships is coupled with information on the nature and magnitude of human exposure to yield an estimate of human risk. The risk-characterization step also includes an interpretation of these estimates in light of the biological, statistical, and exposure assumptions and uncertainties that have arisen throughout the process of assessing risk.

The elements of dose-response assessment are described in section III.A. Guidance on human exposure assessment is provided in another EPA

document (U.S. EPA, 1986); however, section III.B. of these Guidelines includes a brief description of the specific type of exposure information that is useful for carcinogen risk assessment. Finally, in section III.C. on risk characterization, there is a description of the manner in which risk estimates should be presented so as to be most informative.

It should be emphasized that calculation of quantitative estimates of cancer risk does not require that an agent be carcinogenic in humans. The likelihood that an agent is a human carcinogen is a function of the weight of evidence, as this has been described in the hazard identification section of these Guidelines. It is nevertheless important to present quantitative estimates, appropriately qualified and interpreted, in those circumstances in which there is a reasonable possibility, based on human and animal data, that the agent is carcinogenic in humans.

It should be emphasized in every quantitative risk estimation that the results are uncertain. Uncertainties due to experimental and epidemiologic variability as well as uncertainty in the exposure assessment can be important. There are major uncertainties in extrapolating both from animals to humans and from high to low doses. There are important species differences in uptake, metabolism, and organ distribution of carcinogens, as well as species and strain differences in target-site susceptibility. Human populations are variable with respect to genetic constitution, diet, occupational and home environment, activity patterns, and other cultural factors. Risk estimates should be presented together with the associated hazard assessment (section III.C.3.) to ensure that there is an appreciation of the weight of evidence for carcinogenicity that underlies the quantitative risk estimates.

A. Dose-Response Assessment

1. *Selection of Data.* As indicated in section II.D., guidance needs to be given by the individuals doing the qualitative assessment (toxicologists, pathologists, pharmacologists, etc.) to those doing the quantitative assessment as to the appropriate data to be used in the dose-response assessment. This is determined by the quality of the data, its relevance to human modes of exposure, and other technical details.

If available, estimates based on adequate human epidemiologic data are preferred over estimates based on animal data. If adequate exposure data exist in a well-designed and well-conducted negative epidemiologic study, it may be possible to obtain an upper-bound estimate of risk from that study. Animal-based estimates, if available, also should be presented.

In the absence of appropriate human studies, data from a species that responds most like humans should be used, if information to this effect exists. Where, for a given agent, several studies are available, which may involve different animal species, strains, and sexes at several doses and by different routes of exposure, the following approach to selecting the data sets is used: (1) The tumor incidence data are separated according to organ site and tumor type. (2) All biologically and statistically acceptable data sets are presented. (3) The range of the risk estimates is presented with due regard to biological relevance (particularly in the case of animal studies) and appropriateness of route of exposure. (4) Because it is possible that human sensitivity is as high as the most sensitive responding animal species, in the absence of evidence to the contrary, the biologically acceptable data set from long-term animal studies showing the greatest sensitivity should generally be given the greatest emphasis, again with due regard to biological and statistical considerations.

When the exposure route in the species from which the dose-response information is obtained differs from the route occurring in environmental exposures, the considerations used in making the route-to-route extrapolation must be carefully described. All assumptions should be presented along with a discussion of the uncertainties in the extrapolation. Whatever procedure is adopted in a given case, it must be consistent with the existing metabolic and pharmacokinetic information on the chemical (e.g., absorption efficiency via the gut and lung, target organ doses, and changes in placental transport throughout gestation for transplacental carcinogens).

Where two or more significantly elevated tumor sites or types are observed in the same study, extrapolations may be conducted on selected sites or types. These selections will be made on biological grounds. To obtain a total estimate of carcinogenic risk, animals with one or more tumor sites or types showing significantly elevated tumor incidence should be pooled and used for extrapolation. The pooled estimates will generally be used in preference to risk estimates based on single sites or types. Quantitative risk extrapolations will generally not be done on the basis of totals that include tumor sites without statistically significant elevations.

Benign tumors should generally be combined with malignant tumors for risk estimates unless the benign tumors are not considered to have the potential to progress to the associated malignancies of the same histogenic origin. The contribution of the benign tumors, however, to the total risk should be indicated.

2. *Choice of Mathematical Extrapolation Model.* Since risks at low exposure levels cannot be measured directly either by animal experiments or by epidemiologic studies, a number of mathematical models have been developed to extrapolate from high to low dose. Different extrapolation models, however, may fit the observed data reasonably well but may lead to large differences in the projected risk at low doses.

As was pointed out by OSTP (1985; Principle 26),

> No single mathematical procedure is recognized as the most appropriate for low-dose extrapolation in carcinogenesis. When relevant biological evidence on mechanism of action exists (e.g., pharmacokinetics, target organ dose), the models or procedures employed should be consistent with the evidence. When data and information are limited, however, and when much uncertainty exists regarding the mechanism of carcinogenic action, models or procedures which incorporate low-dose linearity are preferred when compatible with the limited information.

At present, mechanisms of the carcinogenesis process are largely unknown and data are generally limited. If a carcinogenic agent acts by accelerating the same carcinogenic process that leads to the background occurrence of cancer, the added effect of the carcinogen at low doses is expected to be virtually linear (Crump et al., 1976).

The Agency will review each assessment as to the evidence on carcinogenesis mechanisms and other biological or statistical evidence that indicates the suitability of a particular extrapolation model. Goodness-of-fit to the experimental observations is not an effective means of discriminating among models (OSTP, 1985). A rationale will be included to justify the use of the chosen model. In the absence of adequate information to the contrary, the linearized multistage procedure will be employed. Where appropriate, the results of using various extrapolation models may be useful for comparison with the linearized multistage procedure. When longitudinal data on tumor development are available, time-to-tumor models may be used.

It should be emphasized that the linearized multistage procedure leads to

a plausible upper limit to the risk that is consistent with some proposed mechanisms of carcinogenesis. Such an estimate, however, does not necessarily give a realistic prediction of the risk. The true value of the risk is unknown, and may be as low as zero. The range of risks, defined by the upper limit given by the chosen model and the lower limit which may be as low as zero, should be explicitly stated. An established procedure does not yet exist for making "most likely" or "best" estimates of risk within the range of uncertainty defined by the upper and lower limit estimates. If data and procedures become available, the Agency will also provide "most likely" or "best" estimates of risk. This will be most feasible when human data are available and when exposures are in the dose range of the data.

In certain cases, the linearized multistage procedure cannot be used with the observed data as, for example, when the data are nonmonotonic or flatten out at high doses. In these cases, it may be necessary to make adjustments to achieve low-dose linearity.

When pharmacokinetic or metabolism data are available, or when other substantial evidence on the mechanistic aspects of the carcinogenesis process exists, a low-dose extrapolation model other than the linearized multistage procedure might be considered more appropriate on biological grounds. When a different model is chosen, the risk assessment should clearly discuss the nature and weight of evidence that led to the choice. Considerable uncertainty will remain concerning response at low doses; therefore, in most cases an upper-limit risk estimate using the linearized multistage procedure should also be presented.

3. *Equivalent Exposure Units Among Species.* Low-dose risk estimates derived from laboratory animal data extrapolated to humans are complicated by a variety of factors that differ among species and potentially affect the response to carcinogens. Included among these factors are differences between humans and experimental test animals with respect to life span, body size, genetic variability, population homogeneity, existence of concurrent disease, pharmacokinetic effects such as metabolism and excretion patterns, and the exposure regimen.

The usual approach for making interspecies comparisons has been to use standardized scaling factors. Commonly employed standardized dosage scales include mg per kg body weight per day, ppm in the diet or water, mg per m^2 body surface area per day, and mg per kg body weight per lifetime. In the absence of comparative toxicological, physiological, metabolic, and pharmacokinetic data for a given suspect carcinogen, the Agency takes the position that the extrapolation on the basis of surface area is considered to be appropriate because certain pharmacological effects commonly scale according to surface area (Dedrick, 1973; Freireich et al., 1966; Pinkel, 1958).

B. Exposure Assessment

In order to obtain a quantitative estimate of the risk, the results of the dose-response assessment must be combined with an estimate of the exposures to which the populations of interest are likely to be subject. While the reader is referred to the Guidelines for Estimating Exposures (U.S. EPA, 1986) for specific details, it is important to convey an appreciation of the impact of the strengths and weaknesses of exposure assessment on the overall cancer risk assessment process.

At present there is no single approach to exposure assessment that is appropriate for all cases. On a case-by-case basis, appropriate methods are selected to match the data on hand and the level of sophistication required. The assumptions, approximations, and uncertainties need to be clearly stated because, in some instances, these will have a major effect on the risk assessment.

In general, the magnitude, duration, and frequency of exposure provide fundamental information for estimating the concentration of the carcinogen to which the organism is exposed. These data are generated from monitoring information, modeling results, and/or reasoned estimates. An appropriate treatment of exposure should consider the potential for exposure via ingestion, inhalation, and dermal penetration from relevant sources of exposures including multiple avenues of intake from the same source.

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. Unless there is evidence to the contrary in a particular case, the cumulative dose received over a lifetime, expressed as average daily exposure prorated over a lifetime, is recommended as an appropriate measure of exposure to a carcinogen. That is, 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. This approach becomes more problematical as the exposures in question become more intense but less frequent, especially when there is evidence that the agent has shown dose-rate effects.

An attempt should be made to assess the level of uncertainty associated with the exposure assessment which is to be used in a cancer risk assessment. This measure of uncertainty should be included in the risk characterization (section III.C.) in order to provide the decision-maker with a clear understanding of the impact of this uncertainty on any final quantitative risk estimate. Subpopulations with heightened susceptibility (either because of exposure or predisposition) should, when possible, be identified.

C. Risk Characterization

Risk characterization is composed of two parts. One is a presentation of the numerical estimates of risk; the other is a framework to help judge the significance of the risk. Risk characterization includes the exposure assessment and dose-response assessment; these are used in the estimation of carcinogenic risk. It may also consist of a unit-risk estimate which can be combined elsewhere with the exposure assessment for the purposes of estimating cancer risk.

Hazard identification and dose-response assessment are covered in sections II and III.A., and a detailed discussion of exposure assessment is contained in EPA's Guidelines for Estimating Exposures (U.S. EPA, 1986). This section deals with the numerical risk estimates and the approach to summarizing risk characterization.

1. *Options for Numerical Risk Estimates.* Depending on the needs of the individual program offices, numerical estimates can be presented in one or more of the following three ways.

a. Unit Risk—Under an assumption of low-dose linearity, the unit cancer risk is the excess lifetime risk due to a continuous constant lifetime exposure of one unit of carcinogen concentration. Typical exposure units include ppm or ppb in food or water, mg/kg/day by ingestion, or ppm or $\mu g/m^3$ in air.

b. Dose Corresponding to a Given Level of Risk—This approach can be useful, particularly when using nonlinear extrapolation models where the unit risk would differ at different dose levels.

c. Individual and Population Risks—Risks may be characterized either in terms of the excess individual lifetime risks, the excess number of cancers

produced per year in the exposed population, or both.

Irrespective of the options chosen, the degree of precision and accuracy in the numerical risk estimates currently do not permit more than one significant figure to be presented.

2. *Concurrent Exposure.* In characterizing the risk due to concurrent exposure to several carcinogens, the risks are combined on the basis of additivity unless there is specific information to the contrary. Interactions of cocarcinogens, promoters, and initiators with known carcinogens should be considered on a case-by-case basis.

3. *Summary of Risk Characterization.* Whichever method of presentation is chosen, it is critical that the numerical estimates not be allowed to stand alone, separated from the various assumptions and uncertainties upon which they are based. The risk characterization should contain a discussion and interpretation of the numerical estimates that affords the risk manager some insight into the degree to which the quantitative estimates are likely to reflect the true magnitude of human risk, which generally cannot be known with the degree of quantitative accuracy reflected in the numerical estimates. The final risk estimate will be generally rounded to one significant figure and will be coupled with the EPA classification of the qualitative weight of evidence. For example, a lifetime individual risk of 2×10^{-4} resulting from exposure to a "probable human carcinogen" (Group B2) should be designated as: 2×10^{-4} [B2]. This bracketed designation of the qualitative weight of evidence should be included with all numerical risk estimates (i.e., unit risks, which are risks at a specified concentration or concentrations corresponding to a given risk). Agency statements, such as **Federal Register** notices, briefings, and action memoranda, frequently include numerical estimates of carcinogenic risk. It is recommended that whenever these numerical estimates are used, the qualitative weight-of-evidence classification should also be included.

The section on risk characterization should summarize the hazard identification, dose-response assessment, exposure assessment, and the public health risk estimates. Major assumptions, scientific judgments, and, to the extent possible, estimates of the uncertainties embodied in the assessment are presented.

IV. EPA Classification System for Categorizing Weight of Evidence for Carcinogenicity From Human and Animal Studies (Adapted From IARC)

A. Assessment of Weight of Evidence for Carcinogenicity From Studies in Humans

Evidence of carcinogenicity from human studies comes from three main sources:

1. Case reports of individual cancer patients who were exposed to the agent(s).

2. Descriptive epidemiologic studies in which the incidence of cancer in human populations was found to vary in space or time with exposure to the agent(s).

3. Analytical epidemiologic (case-control and cohort) studies in which individual exposure to the agent(s) was found to be associated with an increased risk of cancer.

Three criteria must be met before a causal association can be inferred between exposure and cancer in humans:

1. There is no identified bias that could explain the association.

2. The possibility of confounding has been considered and ruled out as explaining the association.

3. The association is unlikely to be due to chance.

In general, although a single study may be indicative of a cause-effect relationship, confidence in inferring a causal association is increased when several independent studies are concordant in showing the association, when the association is strong, when there is a dose-response relationship, or when a reduction in exposure is followed by a reduction in the incidence of cancer.

The weight of evidence for carcinogenicity [1] from studies in humans is classified as:

1. Sufficient evidence of carcinogenicity, which indicates that there is a causal relationship between the agent and human cancer.

2. Limited evidence of carcinogenicity, which indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, could not adequately be excluded.

3. Inadequate evidence, which indicates that one of two conditions prevailed: (a) there were few pertinent data, or (b) the available studies, while showing evidence of association, did not exclude chance, bias, or confounding and therefore a causal interpretation is not credible.

4. No data, which indicates that data are not available.

5. No evidence, which indicates that no association was found between exposure and an increased risk of cancer in well-designed and well-conducted independent analytical epidemiologic studies.

B. Assessment of Weight of Evidence for Carcinogenicity From Studies in Experimental Animals

These assessments are classified into five groups:

1. Sufficient evidence [2] of carcinogenicity, which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors: [3] (a) in multiple species or strains; or (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset.

Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests or on chemical structure.

2. Limited evidence of carcinogenicity, which means that the data suggest a carcinogenic effect but are limited because: (a) the studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see section IV. B.1.c); (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) an increase in the incidence of benign tumors only.

3. Inadequate evidence, which indicates that because of major qualitative or quantitative limitations, the studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

4. No data, which indicates that data are not available.

5. No evidence, which indicates that there is no increased incidence of neoplasms in at least two well-designed

[1] For purposes of public health protection, agents associated with life-threatening benign tumors in humans are included in the evaluation.

[2] An increased incidence of neoplasms that occur with high spontaneous background incidence (e.g., mouse liver tumors and rat pituitary tumors in certain strains) generally constitutes "sufficient" evidence of carcinogenicity, but may be changed to "limited" when warranted by the specific information available on the agent.

[3] Benign and malignant tumors will be combined unless the benign tumors are not considered to have the potential to progress to the associated malignancies of the same histogenic origin.

and well-conducted animal studies in different species.

The classifications "sufficient evidence" and "limited evidence" refer only to the weight of the experimental evidence that these agents are carcinogenic and not to the potency of their carcinogenic action.

C. Categorization of Overall Weight of Evidence for Human Carcinogenicity

The overall scheme for categorization of the weight of evidence of carcinogenicity of a chemical for humans uses a three-step process. (1) The weight of evidence in human studies or animal studies is summarized; (2) these lines of information are combined to yield a tentative assignment to a category (see Table 1); and (3) all relevant supportive information is evaluated to see if the designation of the overall weight of evidence needs to be modified. Relevant factors to be included along with the tumor information from human and animal studies include structure-activity relationships; short-term test findings; results of appropriate physiological, biochemical, and toxicological observations; and comparative metabolism and pharmacokinetic studies. The nature of these findings may cause one to adjust the overall categorization of the weight of evidence.

TABLE 1.—ILLUSTRATIVE CATEGORIZATION OF EVIDENCE BASED ON ANIMAL AND HUMAN DATA [1]

Human evidence	Animal evidence				
	Sufficient	Limited	Indequate	No data	No. Evidence
Sufficient	A	A	A	A	A
Limited	B1	B1	B1	B1	B1
Inadequate	B2	C	D	D	D
No data	B2	C	D	D	E
No evidence	B2	C	D	D	E

[1] The above assignments are presented for illustrative purposes. There may be nuances in the classification of both animal and human data indicating that different categorizations than those given in the table should be assigned. Furthermore, these assignments are tentative and may be modified by ancillary evidence. In this regard all relevant information should be evaluated to determine if the designation of the overall weight of evidence needs to be modified. Relevant factors to be included along with the tumor data from human and animal studies include structure-activity relationships, short-term test findings, results of appropriate physiological, biochemical, and toxicological observations, and comparative metabolism and pharmacokinetic studies. The nature of these findings may cause an adjustment of the overall categorization of the weight of evidence.

The agents are categorized into five groups as follows:

Group A—Human Carcinogen

This group is used only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer.

Group B—Probable Human Carcinogen

This group includes agents for which the weight of evidence of human carcinogenicity based on epidemiologic studies is "limited" and also includes agents for which the weight of evidence of carcinogenicity based on animal studies is "sufficient." The group is divided into two subgroups. Usually, Group B1 is reserved for agents for which there is limited evidence of carcinogenicity from epidemiologic studies. It is reasonable, for practical purposes, to regard an agent for which there is "sufficient" evidence of carcinogenicity in animals as if it presented a carcinogenic risk to humans. Therefore, agents for which there is "sufficient" evidence from animal studies and for which there is "inadequate evidence" or "no data" from epidemiologic studies would usually be categorized under Group B2.

Group C—Possible Human Carcinogen

This group is used for agents with limited evidence of carcinogenicity in animals in the absence of human data. It includes a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor responses of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) responses of marginal statistical significance in a tissue known to have a high or variable background rate.

Group D—Not Classifiable as to Human Carcinogenicity

This group is generally used for agents with inadequate human and animal evidence of carcinogenicity or for which no data are available.

Group E—Evidence of Non-Carcinogenicity for Humans

This group is used for agents that show no evidence for carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies.

The designation of an agent as being in Group E is based on the available evidence and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.

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Part B: Response to Public and Science Advisory Board Comments

I. Introduction

This section summarizes the major issues raised during both the public comment period on the Proposed Guidelines for Carcinogen Risk Assessment published on November 23, 1984 (49 FR 46294), and also during the April 22–23, 1985, meeting of the Carcinogen Risk Assessment Guidelines Panel of the Science Advisory Board (SAB).

In order to respond to these issues the Agency modified the proposed guidelines in two stages. First, changes resulting from consideration of the public comments were made in a draft sent to the SAB review panel prior to their April meeting. Secondly, the guidelines were further modified in response to the panel's recommendations.

The Agency received 62 sets of comments during the public comment period, including 28 from corporations, 9 from professional or trade associations, and 4 from academic institutions. In general, the comments were favorable. The commentors welcomed the update of the 1976 guidelines and felt that the proposed guidelines of 1985 reflected some of the progress that has occurred in understanding the mechanisms of carcinogenesis. Many commentors, however, felt that additional changes were warranted.

The SAB concluded that the guidelines are "reasonably complete in their conceptual framework and are sound in their overall interpretation of the scientific issues" (Report by the SAB Carcinogenicity Guidelines Review Group, June 19, 1985). The SAB suggested various editorial changes and raised some issues regarding the content of the proposed guidelines, which are discussed below. Based on these recommendations, the Agency has modified the draft guidelines.

II. Office of Science and Technology Policy Report on Chemical Carcinogens

Many commentors requested that the final guidelines not be issued until after publication of the report of the Office of Technology and Science Policy (OSTP) on chemical carcinogens. They further requested that this report be incorporated into the final Guidelines for Carcinogen Risk Assessment.

The final OSTP report was published in 1985 (50 FR 10372). In its deliberations, the Agency reviewed the final OSTP report and feels that the Agency's guidelines are consistent with the principles established by the OSTP. In its review, the SAB agreed that the Agency quidelines are generally consistent with the OSTP report. To emphasize this consistency, the OSTP principles have been incorporated into the guidelines when controversial issues are discussed.

III. Inference Guidelines

Many commentors felt that the proposed guidelines did not provide a sufficient distinction between scientific fact and policy decisions. Others felt that EPA should not attempt to propose firm guidelines in the absence of scientific consensus. The SAB report also indicated the need to "distinguish recommendations based on scientific evidence from those based on science policy decisions."

The Agency agrees with the recommendation that policy, judgmental, or inferential decisions should be clearly identified. In its revision of the proposed guidelines, the Agency has included phrases (e.g., "the Agency takes the position that") to more clearly distinguish policy decisions.

The Agency also recognizes the need to establish procedures for action on important issues in the absence of complete scientific knowledge or consensus. This need was acknowledged in both the National Academy of Sciences book entitled *Risk Management in the Federal Government: Managing the Process* and the OSTP report on chemical carcinogens. As the NAS report states, "Risk assessment is an analytic process that is firmly based on scientific considerations, but it also requires judgments to be made when the available information is incomplete. These judgments inevitably draw on both scientific and policy considerations."

The judgments of the Agency have been based on current available scientific information and on the combined experience of Agency experts. These judgments, and the resulting guidance, rely on inference; however, the positions taken in these inference guidelines are felt to be reasonable and scientifically defensible. While all of the guidance is, to some degree, based on inference the guidelines have attempted to distinguish those issues that depended more on judgment. In these cases, the Agency has stated a position but has also retained flexibility to accommodate new data or specific circumstances that demonstrate that the proposed position is inaccurate. The Agency recognizes that scientific opinion will be divided on these issues.

Knowledge about carcinogens and carcinogenesis is progressing at a rapid rate. While these guidelines are considered a best effort at the present time, the Agency has attempted to incorporate flexibility into the current guidelines and also recommends that the guidelines be revised as often as warranted by advances in the field.

IV. Evaluation of Benign Tumors

Several commentors discussed the appropriate interpretation of an increased incidence of benign tumors alone or with an increased incidence of malignant tumors as part of the evaluation of the carcinogenicity of an agent. Some comments were supportive of the position in the proposed guidelines, i.e., under certain circumstances, the incidence of benign and malignant tumors would be combined, and an increased incidence of benign tumors alone would be considered an indication, albeit limited, of carcinogenic potential. Other commentors raised concerns about the criteria that would be used to decide which tumors should be combined. Only a few commentors felt that benign tumors should never be considered in evaluating carcinogenic potential.

The Agency believes that current information supports the use of benign tumors. The guidelines have been modified to incorporate the language of the OSTP report, i.e., benign tumors will be combined with malignant tumors when scientifically defensible. This position allows flexibility in evaluating the data base for each agent. The guidelines have also been modified to indicate that, whenever benign and malignant tumors have been combined, and the agent is considered a candidate for quantitative risk extrapolation, the contribution of benign tumors to the estimation of risk will be indicated.

V. Transplacental and Multigenerational Animal Bioassays

As one of its two proposals for additions to the guidelines, the SAB recommended a discussion of transplacental and multigenerational animal bioassays for carcinogenicity.

The Agency agrees that such data, when available, can provide useful information in the evaluation of a chemical's potential carcinogenicity and has stated this in the final guidelines. The Agency has also revised the guidelines to indicate that such studies may provide additional information on the metabolic and pharmacokinetic properties of the chemical. More guidance on the specific use of these studies will be considered in future revisions of these guidelines.

VI. Maximum Tolerated Dose

The proposed guidelines discussed the implications of using a maximum tolerated dose (MTD) in bioassays for carcinogenicity. Many commentors requested that EPA define MTD. The tone of the comments suggested that the commentors were concerned about the uses and interpretations of high-dose testing.

The Agency recognizes that controversy currently surrounds these issues. The appropriate text from the OSTP report has been incorporated into the final guidelines which suggests that the consequences of high-dose testing be evaluated on a case-by-case basis.

VII. Mouse Liver Tumors

A large number of commentors expressed opinions about the assessment of bioassays in which the only increase in tumor incidence was liver tumors in the mouse. Many felt that mouse liver tumors were afforded too much credence, especially given existing information that indicates that they might arise by a different mechanism, e.g., tissue damage followed by regeneration. Others felt that mouse liver tumors were but one case of a high background incidence of one particular type of tumor and that all such tumors should be treated in the same fashion.

The Agency has reviewed these comments and the OSTP principle regarding this issue. The OSTP report does not reach conclusions as to the treatment of tumors with a high spontaneous background rate, but states, as is now included in the text of the guidelines, that these data require special consideration. Although questions have been raised regarding the validity of mouse liver tumors in general, the Agency feels that mouse liver tumors cannot be ignored as an indicator of carcinogenicity. Thus, the position in the proposed guidelines has not been changed: an increased incidence of only mouse liver tumors will be regarded as "sufficient" evidence of carcinogenicity if all other criteria, e.g., replication and malignancy, are met with the understanding that this classification could be changed to "limited" if warranted. The factors that may cause this re-evaluation are indicated in the guidelines.

VIII. Weight-of-Evidence Categories

The Agency was praised by both the public and the SAB for incorporating a weight-of-evidence scheme into its evaluation of carcinogenic risk. Certain specific aspects of the scheme, however, were criticized.

1. Several commentors noted that while the text of the proposed guidelines clearly states that EPA will use all available data in its categorization of the weight of the evidence that a chemical is a carcinogen, the classification system in Part A, section IV did not indicate the manner in which EPA will use information other than data from humans and long-term animal studies in assigning a weight-of-evidence classification.

The Agency has added a discussion to Part A, section IV.C. dealing with the characterization of overall evidence for human carcinogenicity. This discussion clarifies EPA's use of supportive information to adjust, as warranted, the designation that would have been made solely on the basis of human and long-term animal studies.

2. The Agency agrees with the SAB and those commentors who felt that a simple classification of the weight of evidence, e.g., a single letter or even a descriptive title, is inadequate to describe fully the weight of evidence for each individual chemical. The final guidelines propose that a paragraph summarizing the data should accompany the numerical estimate and weight-of-evidence classification whenever possible.

3. Several commentors objected to the descriptive title E (No Evidence of Carcinogenicity for Humans) because they felt the title would be confusing to people inexperienced with the classification system. The title for Group E, No Evidence of Carcinogenicity for Humans, was thought by these commentors to suggest the absence of data. This group, however, is intended to be reserved for agents for which there exists credible data demonstrating that the agent is not carcinogenic.

Based on these comments and further discussion, the Agency has changed the

title of Group E to "Evidence of Non-Carcinogenicity for Humans."

4. Several commentors felt that the title for Group C, Possible Human Carcinogen, was not sufficiently distinctive from Group B, Probable Human Carcinogen. Other commentors felt that those agents that minimally qualified for Group C would lack sufficient data for such a label.

The Agency recognizes that Group C covers a range of chemicals and has considered whether to subdivide Group C. The consensus of the Agency's Carcinogen Risk Assessment Committee, however, is that the current groups, which are based on the IARC categories, are a reasonable stratification and should be retained at present. The structure of the groups will be reconsidered when the guidelines are reviewed in the future. The Agency also feels that the descriptive title it originally selected best conveys the meaning of the classification within the context of EPA's past and current activities.

5. Some commentors indicated a concern about the distinction between B1 and B2 on the basis of epidemiologic evidence only. This issue has been under discussion in the Agency and may be revised in future versions of the guidelines.

6. Comments were also received about the possibility of keeping the groups for animal and human data separate without reaching a combined classification. The Agency feels that a combined classification is useful; thus, the combined classification was retained in the final guidelines.

The SAB suggested that a table be added to Part A, section IV to indicate the manner in which human and animal data would be combined to obtain an overall weight-of-evidence category. The Agency realizes that a table that would present all permutations of potentially available data would be complex and possibly impossible to construct since numerous combinations of ancillary data (e.g., genetic toxicity, pharmacokinetics) could be used to raise or lower the weight-of-evidence classification. Nevertheless, the Agency decided to include a table to illustrate the most probable weight-of-evidence classification that would be assigned on the basis of standard animal and human data without consideration of the ancillary data. While it is hoped that this table will clarify the weight-of-evidence classifications, it is also important to recognize that an agent may be assigned to a final categorization different from the category which would appear appropriate from the table and still conform to the guidelines.

IX. Quantitative Estimates of Risk

The method for quantitative estimates of carcinogenic risk in the proposed guidelines received substantial comments from the public. Five issues were discussed by the Agency and have resulted in modifications of the guidelines.

1. The major criticism was the perception that EPA would use only one method for the extrapolation of carcinogenic risk and would, therefore, obtain one estimate of risk. Even commentors who concur with the procedure usually followed by EPA felt that some indication of the uncertainty of the risk estimate should be included with the risk estimate.

The Agency feels that the proposed guidelines were not intended to suggest that EPA would perform quantitative risk estimates in a rote or mechanical fashion. As indicated by the OSTP report and paraphrased in the proposed guidelines, no single mathematical procedure has been determined to be the most appropriate method for risk extrapolation. The final guidelines quote rather than paraphrase the OSTP principle. The guidelines have been revised to stress the importance of considering all available data in the risk assessment and now state, "The Agency will review each assessment as to the evidence on carcinogenic mechanisms and other biological or statistical evidence that indicates the suitability of a particular extrapolation model." Two issues are emphasized: First, the text now indicates the potential for pharmacokinetic information to contribute to the assessment of carcinogenic risk. Second, the final guidelines state that time-to-tumor risk extrapolation models may be used when longitudinal data on tumor development are available.

2. A number of commentors noted that the proposed guidelines did not indicate how the uncertainties of risk characterization would be presented. The Agency has revised the proposed guidelines to indicate that major assumptions, scientific judgments, and, to the extent possible, estimates of the uncertainties embodied in the risk assessment will be presented along with the estimation of risk.

3. The proposed guidelines stated that the appropriateness of quantifying risks for chemicals in Group C (Possible Human Carcinogen), specifically those agents that were on the boundary of Groups C and D (Not Classifiable as to Human Carcinogenicity), would be judged on a case-by-case basis. Some commentors felt that quantitative risk assessment should not be performed on any agent in Group C.

Group C includes a wide range of agents, including some for which there are positive results in one species in one good bioassay. Thus, the Agency feels that many agents in Group C will be suitable for quantitative risk assessment, but that judgments in this regard will be made on a case-by-case basis.

4. A few commentors felt that EPA intended to perform quantitative risk estimates on aggregate tumor incidence. While EPA will consider an increase in total aggregate tumors as suggestive of potential carcinogenicity, EPA does not generally intend to make quantitative estimates of carcinogenic risk based on total aggregate tumor incidence.

5. The proposed choice of body surface area as an interspecies scaling factor was criticized by several commentors who felt that body weight was also appropriate and that both methods should be used. The OSTP report recognizes that both scaling factors are in common use. The Agency feels that the choice of the body surface area scaling factor can be justified from the data on effects of drugs in various species. Thus, EPA will continue to use this scaling factor unless data on a specific agent suggest that a different scaling factor is justified. The uncertainty engendered by choice of scaling factor will be included in the summary of uncertainties associated with the assessment of risk mentioned in point 1, above.

In the second of its two proposals for additions to the proposed guidelines, the SAB suggested that a sensitivity analysis be included in EPA's quantitative estimate of a chemical's carcinogenic potency. The Agency agrees that an analysis of the assumptions and uncertainties inherent in an assessment of carcinogenic risk must be accurately portrayed. Sections of the final guidelines that deal with this issue have been strengthened to reflect the concerns of the SAB and the Agency. In particular, the last paragraph of the guidelines states that "major assumptions, scientific judgments, and, to the extent possible, estimates of the uncertainties embodied in the assessment" should be presented in the summary characterizing the risk. Since the assumptions and uncertainties will vary for each assessment, the Agency feels that a formal requirement for a particular type of sensitivity analysis would be less useful than a case-by-case evaluation of the particular assumptions and uncertainties most significant for a particular risk assessment.

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Part III

Environmental Protection Agency

Guidelines for Mutagenicity Risk Assessment

ENVIRONMENTAL PROTECTION AGENCY

[FRL-2983-9]

Guidelines for Mutagenicity Risk Assessment

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final Guidelines for Mutagenicity Risk Assessment.

SUMMARY: The U.S. Environmental Protection Agency is today issuing five guidelines for assessing the health risks of environmental pollutants.

Guidelines for Carcinogen Risk Assessment
Guidelines for Estimating Exposures
Guidelines for Mutagenicity Risk Assessment
Guidelines for the Health Assessment of Suspect Developmental Toxicants
Guidelines for the Health Risk Assessment of Chemical Mixtures

This notice contains the Guidelines for Mutagenicity Risk Assessment; the other guidelines appear elsewhere in today's **Federal Register.**

The Guidelines for Mutagenicity Risk Assessment (hereafter "Guidelines") are intended to guide Agency analysis of mutagenicity data in line with the policies and procedures established in the statutes administered by the EPA. These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Office of Health and Environmental Assessment (OHEA) in the Agency's Office of Research and Development. They reflect Agency consideration of public and Science Advisory Board (SAB) comments on the Proposed Guidelines for Mutagenicity Risk Assessment published November 23, 1984 (49 FR 46314).

This publication completes the first round of risk assessment guidelines development. These Guidelines will be revised, and new guidelines will be developed, as appropriate.

EFFECTIVE DATE: The Guidelines will be effective September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Dr. Lawrence R. Valcovic, Reproductive Effects Assessment Group, Office of Health and Environmental Assessment (RD-689), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202-382-7303.

SUPPLEMENTARY INFORMATION: In 1983, the National Academy of Sciences (NAS) published its book entitled *Risk Assessment in the Federal Government: Managing the Process.* In that book, the NAS 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. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

General

The guidelines published today are products of a two-year Agencywide effort, which has included many scientists from the larger scientific community. These guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments, and to inform Agency decision makers and the public about these procedures. In particular, the guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific information on each agent and use the most scientifically appropriate interpretation to assess risk. The guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Finally, the guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Guidelines for Mutagenicity Risk Assessment

Work on the Guidelines for Mutagenicity Risk Assessment began in January 1984. Draft guidelines were developed by Agency work groups composed of expert scientists from throughout the Agency. The drafts were peer-reviewed by expert scientists in the field of genetic toxicology from universities, environmental groups, industry, labor, and other governmental agencies. They were then proposed for public comment in the **Federal Register** (49 FR 46314). On November 9, 1984, the Administrator directed that Agency offices use the proposed guidelines in performing risk assessments until final guidelines become available.

After the close of the public comment period, Agency staff prepared summaries of the comments, analyses of the major issues presented by the commentors, and preliminary Agency responses to those comments. These analyses were presented to review panels of the SAB on March 4 and April 22-23, 1985, and to the Executive Committee of the SAB on April 25-26, 1985. The SAB meetings were announced in the **Federal Register** as follows: February 12, 1985 (50 FR 5811) and April 4, 1985 (50 FR 13420 and 13421).

In a letter to the Administrator dated June 19, 1985, the Executive Committee generally concurred on all five of the guidelines, but recommended certain revisions, and requested that any revised guidelines be submitted to the appropriate SAB review panel chairman for review and concurrence on behalf of the Executive Committee. As described in the responses to comments (see Part B: Response to the Public and Science Advisory Board Comments), each guidelines document was revised, where appropriate, consistent with the SAB recommendations, and revised draft guidelines were submitted to the panel chairmen. Revised draft Guidelines for Mutagenicity Risk Assessment were concurred on in a letter dated September 24, 1985. Copies of the letters are available at the Public Information Reference Unit, EPA Headquarters Library, as indicated elsewhere in this notice.

Following this Preamble are two parts: Part A contains the Guidelines and Part B, the Response to the Public and Science Advisory Board Comments (a summary of the major public comments, SAB comments, and Agency responses to those comments).

The Agency is continuing to study the risk assessment issues raised in the guidelines and will revise these Guidelines in line with new information as appropriate.

References, supporting documents, and comments received on the proposed guidelines, as well as copies of the final guidelines, are available for inspection and copying at the Public Information Reference Unit (202-382-5926), EPA Headquarters Library, 401 M Street, SW, Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m.

I certify that these Guidelines are not major rules as defined by Executive Order 12291, because they are nonbinding policy statements and have no direct effect on the regulated community. Therefore, they will have no effect on costs or prices, and they will have no other significant adverse effects on the economy. These Guidelines were reviewed by the Office of Management

and Budget under Executive Order 12291.

Dated: August 22, 1986.

Lee M. Thomas,

Administrator.

CONTENTS

Part A: Guidelines for Mutagenicity Risk Assessment

I. Introduction

This section describes the procedures that the U.S. Environmental Protection Agency will follow in evaluating the potential genetic risk associated with human exposure to chemicals. The central purpose of the health risk assessment is to provide a judgment concerning the weight of evidence that an agent is a potential human mutagen, capable of inducing transmitted genetic changes, and, if so, to provide a judgment on how great an impact this agent is likely to have on public health. Regulatory decision making involves two components: risk assessment and risk management. Risk assessment estimates the potential adverse health consequences of exposure to toxic chemicals; risk management combines the risk assessment with the directives of the enabling regulatory legislation—together with socioeconomic, technical, political, and other considerations—to reach a decision as to whether or how much to control future exposure to the chemicals. The issue of risk management will not be dealt with in these Guidelines.

Risk assessment is comprised of the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization (1). Hazard identification is the qualitative risk assessment, dealing with the inherent toxicity of a chemical substance. The qualitative mutagenicity assessment answers the question of how likely an agent is to be a human mutagen. The three remaining components comprise quantitative risk assessment, which provides a numerical estimate of the public health consequences of exposure to an agent. The quantitative mutagenicity risk assessment deals with the question of how much mutational damage is likely to be produced by exposure to a given agent under particular exposure scenarios.

In a dose-response assessment, the relationship between the dose of a chemical and the probability of induction of an adverse effect is defined. The component generally entails an extrapolation from the high doses administered to experimental animals or noted in some epidemiologic studies to the low exposure levels expected from human contact with the chemical in the environment.

The exposure assessment identifies populations exposed to toxic chemicals, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the chemicals. This component is developed independently of the other components of the mutagenicity assessment and is addressed in separate Agency guidelines (2).

In risk characterization, the outputs of the exposure assessment and the dose-response assessment are combined to estimate quantitatively the mutation risk, which is expressed as either estimated increase of genetic disease per generation or per lifetime, or the fractional increase in the assumed background mutation rate of humans. In each step of the assessment, the strengths and weaknesses of the major assumptions need to be presented, and the nature and magnitude of uncertainties need to be characterized.

The procedures set forth in these Guidelines will ensure consistency in the Agency's scientific risk assessments for mutagenic effects. The necessity for a consistent approach to the evaluation of mutagenic risk from chemical substances arises from the authority conferred upon the Agency by a number of statutes to regulate potential mutagens. As appropriate, these Guidelines will apply to statutes administered by the Agency, including the Federal Insecticide, Fungicide, and Rodenticide Act; the Toxic Substances Control Act; the Clean Air Act; the Federal Water Pollution Control Act; the Safe Drinking Water Act; the Resource Conservation and Recovery Act; and the Comprehensive Environmental Response, Compensation, and Liability Act. Because each statute is administered by separate offices, a consistent Agency-wide approach for performing risk assessments is desirable.

The mutagenicity risk assessments prepared pursuant to these Guidelines will be utilized with the requirements and constraints of the applicable statutes to arrive at regulatory decisions concerning mutagenicity. The standards of the applicable statutes and regulations may dictate that additional considerations (e.g., the economic and social benefits associated with use of the chemical substance) will come into play in reaching appropriate regulatory decisions.

The Agency has not attempted to provide in the Guidelines a detailed discussion of the mechanisms of mutagenicity or of the various test systems that are currently in use to detect mutagenic potential. Background information on mutagenesis and mutagenicity test systems is available in "Identifying and Estimating the Genetic Impact of Chemical Mutagens", National Academy of Sciences (NAS) Committee on Chemical Environmental Mutagens (3), as well as in other recent publications (4, 5).

The Agency is concerned with the risk associated with both germ-cell mutations and somatic-cell mutations. Mutations carried in germ cells may be inherited by future generations and may contribute to genetic disease, whereas mutations occurring in somatic cells may be implicated in the etiology of several disease states, including cancer. These Guidelines, however, are only concerned with genetic damage as it relates to germ-cell mutations. The use of mutagenicity test results in the assessment of carcinogenic risk is described in the Guidelines for Carcinogen Risk Assessment (6).

As a result of the progress in the control of infectious diseases, increases in average human life span, and better procedures for identifying genetic disorders, a considerable heritable genetic disease burden has been recognized in the human population. It is estimated that at least 10% of all human disease is related to specific genetic abnormalities, such as abnormal composition, arrangement, or dosage of genes and chromosomes (3, 7, 8). Such genetic abnormalities can lead to structural or functional health impairments. These conditions may be expressed *in utero;* at the time of birth; or during infancy, childhood, adolescence, or adult life; they may be chronic or acute in nature. As a result, they often have a severe impact upon the affected individuals and their families in terms of physical and mental

suffering and economic losses, and upon society in general, which often becomes responsible for institutional care of severely affected individuals. Some examples of genetic disorders are Down and Klinefelter syndromes, cystic fibrosis, hemophilia, sickle-cell anemia, and achondroplastic dwarfism. Other commonly recognized conditions that are likely to have a genetic component include hypercholesterolemia, hypertension, pyloric stenosis, glaucoma, allergies, several types of cancer, and mental retardation. These disorders are only a few of the thousands that are at least partially genetically determined (9).

Estimation of the fraction of human genetic disorders that result from new mutations is difficult, although in certain specific cases insights are available (10). It is clear that recurring mutation is important in determining the incidence of certain genetic disorders, such as some chromosomal aberration syndromes (e.g., Down syndrome) and rare dominant and X-linked recessive diseases (e.g., achondroplasia and hemophilia A). For other single-factor disorders (e.g., sickle-cell anemia) and certain multifactorial disorders (e.g., pyloric stenosis), the contribution of new mutations to disease frequency is probably small. However, it is generally recognized that most newly-arising mutations that are phenotypically expressed are in some ways deleterious to the organism receiving them (3, 7, 8). Adverse effects may be manifested at the biochemical, cellular, or physiological levels of organization. Although mutations are the building blocks for further evolutionary change of species, it is believed that increases in the mutation rate could lead to an increased frequency of expressed genetic disorders in the first and subsequent generations.

Life in our technological society results in exposure to many natural and synthetic chemicals. Some have been shown to have mutagenic activity in mammalian and submammalian test systems, and thus may have the potential to increase genetic damage in the human population. Chemicals exhibiting mutagenic activity in various test systems have been found distributed among foods, tobacco, drugs, food additives, cosmetics, industrial compounds, pesticides, and consumer products. The extent to which exposure to natural and synthetic environmental agents may have increased the frequency of genetic disorders in the present human population and contributed to the mutational "load" that will be transmitted to future generations is unknown at this time. However, for the reasons cited above, it seems prudent to limit exposures to potential human mutagens.

A. Concepts Relating to Heritable Mutagenic Risk

These Guidelines are concerned with chemical substances or mixtures of substances that can induce alterations in the genome of either somatic or germinal cells. The mutagenicity of physical agents (e.g., radiation) is not addressed here. There are several mutagenic end points of concern to the Agency. These include point mutations (i.e., submicroscopic changes in the base sequence of DNA) and structural or numerical chromosome aberrations. Structural aberrations include deficiencies, duplications, insertions, inversions, and translocations, whereas numerical aberrations are gains or losses of whole chromosomes (e.g., trisomy, monosomy) or sets of chromosomes (haploidy, polyploidy).

Certain mutagens, such as alkylating agents, can directly induce alterations in the DNA. Mutagenic effects may also come about through mechanisms other than chemical alterations of DNA. Among these are interference with normal DNA synthesis (as caused by some metal mutagens), interference with DNA repair, abnormal DNA methylation, abnormal nuclear division processes, or lesions in non-DNA targets (e.g., protamine, tubulin).

Evidence that an agent induces heritable mutations in human beings could be derived from epidemiologic data indicating a strong association between chemical exposure and heritable effects. It is difficult to obtain such data because any specific mutation is a rare event, and only a small fraction of the estimated thousands of human genes and conditions are currently useful as markers in estimating mutation rates. Human genetic variability, small numbers of offspring per individual, and long generation times further complicate such studies. In addition, only disorders caused by dominant mutations, some sex-linked recessive mutations, and certain chromosome aberrations can be detected in the first generation after their occurrence. Conditions caused by autosomal recessive disorders (which appear to occur more frequently than dominant disorders) or by polygenic traits may go unrecognized for many generations. Therefore, in the absence of human epidemiological data, it is appropriate to rely on data from experimental animal systems as long as the limitations of using surrogate and model systems are clearly stated.

Despite species differences in metabolism, DNA repair, and other physiological processes affecting chemical mutagenesis, the virtual universality of DNA as the genetic material and of the genetic code provides a rationale for using various nonhuman test systems to predict the intrinsic mutagenicity of test chemicals. Additional support for the use of nonhuman systems is provided by the observation that chemicals causing genetic effects in one species or test system frequently cause similar effects in other species or systems. Evidence also exists that chemicals can induce genetic damage in somatic cells of exposed humans. For example, high doses of mutagenic chemotherapeutic agents have been shown to cause chromosomal abnormalities (11), sister chromatic exchange (11), and, quite probably, point mutations in human lymphocytes exposed *in vivo* (12). While these results are not in germ cells, they do indicate that it is possible to induce mutagenic events in human cells *in vivo*. Furthermore, a wide variety of different types of mutations have been observed in humans including numerical chromosome aberrations, translocations, base-pair substitutions, and frameshift mutations. Although the cause of these mutations is uncertain, it is clear from these observations that the human germ-cell DNA is subject to the same types of mutational events that are observed in other species and test systems.

Certain test systems offer notable advantages: cost; anatomical, histological, and/or metabolic similarities to humans; suitability for handling large numbers of test organisms; a large data base; or a basis for characterizing genetic events.

B. Test Systems

Many test systems are currently available that can contribute information about the mutagenic potential of a test compound with respect to various genetic end points. These tests have recently been evaluated through the EPA Gene-Tox Programs and the results of Phase I have been published (5). The Agency's Office of Pesticides and Toxic Substances has published various testing guidelines for the detection of mutagenic effects (13, 14).

Test systems for detecting point mutations include those in bacteria, eukaryotic microorganisms, higher plants, insects, mammalian somatic cells in culture, and germinal cells of intact mammals. Data from heritable, mammalian germ-cell tests provide the best experimental evidence that a

chemical is a potential human germ-cell mutagen since these tests require that mutations occur in germinal cells and that they are transmitted to the next generation. To date, the most extensively used test for the induction of heritable mutation is the mouse specific-locus test which measures the induction of recessive mutations at seven loci concerned with coat color and ear morphology. While this test has a large data base compared to other germ-cell assays, it is difficult to extrapolate results to humans since recessive mutations may occur more frequently than dominants, and the impact of recessive mutations is not seen for many generations. Information on frequencies of induced mutations resulting in health disorders in the first generation may be obtained from mouse systems designed to detect skeletal abnormalities, cataracts, or general morphological abnormalities. However, these assays have been used to a relatively limited extent, and there is a need for additional studies with known, chemical germ-cell mutagens to further characterize the test systems. Because large numbers of offspring must usually be generated in the systems described above, it is not expected that many chemicals will be tested using these systems. To obtain data on a large number of environmental chemicals, it will be necessary to rely on other tests to identify and characterize hazards from gene mutations.

Test systems for detecting structural chromosome aberrations have been developed in a variety of organisms including higher plants, insects, fish, birds, and several mammalian species. Many of these assays can be performed *in vitro* or *in vivo*, and in either germ or somatic cells. Procedures available for detecting structural chromosome aberrations in mammalian germ cells include measurement of heritable translocations or dominant lethality, as well as direct cytogenetic analyses of germ cells and early embryos in rodents.

Some chemicals may cause numerical chromosome changes (i.e., aneuploidy) as their sole mutagenic effect. These agents may not be detected as mutagens if evaluated only in tests for DNA damage, gene mutations, or chromosome breakage and rearrangement. Therefore, it is important to consider tests for changes in chromosome number in the total assessment of mutagenic hazards. Although tests for the detection of variation in the chromosome number are still at an early stage of development, systems exist in such diverse organisms as fungi, Drosophila, mammalian cells in culture, and intact mammals (e.g., mouse X-chromosome loss assay). Aneuploidy can arise from disturbances in a number of events affecting the meiotic process (15, 16). Although the mechanisms by which nondisjunction occurs are not well understood, mitotic structures other than DNA may be the target molecules for at least some mechanisms of induced nondisjunction.

Other end points that provide information bearing on the mutagenicity of a chemical can be detected by a variety of test systems. Such tests measure DNA damage in eukaryotic or prokaryotic cells, unscheduled DNA synthesis in mammalian somatic and germ cells, mitotic recombination and gene conversion in yeast, and sister-chromatid exchange in mammalian somatic and germ cells. Results in these assays are useful because the induction of these end points often correlates positively with the potential of a chemical to induce mutations.

In general, for all three end points (i.e., point mutations and numerical and structural aberrations), the Agency will place greater weight on tests conducted in germ cells than in somatic cells, on tests performed *in vivo* rather than *in vitro*, in eukaryotes rather than prokaryotes, and in mammalian species rather than in submammalian species. Formal numerical weighting systems have been developed (17); however, the Agency has concluded that these do not readily accommodate such variables as dose range, route of exposure, and magnitude of response.

The Agency anticipates that from time to time somatic cell data from chemically exposed human beings will be available (e.g., cytogenetic markers in peripheral lymphocytes). When possible, the Agency will use such data in conjunction with somatic and germ cell comparisons from *in vivo* mammalian experimental systems as a component in performing risk assessments.

The test systems mentioned previously are not the only ones that will provide evidence of mutagenicity or related DNA effects. These systems are enumerated merely to demonstrate the breadth of the available techniques for characterizing mutagenic hazards, and to indicate the types of data that the Agency will consider in its evaluation of mutagenic potential of a chemical agent. Most systems possess certain limitations that must be taken into account. The selection and performance of appropriate tests for evaluating the risks associated with human exposure to any suspected mutagen will depend on sound scientific judgment and experience, and may necessitate consultation with geneticists familiar with the sensitivity and experimental design of the test system in question. In view of the rapid advances in test methodology, the Agency expects that both the number and quality of the tools for assessing genetic risk to human beings will increase with time. The Agency will closely monitor developments in mutagenicity evaluation and will refine its risk assessment scheme as better test systems become available.

II. Qualitative Assessment (Hazard Identification)

The assessment of potential human germ-cell mutagenic risk is a multistep process. The first step is an analysis of the evidence bearing on a chemical's ability to induce mutagenic events, while the second step involves an analysis of its ability to produce these events in the mammalian gonad. All relevant information is then integrated into a weight-of-evidence scheme which presents the strength of the information bearing on the chemical's potential ability to produce mutations in human germ cells. For chemicals demonstrating this potential, one may decide to proceed with an evaluation of the quantitative consequences of mutation following expected human exposure.

For hazard identification, it is clearly desirable to have data from mammalian germ-cell tests, such as the mouse specific-locus test for point mutations and the heritable translocation or germ-cell cytogenetic tests for structural chromosome aberrations. It is recognized, however, that in most instances such data will not be available, and alternative means of evaluation will be required. In such cases the Agency will evaluate the evidence bearing on the agent's mutagenic activity and the agent's ability to interact with or affect the mammalian gonadal target. When evidence exists that an agent possesses both these attributes, it is reasonable to deduce that the agent is a potential human germ-cell mutagen.

While mammalian germ-cell assays are presently primarily performed on male animals, a chemical cannot be considered to be a non-mutagen for mammalian germ cells unless it is shown to be negative in both sexes. Furthermore, because most mammalian germ-cell assays are performed in mice, it is noteworthy that the data from ionizing radiation suggest that the female mouse immature oocyte may not be an appropriate surrogate for the same stage in the human female in mutagenicity testing. However,

mutagenicity data on the maturing and mature oocyte of the mouse may provide a useful model for human risk assessment.

A. Mutagenic Activity

In evaluating chemicals for mutagenic activity, a number of factors will be considered: (1) genetic end points (e.g., gene mutations, structural or numerical chromosomal aberrations) detected by the test systems, (2) sensitivity and predictive value of the test systems for various classes of chemical compounds, (3) number of different test systems used for detecting each genetic end point, (4) consistency of the results obtained in different test systems and different species, (5) aspects of the dose-response relationship, and (6) whether the tests are conducted in accordance with appropriate test protocols agreed upon by experts in the field.

B. Chemical Interactions in the Mammalian Gonad

Evidence for chemical interaction in the mammalian gonad spans a range of different types of findings. Each chemical under consideration needs to be extensively reviewed since this type of evidence may be part of testing exclusive of mutagenicity per se (e.g., reproduction, metabolism, and mechanistic investigations). Although it is not possible to classify clearly each type of information that may be available on a chemical, two possible groups are illustrated.

1. *Sufficient evidence* of chemical interaction is given by the demonstration that an agent interacts with germ-cell DNA or other chromatin constituents, or that it induces such end points as unscheduled DNA synthesis, sister-chromatid exchange, or chromosomal abberations in germinal cells.

2. *Suggestive evidence* will include the finding of adverse gonadal effects such as sperm abnormalities following acute, subchronic, or chronic toxicity testing, or findings of adverse reproductive effects such as decreased fertility, which are consistent with the chemical's interaction with germ cells.

C. Weight-of-Evidence Determination

The evidence for a chemical's ability to produce mutations and to interact with the germinal target are integrated into a weight-of-evidence judgment that the agent may pose a hazard as a potential human germ-cell mutagen. All information bearing on the subject, whether indicative of potential concern or not, must be evaluated. Whatever evidence may exist from humans must also be factored into the assessment.

All germ-cell stages are important in evaluating chemicals because some chemicals have been shown to be positive in postgonial stages but not in gonia (18). When human exposures occur, effects on postgonial stages should be weighted by the relative sensitivity and the duration of the stages. Chemicals may show positive effects for some end points and in some test systems, but negative responses in others. Each review must take into account the limitations in the testing and in the types of responses that may exist.

To provide guidance as to the categorization of the weight of evidence, a classification scheme is presented to illustrate, in a simplified sense, the strength of the information bearing on the potential for human germ-cell mutagenicity. It is not possible to illustrate all potential combinations of evidence, and considerable judgment must be exercised in reaching conclusions. In addition, certain responses in tests that do not measure direct mutagenic end points (e.g., SCE induction in mammalian germ cells) may provide a basis for raising the weight of evidence from one category to another. The categories are presented in decreasing order of strength of evidence.

1. Positive data derived from human germ-cell mutagenicity studies, when available, will constitute the highest level of evidence for human mutagenicity.

2. Valid positive results from studies on heritable mutational events (of any kind) in mammalian germ cells.

3. Valid positive results from mammalian germ-cell chromosome aberration studies that do not include an intergeneration test.

4. Sufficient evidence for a chemical's interaction with mammalian germ cells, together with valid positive mutagenicity test results from two assay systems, at least one of which is mammalian (*in vitro* or *in vivo*). The positive results may both be for gene mutations or both for chromosome aberrations; if one is for gene mutations and the other for chromosome aberrations, both must be from mammalian systems.

5. Suggestive evidence for a chemical's interaction with mammalian germ cells, together with valid positive mutagenicity evidence from two assay systems as described under 4, above. Alternatively, positive mutagenicity evidence of less strength than defined under 4, above, when combined with sufficient evidence for a chemical's interaction with mammalian germ cells.

6. Positive mutagenicity test results of less strength than defined under 4, combined with suggestive evidence for a chemical's interaction with mammalian germ cells.

7. Although definitive proof of non-mutagenicity is not possible, a chemical could be classified operationally as a non-mutagen for human germ cells, if it gives valid negative test results for all end points of concern.

8. Inadequate evidence bearing on either mutagenicity or chemical interaction with mammalian germ cells.

III. Quantitative Assessment

The preceding section addressed primarily the processes of hazard identification, i.e., the determination of whether a substance is a potential germ-cell mutagen. Often, no further data will be available, and judgments will need to be based mainly on qualitative criteria. Quantitative risk assessment is a two-step process: determination of the heritable effect per unit of exposure (dose-response) and the relationship between mutation rate and disease incidence. The procedures that are presently accepted for the estimation of an increase in disease resulting from increased mutation have been described (3, 7, 8). Dose-response information is combined with anticipated levels and patterns of human exposure in order to derive a quantitative assessment (risk characterization).

A. Dose Response

Dose-response assessments can presently only be performed using data from *in vivo*, heritable mammalian germ-cell tests, until such time as other approaches can be demonstrated to have equivalent predictability. The morphological specific locus and biochemical specific locus assays can provide data on the frequencies of recessive mutations induced by different chemical exposure levels, and similar data can be obtained for heritable chromosomal damage using the heritable translocation test. Data on the frequencies of induced mutations resulting in health disorders in the first generation may be obtained from mouse systems designed to detect skeletal abnormalities, cataracts, or general morphological abnormalities. Assays that directly detect heritable health effects in the first generation may provide the best basis for predicting human health risks that result from mutagen exposure. The experimental data on induced mutation frequency are usually obtained at exposure levels much higher than those that will be experienced by human beings. An assessment of human risk is obtained by extrapolating the induced mutation frequency or the observed phenotypic

effect downward to the approximate level of anticipated human exposure. In performing these extrapolations, the Agency will place greater weight on data derived from exposures and exposure rates that most closely simulate those experienced by the human population under study.

The Agency will strive to use the most appropriate extrapolation models for risk analysis and will be guided by the available data and mechanistic considerations in this selection. However, it is anticipated that for tests involving germ cells of whole mammals, few dose points will be available to define dose-response functions. The Agency is aware that for at least one chemical that has been tested for mutations in mammalian germ cells, there exist departures from linearity at low exposure and exposure rates in a fashion similar to that seen for ionizing radiation that has a low linear energy transfer (19). The Agency will consider all relevant models for gene and chromosomal mutations in performing low-dose extrapolations and will choose the most appropriate model. This choice will be consistent both with the experimental data available and with current knowledge of relevant mutational mechanisms.

An experimental approach for quantitative assessment of genetic risk, which may have utility in the future, uses molecular dosimetry data from intact mammals in conjunction with mutagenicity and dosimetry data from other validated test systems (20). The intact mammal is used primarily for relating the exposure level for a given route of administration of a chemical to germ-cell dose, i.e., the level of mutagen-DNA interactions. This information is then used in conjunction with results obtained from mutagenicity test systems in which the relationship between the induction of mutations and chemical interactions with DNA can be derived. With mutagen-DNA interactions as the common denominator, a relationship can be constructed between mammalian exposure and the induced mutation frequency. The amount of DNA binding induced by a particular chemical agent may often be determined at levels of anticipated human exposure.

For some mutagenic events, DNA may not necessarily be the critical target. Interaction of chemicals with other macromolecules, such as tubulin, which is involved in the separation of chromosomes during nuclear division, can lead to chromosomal nondisjunction. At present, general approaches are not available for dose-response assessments for these types of mutations. Ongoing research should provide the means to make future assessments on chemicals causing aneuploidy.

B. Exposure Assessment

The exposure assessment identifies populations exposed to toxic chemicals; describes their composition and size; and presents the types, magnitudes, frequencies, and durations of exposure to the chemicals. This component is developed independently of the other components of the mutagenicity assessment (2).

C. Risk Characterization

In performing mutagenicity risk assessments, it is important to consider each genetic end point individually. For example, although certain chemical substances that interact with DNA may cause both point and chromosomal mutations, it is expected that the ratio of these events may differ among chemicals and between doses for a given chemical. Furthermore, transmissible chromosomal aberrations are recoverable with higher frequencies from meiotic and postmeiotic germ-cell stages, which have a brief life span, than in spermatogonial stem cells, which can accumulate genetic damage throughout the reproductive life of an individual. For these reasons, when data are available, the Agency, to the best extent possible, will assess risks associated with all genetic end points.

Any risk assessment should clearly delineate the strengths and weaknesses of the data, the assumptions made, the uncertainties in the methodology, and the rationale used in reaching the conclusions, e.g., similar or different routes of exposure and metabolic differences between humans and test animals. When possible, quantitative risk assessments should be expressed in terms of the estimated increase of genetic disease per generation, or the fractional increase in the assumed background spontaneous mutation rate of humans (7). Examples of quantitative risk estimates have been published (7, 8, 21); these examples may be of use in performing quantitative risk assessments for mutagens.

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Part B: Response to Public and Science Advisory Board Comments

This section summarizes some of the issues raised in public and Science Advisory Board (SAB) comments on the Proposed Guidelines for Mutagenicity Risk Assessment published on November 23, 1984 (49 FR 46314). Unlike the other guidelines published on the same date, the Proposed Guidelines for Mutagenicity Risk Assessment contained a detailed section dealing with public comments received in response to the original proposal of 1980 (45 FR 74984). Several of the comments received in response to the proposed guidelines of 1984 were similar to those received in response to the proposed guidelines of 1980. Those comments are not addressed here because the position of the Agency on those issues has been presented in the responses included with the 1984 proposed guidelines (49 FR 46315–46316).

A total of 44 comments were received in response to the proposed guidelines of 1984: 21 from manufacturers of regulated products, 10 from associations, 9 from government agencies, 2 from educational institutions, 1 from an individual, and 1 from a private consulting firm. The proposed guidelines and the public comments received were transmitted to the Agency's SAB prior to its public review of the proposed guidelines held April 22–23, 1985. The majority of the comments were favorable and expressed the opinion that the proposed guidelines accurately represent the existing state of knowledge in the field of mutagenesis. Several commentors offered suggestions for further clarification of particular issues, and many of the suggestions have been incorporated.

The two areas that received the most substantive comments were the sections concerning Weight-of-Evidence Determination and Dose Response. The comments on the proposed weight-of-evidence scheme ranged from suggestions for the elimination of a formal scheme to the expansion of the scheme to cover more potential data configurations. The SAB recommended an eight-level rank ordering scheme to define levels of evidence relating to human germ-cell mutagenicity. The Agency has incorporated this scheme into the Guidelines. Some commentors and the SAB suggested that the molecular dosimetry approach to dose-response data be presented as a concept that may be useful in the future rather than being available for use now. The Agency agrees that the data base at the present time is too sparse to recommend a general application of this approach to a wide range of chemical classes, and the Guidelines have been changed to reflect this. It should be noted, however, that the Agency strongly supports the development of molecular dosimetry methodologies as they relate to both an understanding of dose-response relationships and to methods for studying human exposure. A number of comments suggesting clarifications and editorial changes have been incorporated and the references have been expanded.

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September 24, 1986

Part IV

Environmental Protection Agency

Guidelines for the Health Risk Assessment of Chemical Mixtures

ENVIRONMENTAL PROTECTION AGENCY

[FRL-2984-2]

Guidelines for the Health Risk Assessment of Chemical Mixtures

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final Guidelines for the Health Risk Assessment of Chemical Mixtures.

SUMMARY: The U.S. Environmental Protection Agency is today issuing five guidelines for assessing the health risks of environmental pollutants. These are:

Guidelines for Carcinogen Risk Assessment
Guidelines for Estimating Exposures
Guidelines for Mutagenicity Risk Assessment
Guidelines for the Health Assessment of Suspect Developmental Toxicants
Guidelines for the Health Risk Assessment of Chemical Mixtures

This notice contains the Guidelines for the Health Risk Assessment of Chemical Mixtures; the other guidelines appear elsewhere in today's **Federal Register.**

The Guidelines for the Health Risk Assessment of Chemical Mixtures (hereafter "Guidelines") are intended to guide Agency analysis of information relating to health effects data on chemical mixtures in line with the policies and procedures established in the statutes administered by the EPA. These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Office of Health and Environmental Assessment (OHEA) in the Agency's Office of Research and Development. They reflect Agency consideration of public and Science Advisory Board (SAB) comments on the Proposed Guidelines for the Health Risk Assessment of Chemical Mixtures published January 9, 1985 (50 FR 1170).

This publication completes the first round of risk assessment guidelines development. These Guidelines will be revised, and new guidelines will be developed, as appropriate.

EFFECTIVE DATE: The Guidelines will be effective September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Dr. Richard Hertzberg, Methods Evaluation and Development Staff, Environmental Criteria and Assessment Office, U.S. Environmental Protection Agency, 26 W. St. Clair Street, Cincinnati, OH 45268, 513-569-7582.

SUPPLEMENTARY INFORMATION: In 1983, the National Academy of Sciences (NAS) published its book entitled *Risk Assessment in the Federal Government: Managing the Process.* In that book, the NAS 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. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

General

The guidelines published today are products of a two-year Agencywide effort, which has included many scientists from the larger scientific community. These guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments, and to inform Agency decision makers and the public about these procedures. In particular, the guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific information on each agent and use the most scientifically appropriate interpretation to assess risk. The guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Finally, the guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Guidelines for Health Risk Assessment of Chemical Mixtures

Work on the Guidelines for the Health Risk Assessment of Chemical Mixtures began in January 1984. Draft guidelines were developed by Agency work groups composed of expert scientists from throughout the Agency. The drafts were peer-reviewed by expert scientists in the fields of toxicology, pharmacokinetics, and statistics from universities, environmental groups, industry, labor, and other governmental agencies. They were then proposed for public comment in the **Federal Register** (50 FR 1170). On November 9, 1984, the Administrator directed that Agency offices use the proposed guidelines in performing risk assessments until final guidelines become available.

After the close of the public comment period, Agency staff prepared summaries of the comments, analyses of the major issues presented by the commentors, and preliminary Agency responses to those comments. These analyses were presented to review panels of the SAB on March 4 and April 22-23, 1985, and to the Executive Committee of the SAB on April 25-26, 1985. The SAB meetings were announced in the **Federal Register** as follows: February 12, 1985 (50 FR 5811) and April 4, 1985 (50 FR 13420 and 13421).

In a letter to the Administrator dated June 19, 1985, the Executive Committee generally concurred on all five of the guidelines, but recommended certain revisions, and requested that any revised guidelines be submitted to the appropriate SAB review panel chairman for review and concurrence on behalf of the Executive Committee. As described in the responses to comments (see Part B: Response to the Public and Science Advisory Board Comments), each guidelines document was revised, where appropriate, consistent with the SAB recommendations, and revised draft guidelines were submitted to the panel chairmen. Revised draft Guidelines for the Health Risk Assessment of chemical mixtures were concurred on in a letter dated August 16, 1985. Copies of the letters are available at the Public Information Reference Unit, EPA Headquarters Library, as indicated elsewhere in this notice.

Following this Preamble are two parts: Part A contains the Guidelines and Part B, the Response to the Public and Science Advisory Board Comments (a summary of the major public comments, SAB comments, and Agency responses to those comments).

The SAB requested that the Agency develop a technical support document for these Guidelines. The SAB identified the need for this type of document due to the limited knowledge on interactions of chemicals in biological systems. Because of this, the SAB commented that progress in improving risk assessment will be particularly dependent upon progress in the science of interactions.

Agency staff have begun preliminary work on the technical support document and expect it to be completed by early 1987. The Agency is continuing to study the risk assessment issues raised in the guidelines and will revise these Guidelines in line with new information as appropriate.

References, supporting documents, and comments received on the proposed guidelines, as well as copies of the final guidelines, are available for inspection and copying at the Public Information Reference Unit (202–382–5926), EPA Headquarters Library, 401 M Street, SW, Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m.

I certify that these Guidelines are not major rules as defined by Executive Order 12291, because they are nonbinding policy statements and have no direct effect on the regulated community. Therefore, they will have no effect on costs or prices, and they will have no other significant adverse effects on the economy. These Guidelines were reviewed by the Office of Management and Budget under Executive Order 12291.

Dated: August 22, 1986.

Lee M. Thomas,

Administrator.

Contents

Part A: Guidelines for the Health Risk Assessment of Chemical Mixtures

I. Introduction

The primary purpose of this document is to generate a consistent Agency approach for evaluating data on the chronic and subchronic effects of chemical mixtures. It is a procedural guide that emphasizes broad underlying principles of the various science disciplines (toxicology, pharmacology, statistics) necessary for assessing health risk from chemical mixture exposure. Approaches to be used with respect to the analysis and evaluation of the various data are also discussed.

It is not the intent of these Guidelines to regulate any social or economic aspects concerning risk of injury to human health or the environment caused by exposure to a chemical agent(s). All such action is addressed in specific statutes and federal legislation and is independent of these Guidelines.

While some potential environmental hazards involve significant exposure to only a single compound, most instances of environmental contamination involve concurrent or sequential exposures to a mixture of compounds that may induce similar or dissimilar effects over exposure periods ranging from short-term to lifetime. For the purposes of these Guidelines, mixtures will be defined as any combination of two or more chemical substances regardless of source or of spatial or temporal proximity. In some instances, the mixtures are highly complex consisting of scores of compounds that are generated simultaneously as by-products from a single source or process (e.g., coke oven emissions and diesel exhaust). In other cases, complex mixtures of related compounds are produced as commercial products (e.g., PCBs, gasoline and pesticide formulations) and eventually released to the environment. Another class of mixtures consists of compounds, often unrelated chemically or commercially, which are placed in the same area for disposal or storage, eventually come into contact with each other, and are released as a mixture to the environment. The quality and quantity of pertinent information available for risk assessment varies considerably for different mixtures. Occasionally, the chemical composition of a mixture is well characterized, levels of exposure to the population are known, and detailed toxicologic data on the mixture are available. Most frequently, not all components of the mixture are known, exposure data are uncertain, and toxicologic data on the known components of the mixture are limited. Nonetheless, the Agency may be required to take action because of the number of individuals at potential risk or because of the known toxicologic effects of these compounds that have been identified in the mixture.

The prediction of how specific mixtures of toxicants will interact must be based on an understanding of the mechanisms of such interactions. Most reviews and texts that discuss toxicant interactions attempt to discuss the biological or chemical bases of the interactions (e.g., Klaassen and Doull, 1980; Levine, 1973; Goldstein et al., 1974; NRC, 1980a; Veldstra, 1956; Withey, 1981). Although different authors use somewhat different classification schemes when discussing the ways in which toxicants interact, it generally is recognized that toxicant interactions may occur during any of the toxicologic processes that take place with a single compound: absorption, distribution, metabolism, excretion, and activity at the receptor site(s). Compounds may interact chemically, yielding a new toxic component or causing a change in the biological availability of the existing component. They may also interact by causing different effects at different receptor sites.

Because of the uncertainties inherent in predicting the magnitude and nature of toxicant interactions, the assessment of health risk from chemical mixtures must include a thorough discussion of all assumptions. No single approach is recommended in these Guidelines. Instead, guidance is given for the use of several approaches depending on the nature and quality of the data. Additional mathematical details are presented in section IV.

In addition to these Guidelines, a supplemental technical support document is being developed which will contain a thorough review of all available information on the toxicity of chemical mixtures and a discussion of research needs.

II. Proposed Approach

No single approach can be recommended to risk assessments for multiple chemical exposures. Nonetheless, general guidelines can be recommended depending on the type of mixture, the known toxic effects of its components, the availability of toxicity data on the mixture or similar mixtures,

the known or anticipated interactions among components of the mixture, and the quality of the exposure data. Given the complexity of this issue and the relative paucity of empirical data from which sound generalizations can be constructed, emphasis must be placed on flexibility, judgment, and a clear articulation of the assumptions and limitations in any risk assessment that is developed. The proposed approach is summarized in Table 1 and Figure 1 and is detailed below. An alphanumeric scheme for ranking the quality of the data used in the risk assessment is given in Table 2.

A. Data Available on the Mixture of Concern

For predicting the effects of subchronic or chronic exposure to mixtures, the preferred approach usually will be to use subchronic or chronic health effects data on the mixture of concern and adopt procedures similar to those used for single compounds, either systemic toxicants or carcinogens (see U.S. EPA, 1986a–c). The risk assessor must recognize, however, that dose-response models used for single compounds are often based on biological mechanisms of the toxicity of single compounds, and may not be as well justified when applied to the mixture as a whole. Such data are most likely to be available on highly complex mixtures, such as coke oven emissions or diesel exhaust, which are generated in large quantities and associated with or suspected of causing adverse health effects. Attention should also be given to the persistence of the mixture in the environment as well as to the variability of the mixture composition over time or from different sources of emissions. If the components of the mixture are known to partition into different environmental compartments or to degrade or transform at different rates in the environment, then those factors must also be taken into account, or the confidence in and applicability of the risk assessment is diminished.

Table 1.—Risk Assessment Approach for Chemical Mixtures

1. Assess the quality of the data on interactions, health effects, and exposure (see Table 2).
   a. If adequate, proceed to Step 2.
   b. If inadequate, proceed to Step 14.
2. Health effects information is available on the chemical mixture of concern.
   a. If yes, proceed to Step 3.
   b. If no, proceed to Step 4.
3. Conduct risk assessment on the mixture of concern based on health effects data on the mixture. Use the same procedures as those for single compounds. Proceed to Step 7 (optional) and Step 12.
4. Health effects information is available on a mixture that is similar to the mixture of concern.
   a. If yes, proceed to Step 5.
   b. If no, proceed to Step 7.
5. Assess the similarity of the mixture on which health effects data are available to the mixture of concern, with emphasis on any differences in components or proportions of components, as well as the effects that such differences would have on biological activity.
   a. If sufficiently similar, proceed to Step 6.
   b. If not sufficiently similar, proceed to Step 7.
6. Conduct risk assessment on the mixture of concern based on health effects data on the similar mixture. Use the same procedures as those for single compounds. Proceed to Step 7 (optional) and Step 12.
7. Compile health effects and exposure information on the components of the mixture.
8. Derive appropriate indices of acceptable exposure and/or risk on the individual components in the mixture. Proceed to Step 9.
9. Assess data on interactions of components in the mixtures.
   a. If sufficient quantitative data are available on the interactions of two or more components in the mixture, proceed to Step 10.
   b. If sufficient quantitative data are not available, use whatever information is available to qualitatively indicate the nature of potential interactions. Proceed to Step 11.
10. Use an appropriate interaction model to combine risk assessments on compounds for which data are adequate, and use an additivity assumption for the remaining compounds. Proceed to Step 11 (optional) and Step 12.
11. Develop a risk assessment based on an additivity approach for all compounds in the mixture. Proceed to Step 12.
12. Compare risk assessments conducted in Steps 5, 8, and 9. Identify and justify the preferred assessment, and quantify uncertainty, if possible. Proceed to Step 13.
13. Develop an integrated summary of the qualitative and quantitative assessments with special emphasis on uncertainties and assumptions. Classify the overall quality of the risk assessment, as indicated in Table 2. Stop.
14. No risk assessment can be conducted because of inadequate data on interactions, health effects, or exposure. Qualitatively assess the nature of any potential hazard and detail the types of additional data necessary to support a risk assessment. Stop.

Note.—Several decisions used here, especially those concerning adequacy of data and similarity between two mixtures, are not precisely characterized and will require considerable judgment. See text.

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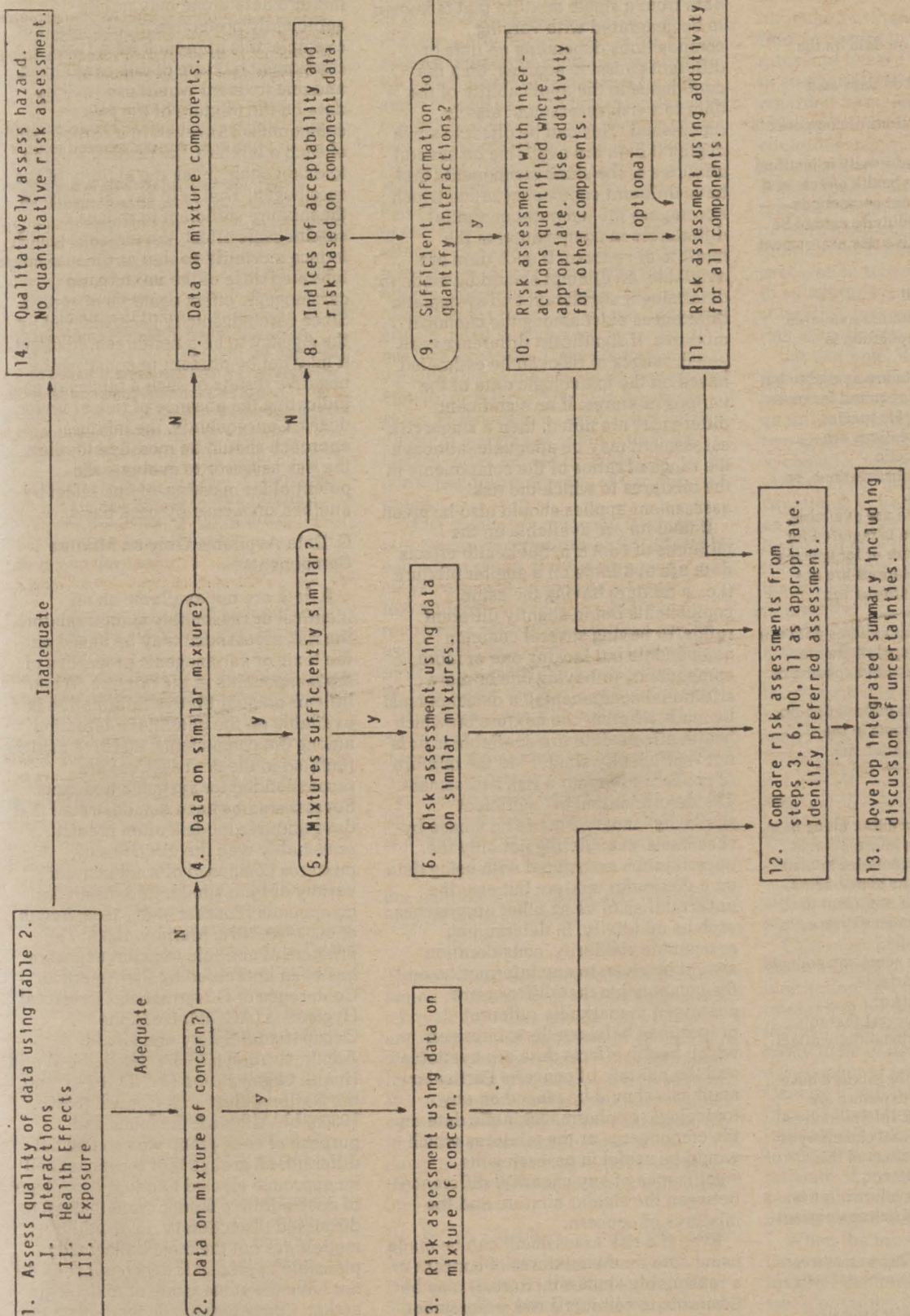

Figure 1. Flow chart of the risk assessment approach in Table 1. Note that it may be desirable to conduct all three assessments when possible (i.e., using data on the mixture, a similar mixture, or the components) in order to make the fullest use of the available data. See text for further discussion.

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Table 2.—Classification Scheme for the Quality of the Risk Assessment of the Mixture [a]

Information on Interactions

I. Assessment is based on data on the mixture of concern.

II. Assessment is based on data on a sufficiently similar mixture.

III. Quantitative interactions of components are well characterized.

IV. The assumption of additivity is justified based on the nature of the health effects and on the number of component compounds.

V. An assumption of additivity cannot be justified, and no quantitative risk assessment can be conducted.

Health Effects Information

A. Full health effects data are available and relatively minor extrapolation is required.

B. Full health effects data are available but extensive extrapolation is required for route or duration of exposure or for species differences. These extrapolations are supported by pharmacokinetic considerations, empirical observations, or other relevant information.

C. Full health effects data are available, but extensive extrapolation is required for route or duration of exposure or for species differences. These extrapolations are not directly supported by the information available.

D. Certain important health effects data are lacking and extensive extrapolations are required for route or duration of exposure or for species differences.

E. A lack of health effects information on the mixture and its components in the mixture precludes a quantitative risk assessment.

Exposure Information[b]

1. Monitoring information either alone or in combination with modeling information is sufficient to accurately characterize human exposure to the mixture or its components.

2. Modeling information is sufficient to reasonably characterize human exposure to the mixture or its components.

3. Exposure estimates for some components are lacking, uncertain, or variable. Information on health effects or environmental chemistry suggest that this limitation is not likely to substantially affect the risk assessment.

4. Not all components in the mixture have been identified or levels of exposure are highly uncertain or variable. Information on health effects or environmental chemistry is not sufficient to assess the effect of this limitation on the risk assessment.

5. The available exposure information is insufficient for conducting a risk assessment.

[a] See text for discussion of sufficient similarity, adequacy of data, and justification for additivity assumptions.

[b] See the Agency's Guidelines for Estimating Exposures (U.S. EPA, 1986d) for more complete information on performing exposure assessments and evaluating the quality of exposure data.

B. Data Available on Similar Mixtures

If the risk assessment is based on data from a single mixture that is known to be generated with varying compositions depending on time or different emission sources, then the confidence in the applicability of the data to a risk assessment also is diminished. This can be offset to some degree if data are available on several mixtures of the same components that have different component ratios which encompass the temporal or spatial differences in composition of the mixture of concern. If such data are available, an attempt should be made to determine if significant and systematic differences exist among the chemical mixtures. If significant differences are noted, ranges of risk can be estimated based on the toxicologic data of the various mixtures. If no significant differences are noted, then a single risk assessment may be adequate, although the range of ratios of the components in the mixtures to which the risk assessment applies should also be given.

If no data are available on the mixtures of concern, but health effects data are available on a similar mixture (i.e., a mixture having the same components but in slightly different ratios, or having several common components but lacking one or more components, or having one or more additional components), a decision must be made whether the mixture on which health effects data are available is or is not "sufficiently similar" to the mixture of concern to permit a risk assessment. The determination of "sufficient similarity" must be made on a case-by-case basis, considering not only the uncertainties associated with using data on a dissimilar mixture but also the uncertainties of using other approaches such as additivity. In determining reasonable similarity, consideration should be given to any information on the components that differ or are contained in markedly different proportions between the mixture on which health effects data are available and the mixture of concern. Particular emphasis should be placed on any toxicologic or pharmacokinetic data on the components or the mixtures which would be useful in assessing the significance of any chemical difference between the similar mixture and the mixtures of concern.

Even if a risk assessment can be made using data on the mixtures of concern or a reasonably similar mixture, it may be desirable to conduct a risk assessment based on toxicity data on the components in the mixture using the procedure outlined in section II.B. In the case of a mixture containing carcinogens and toxicants, an approach based on the mixture data alone may not be sufficiently protective in all cases. For example, this approach for a two-component mixture of one carcinogen and one toxicant would use toxicity data on the mixture of the two compounds. However, in a chronic study of such a mixture, the presence of the toxicant could mask the activity of the carcinogen. That is to say, at doses of the mixture sufficient to induce a carcinogenic effect, the toxicant could induce mortality so that at the maximum tolerated dose of the mixture, no carcinogenic effect could be observed. Since carcinogenicity is considered by the Agency to be a nonthreshold effect, it may not be prudent to construe the negative results of such a bioassay as indicating the absence of risk at lower doses. Consequently, the mixture approach should be modified to allow the risk assessor to evaluate the potential for masking, of one effect by another, on a case-by-case basis.

C. Data Available Only on Mixture Components

If data are not available on an identical or reasonably similar mixture, the risk assessment may be based on the toxic or carcinogenic properties of the components in the mixture. When little or no quantitative information is available on the potential interaction among the components, additive models (defined in the next section) are recommended for systemic toxicants. Several studies have demonstrated that dose additive models often predict reasonably well the toxicities of mixtures composed of a substantial variety of both similar and dissimilar compounds (Pozzani et al., 1959; Smyth et al., 1969, 1970; Murphy, 1980). The problem of multiple toxicant exposure has been addressed by the American Conference of Governmental Industrial Hygienists (ACGIH, 1983), the Occupational Safety and Health Administration (OSHA, 1983), the World Health Organization (WHO, 1981), and the National Research Council (NRC, 1980a, b). Although the focus and purpose of each group was somewhat different, all groups that recommended an approach elected to adopt some type of dose additive model. Nonetheless, as discussed in section IV, dose additive models are not the most biologically plausible approach if the compounds do not have the same mode of toxicologic action. Consequently, depending on the nature of the risk assessment and the available information on modes of action and patterns of joint action, the

most reasonable additive model should be used.

1. *Systemic Toxicants.* For systemic toxicants, the current risk assessment methodology used by the Agency for single compounds most often results in the derivation of an exposure level which is not anticipated to cause significant adverse effects. Depending on the route of exposure, media of concern, and the legislative mandate guiding the risk assessments, these exposure levels may be expressed in a variety of ways such as acceptable daily intakes (ADIs) or reference doses (RfDs), levels associated with various margins of safety (MOS), or acceptable concentrations in various media. For the purpose of this discussion, the term "acceptable level" (AL) will be used to indicate any such criteria or advisories derived by the Agency. Levels of exposure (E) will be estimates obtained following the most current Agency Guidelines for Estimating Exposures (U.S. EPA, 1986d). For such estimates, the "hazard index" (HI) of a mixture based on the assumption of dose addition may be defined as:

$$HI = E_1/AL_1 + E_2/AL_2 + \ldots + E_i/AL_i \quad (II\text{–}1)$$

where:

E_i = exposure level to the i^{th} toxicant* and
AL_i = maximum acceptable level for the i^{th} toxicant.

Since the assumption of dose addition is most properly applied to compounds that induce the same effect by similar modes of action, a separate hazard index should be generated for each end point of concern. Dose addition for dissimilar effects does not have strong scientific support, and, if done, should be justified on a case-by-case basis in terms of biological plausibility.

The assumption of dose addition is most clearly justified when the mechanisms of action of the compounds under consideration are known to be the same. Since the mechanisms of action for most compounds are not well understood, the justification of the assumption of dose addition will often be limited to similarities in pharmacokinetic and toxicologic characteristics. In any event, if a hazard index is generated, the quality of the experimental evidence supporting the assumption of dose addition must be clearly articulated.

The hazard index provides a rough measure of likely toxicity and requires cautious interpretation. The hazard index is only a numerical indication of the nearness to acceptable limits of exposure or the degree to which acceptable exposure levels are exceeded. As this index approaches unity, concern for the potential hazard of the mixture increases. If the index exceeds unity, the concern is the same as if an individual chemical exposure exceeded its acceptable level by the same proportion. The hazard index does not define dose-response relationships, and its numerical value should not be construed to be a direct estimate of risk. Nonetheless, if sufficient data are available to derive individual acceptable levels for a spectrum of effects (e.g., MFO induction, minimal effects in several organs, reproductive effects, and behavioral effects), the hazard index may suggest what types of effects might be expected from the mixture exposure. If the components' variabilities of the acceptable levels are known, or if the acceptable levels are given as ranges (e.g., associated with different margins of safety), then the hazard index should be presented with corresponding estimates of variation or range.

Most studies on systemic toxicity report only descriptions of the effects in each dose group. If dose-response curves are estimated for systemic toxicants, however, dose-additive or response-additive assumptions can be used, with preference given to the most biologically plausible assumption (see section IV for the mathematical details).

2. *Carcinogens.* For carcinogens, whenever linearity of the individual dose-response curves has been assumed (usually restricted to low doses), the increase in risk P (also called excess or incremental risk), caused by exposure d, is related to carcinogenic potency B, as:

$$P = d\,B \quad (II\text{–}2)$$

For multiple compounds, this equation may be generalized to:

$$P = \Sigma\, d_i B_i \quad (II\text{–}3)$$

This equation assumes independence of action by the several carcinogens and is equivalent to the assumption of dose addition as well as to response addition with completely negative correlation of tolerance, as long as $P < 1$ (see section IV). Analogous to the procedure used in equation II–1 for systemic toxicants, an index for n carcinogens can be developed by dividing exposure levels (E) by doses (DR) associated with a set level of risk:

$$HI = E_1/DR_1 + E_2/DR_2 + \ldots + E_n/DR_n \quad (II\text{–}4)$$

Note that the less linear the dose-response curve is, the less appropriate equations II–3 and II–4 will be, perhaps even at low doses. It should be emphasized that because of the uncertainties in estimating dose-response relationships for single compounds, and the additional uncertainties in combining the individual estimate to assess response from exposure to mixtures, response rates and hazard indices may have merit in comparing risks but should not be regarded as measures of absolute risk.

3. *Interactions.* None of the above equations incorporates any form of synergistic or antagonistic interaction. Some types of information, however, may be available that suggest that two or more components in the mixture may interact. Such information must be assessed in terms of both its relevance to subchronic or chronic hazard and its suitability for quantitatively altering the risk assessment.

For example, if chronic or subchronic toxicity or carcinogenicity studies have been conducted that permit a quantitative estimation of interaction for two chemicals, then it may be desirable to consider using equations detailed in section IV, or modifications of these equations, to treat the two compounds as a single toxicant with greater or lesser potency than would be predicted from additivity. Other components of the mixture, on which no such interaction data are available, could then be separately treated in an additive manner. Before such a procedure is adopted, however, a discussion should be presented of the likelihood that other compounds in the mixture may interfere with the interaction of the two toxicants on which quantitative interaction data are available. If the weight of evidence suggests that interference is likely, then a quantitative alteration of the risk assessment may not be justified. In such cases, the risk assessment may only indicate the likely nature of interactions, either synergistic or antagonistic, and not quantify their magnitudes.

Other types of information, such as those relating to mechanisms of toxicant interaction, or quantitative estimates of interaction between two chemicals derived from acute studies, are even less likely to be of use in the quantitative assessment of long-term health risks. Usually it will be appropriate only to discuss these types of information, indicate the relevance of the information to subchronic or chronic exposure, and indicate, if possible, the nature of potential interactions, without attempting to quantify their magnitudes.

When the interactions are expected to have a minor influence on the mixture's toxicity, the assessment should indicate, when possible, the compounds most responsible for the predicted toxicity. This judgment should be based on predicted toxicity of each component,

* See the Agency's guidelines (U.S. EPA, 1986d) for information on how to estimate this value.

based on exposure and toxic or carcinogenic potential. This potential alone should not be used as an indicator of the chemicals posing the most hazard.

4. *Uncertainties.* For each risk assessment, the uncertainties should be clearly discussed and the overall quality of the risk assessment should be characterized. The scheme outlined in Table 2 should be used to express the degree of confidence in the quality of the data on interaction, health effects, and exposure.

a. Health Effects—In some cases, when health effects data are incomplete, it may be possible to argue by analogy or quantitative structure-activity relationships that the compounds on which no health effects data are available are not likely to significantly affect the toxicity of the mixture. If a risk assessment includes such an argument, the limitations of the approach must be clearly articulated. Since a methodology has not been adopted for estimating an acceptable level (e.g., ADI) or carcinogenic potential for single compounds based either on quantitative structure-activity relationships or on the results of short-term screening tests, such methods are not at present recommended as the sole basis of a risk assessment on chemical mixtures.

b. Exposure Uncertainties—The general uncertainties in exposure assessment have been addressed in the Agency's Guidelines for Estimating Exposures (U.S. EPA, 1986d). The risk assessor should discuss these exposure uncertainties in terms of the strength of the evidence used to quantify the exposure. When appropriate, the assessor should also compare monitoring and modeling data and discuss any inconsistencies as a source of uncertainty. For mixtures, these uncertainties may be increased as the number of compounds of concern increases.

If levels of exposure to certain compounds known to be in the mixture are not available, but information on health effects and environmental persistence and transport suggest that these compounds are not likely to be significant in affecting the toxicity of the mixture, then a risk assessment can be conducted based on the remaining compounds in the mixture, with appropriate caveats. If such an argument cannot be supported, no final risk assessment can be performed until adequate monitoring data are available. As an interim procedure, a risk assessment may be conducted for those components in the mixture for which adequate exposure and health effects data are available. If the interim risk assessment does not suggest a hazard, there is still concern about the risk from such a mixture because not all components in the mixture have been considered.

c. Uncertainties Regarding Composition of the Mixture—In perhaps a worst case scenario, information may be lacking not only on health effects and levels of exposure, but also on the identity of some components of the mixture. Analogous to the procedure described in the previous paragraph, an interim risk assessment can be conducted on those components of the mixture for which adequate health effects and exposure information are available. If the risk is considered unacceptable, a conservative approach is to present the quantitative estimates of risk, along with appropriate qualifications regarding the incompleteness of the data. If no hazard is indicated by this partial assessment, the risk assessment should not be quantified until better health effects and monitoring data are available to adequately characterize the mixture exposure and potential hazards.

III. Assumptions and Limitations

A. Information on Interactions

Most of the data available on toxicant interactions are derived from acute toxicity studies using experimental animals in which mixtures of two compounds were tested, often in only a single combination. Major areas of uncertainty with the use of such data involve the appropriateness of interaction data from an acute toxicity study for quantitatively altering a risk assessment for subchronic or chronic exposure, the appropriateness of interaction data on two component mixtures for quantitatively altering a risk assessment on a mixture of several compounds, and the accuracy of interaction data on experimental animals for quantitatively predicting interactions in humans.

The use of interaction data from acute toxicity studies to assess the potential interactions on chronic exposure is highly questionable unless the mechanism(s) of the interaction on acute exposure were known to apply to low-dose chronic exposure. Most known biological mechanisms for toxicant interactions, however, involve some form of competition between the chemicals or phenomena involving saturation of a receptor site or metabolic pathway. As the doses of the toxicants are decreased, it is likely that these mechanisms either no longer will exert a significant effect or will be decreased to an extent that cannot be measured or approximated.

The use of information from two-component mixtures to assess the interactions in a mixture containing more than two compounds also is questionable from a mechanistic perspective. For example, if two compounds are known to interact, either synergistically or antagonistically, because of the effects of one compound on the metabolism or excretion of the other, the addition of a third compound which either chemically alters or affects the absorption of one of the first two compounds could substantially alter the degree of the toxicologic interaction. Usually, detailed studies quantifying toxicant interactions are not available on multicomponent mixtures, and the few studies that are available on such mixtures (e.g., Gullino et al., 1956) do not provide sufficient information to assess the effects of interactive interference.

Concerns with the use of interaction data on experimental mammals to assess interactions in humans is based on the increasing appreciation for systematic differences among species in their response to individual chemicals. If systematic differences in toxic sensitivity to single chemicals exist among species, then it seems reasonable to suggest that the magnitude of toxicant interactions among species also may vary in a systematic manner. Consequently, even if excellent chronic data are available on the magnitude of toxicant interactions in a species of experimental mammal, there is uncertainty that the magnitude of the interaction will be the same in humans. Again, data are not available to properly assess the significance of this uncertainty.

Last, it should be emphasized that none of the models for toxicant interaction can predict the magnitude of toxicant interactions in the absence of extensive data. If sufficient data are available to estimate interaction coefficients as described in section IV, then the magnitude of the toxicant interactions for various proportions of the same components can be predicted. The availability of an interaction ratio (observed response divided by predicted response) is useful only in assessing the magnitude of the toxicant interaction for the specific proportions of the mixture which was used to generate the interaction ratio.

The basic assumption in the recommended approach is that risk assessments on chemical mixtures are best conducted using toxicologic data on the mixture of concern or a reasonably similar mixture. While such risk

assessments do not formally consider toxicologic interactions as part of a mathematical model, it is assumed that responses in experimental mammals or human populations noted after exposure to the chemical mixture can be used to conduct risk assessments on human populations. In bioassays of chemical mixtures using experimental mammals, the same limitations inherent in species-to-species extrapolation for single compounds apply to mixtures. When using health effects data on chemical mixtures from studies on exposed human populations, the limitations of epidemiologic studies in the risk assessment of single compounds also apply to mixtures. Additional limitations may be involved when using health effects data on chemical mixtures if the components in the mixture are not constant or if the components partition in the environment.

B. Additivity Models

If sufficient data are not available on the effects of the chemical mixture of concern or a reasonably similar mixture, the proposed approach is to assume additivity. Dose additivity is based on the assumption that the components in the mixture have the same mode of action and elicit the same effects. This assumption will not hold true in most cases, at least for mixtures of systemic toxicants. For systemic toxicants, however, most single compound risk assessments will result in the derivation of acceptable levels, which, as currently defined, cannot be adapted to the different forms of response additivity as described in section IV.

Additivity models can be modified to incorporate quantitative data on toxicant interactions from subchronic or chronic studies using the models given in section IV or modifications of these models. If this approach is taken, however, it will be under the assumption that other components in the mixture do not interfere with the measured interaction. In practice, such subchronic or chronic interactions data seldom will be available. Consequently, most risk assessments (on mixtures) will be based on an assumption of additivity, as long as the components elicit similar effects.

Dose-additive and response-additive assumptions can lead to substantial errors in risk estimates if synergistic or antagonistic interactions occur. Although dose additivity has been shown to predict the acute toxicities of many mixtures of similar and dissimilar compounds (e.g., Pozzani et al., 1959; Smyth et al., 1969, 1970; Murphy, 1980), some marked exceptions have been noted. For example, Smyth et al. (1970) tested the interaction of 53 pairs of industrial chemicals based on acute lethality in rats. For most pairs of compounds, the ratio of the predicted LD_{50} to observed LD_{50} did not vary by more than a factor of 2. The greatest variation was seen with an equivolume mixture of morpholine and toluene, in which the observed LD_{50} was about fives times less than the LD_{50} predicted by dose addition. In a study by Hammond et al. (1979), the relative risk of lung cancer attributable to smoking was 11, while the relative risk associated with asbestos exposure was 5. The relative risk of lung cancer from both smoking and asbestos exposure was 53, indicating a substantial synergistic effect. Consequently, in some cases, additivity assumptions may substantially underestimate risk. In other cases, risk may be overestimated. While this is certainly an unsatisfactory situation, the available data on mixtures are insufficient for estimating the magnitude of these errors. Based on current information, additivity assumptions are expected to yield generally neutral risk estimates (i.e., neither conservative nor lenient) and are plausible for component compounds that induce similar types of effects at the same sites of action.

IV. Mathematical Models and the Measurement of Joint Action

The simplest mathematical models for joint action assume no interaction in any mathematical sense. They describe either dose addition or response addition and are motivated by data on acute lethal effects of mixtures of two compounds.

A. Dose Addition

Dose addition assumes that the toxicants in a mixture behave as if they were dilutions or concentrations of each other, thus the true slopes of the dose-response curves for the individual compounds are identical, and the response elicited by the mixture can be predicted by summing the individual doses after adjusting for differences in potency; this is defined as the ratio of equitoxic doses. Probit transformation typically makes this ratio constant at all doses when parallel straight lines are obtained. Although this assumption can be applied to any model (e.g., the one-hit model in NRC, 1980b), it has been most often used in toxicology with the log-dose probit response model, which will be used to illustrate the assumption of dose addition. Suppose that two toxicants show the following log-dose probit response equations:

$$Y_1 = 0.3 + 3 \log Z_1 \qquad \text{(IV-1)}$$
$$Y_2 = 1.2 + 3 \log Z_2 \qquad \text{(IV-2)}$$

where Y_i is the probit response associated with a dose of Z_i ($i=1, 2$). The potency, p, of toxicant #2 with respect to toxicant #1 is defined by the quantity Z_1/Z_2 when $Y_1 = Y_2$ (that is what is meant by equitoxic doses). In this example, the potency, p, is approximately 2. Dose addition assumes that the response, Y, to any mixture of these two toxicants can be predicted by:

$$Y = 0.3 + 3 \log (Z_1 + pZ_2) \qquad \text{(IV-3)}$$

Thus, since p is defined as Z_1/Z_2, equation IV-3 essentially converts Z_2 into an equivalent dose of Z_1 by adjusting for the difference in potency. A more generalized form of this equation for any number of toxicants is:

$$Y = a_1 + b \log (f_1 + \Sigma f_i p_i) + b \log Z \qquad \text{(IV-4)}$$

where:

a_1 = the y-intercept of the dose-response equation for toxicant #1
b = the slope of the dose-response lines for the toxicants
f_i = the proportion of the i^{th} toxicant in the mixture
p_i = the potency of the i^{th} toxicant with respect to toxicant #1 (i.e., Z_1/Z_i), and
Z = the sum of the individual doses in the mixture.

A more detailed discussion of the derivation of the equations for dose addition is presented by Finney (1971).

B. Response Addition

The other form of additivity is referred to as response addition. As detailed by Bliss (1939), this type of joint action assumes that the two toxicants act on different receptor systems and that the correlation of individual tolerances may range from completely negative ($r=-1$) to completely positive ($r=+1$). Response addition assumes that the response to a given concentration of a mixture of toxicants is completely determined by the responses to the components and the pairwise correlation coefficient. Taking P as the proportion of organisms responding to a mixture of two toxicants which evoke individual responses of P_1 and P_2, then

$P = P_1$ if $r=1$ and $P_1 > P_2$ (IV-5)
$P = P_2$ if $r=1$ and $P_1 < P_2$ (IV-6)
$P = P_1 + P_2 (1-P_1)$ if $r=0$ (IV-7)
$P = P_1 + P_2$ if $r=-1$ and $P<1$. (IV-8)

More generalized mathematical models for this form of joint action have been given by Plackett and Hewlett (1948).

C. Interactions

All of the above models assume no interactions and therefore do not incorporate measurements of synergistic or antagonistic effects. For measuring toxicant interactions for mixtures of two compounds, Finney (1942) proposed the

following modification of equation IV–4 for dose addition:

$$Y = a_1 + b \log (f_1 + pf_2 + K [pf_1f_2]^{0.5}) + b \log Z \quad \text{(IV–9)}$$

where a_1, b, f_1, f_2, p, and Z are defined as before, and K is the coefficient of interaction. A positive value of K indicates synergism, a negative value indicates antagonism, and a value of zero corresponds to dose addition as in equation IV–4. Like other proposed modifications of dose addition (Hewlett, 1969), the equation assumes a consistent interaction throughout the entire range of proportions of individual components. To account for such asymmetric patterns of interaction as those observed by Alstott et al. (1973), Durkin (1981) proposed the following modification to equation IV–9:

$$Y = a_1 + b \log (f_1 + pf_2 + K_1f_1 [pf_1f_2]^{0.5} + K_2f_2 [pf_1f_2]^{0.5}) + b \log Z \quad \text{(IV–10)}$$

in which $K(pf_1f_2)^{0.5}$ is divided into two components, $K_1f_1(pf_1f_2)^{0.5}$ and $K_2f_2(pf_1f_2)^{0.5}$. Since K_1 and K_2 need not have the same sign, apparent instances of antagonism at one receptor site and synergism at another receptor site can be estimated. When K_1 and K_2 are equal, equation IV–10 reduces to Equation IV–9.

It should be noted that to obtain a reasonable number of degrees of freedom in the estimation of K in equation IV–9 or K_1 and K_2 in equation IV–10, the toxicity of several different combinations of the two components must be assayed along with assays of the toxicity of the individual components. Since this requires experiments with large numbers of animals, such analyses have been restricted for the most part to data from acute bioassays using insects (e.g., Finney, 1971) or aquatic organisms (Durkin, 1979). Also, because of the complexity of experimental design and the need for large numbers of animals, neither equation IV–9 nor equation IV–10 has been generalized or applied to mixtures of more than two toxicants. Modifications of response-additive models to include interactive terms have also been proposed, along with appropriate statistical tests for the assumption of additivity (Korn and Liu, 1983; Wahrendorf et al., 1981).

In the epidemiologic literature, measurements of the extent of toxicant interactions, S. can be expressed as the ratio of observed relative risk to relative risk predicted by some form of additivity assumption. Analogous to the ratio of interaction in classical toxiocology studies, $S = 1$ indicates no interaction, $S > 1$ indicates synergism, and $S < 1$ indicates anagonism. Several models for both additive and multiplicative risks have been proposed (e.g., Hogan et al., 1978; NRC, 1980b; Walter, 1976). For instance, Rothman (1976) has discussed the use of the following measurement of toxicant interaction based on the assumption of risk additivity:

$$S = (R_{11}-1)/(R_{10}+R_{01}-2) \quad \text{(IV–11)}$$

where R_{10} is the relative risk from compound #1 in the absence of compound #2, R_{01} is the relative risk from compound #2 in the absence of compound #1, and R_{11} is the relative risk from exposure to both compounds. A multiplicative risk model adapted from Walter and Holford (1978, equation 4) can be stated as:

$$S = R_{11}/(R_{10}R_{01}) \quad \text{(IV–12)}$$

As discussed by both Walter and Holford (1978) and Rothman (1976), the risk-additive model is generally applied to agents causing diseases while the multiplicative model is more appropriate to agents that prevent disease. The relative merits of these and other indices have been the subject of considerable discussion in the epidemiologic literature (Hogan et al., 1978; Kupper and Hogan, 1978; Rothman, 1978; Rothman et al., 1980; Walter and Holford, 1978). There seems to be a consensus that for public health concerns regarding causative (toxic) agents, the additive model is more appropriate.

Both the additive and multiplicative models assume statistical independence in that the risk associated with exposure to both compounds in combination can be predicted by the risks associated with separate exposure to the individual compounds. As illustrated by Siemiatycki and Thomas (1981) for multistage carcinogenesis, the better fitting statistical model will depend not only upon actual biological interactions, but also upon the stages of the disease process which the compounds affect. Consequently, there is no *a priori* basis for selecting either type of model in a risk assessment. As discussed by Stara et al. (1983), the concepts of multistage carcinogenesis and the effects of promoters and cocarcinogens on risk are extremely complex issues. Although risk models for promoters have been proposed (e.g., Burns et al., 1983), no single approach can be recommended at this time.

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Part B. Response to Public and Science Advisory Board Comments

I. Introduction

This section summarizes some of the major issues raised in public comments on the Proposed Guidelines for the Health Risk Assessment of Chemical Mixtures published on January 9, 1985 (50 FR 1170). Comments were received from 14 individuals or organizations. An issue paper reflecting public and external review comments was presented to the Chemical Mixtures Guidelines Panel of the Science Advisory Board (SAB) on March 4, 1985. At its April 22–23, 1985, meeting, the SAB Panel provided the Agency with additional suggestions and recommendations concerning the Guidelines. This section also summarizes the issues raised by the SAB.

The SAB and public commentors expressed diverse opinions and addressed issues from a variety of perspectives. In response to comments, the Agency has modified or clarified many sections of the Guidelines, and is planning to develop a technical support document in line with the SAB recommendations. The discussion that follows highlights significant issues raised in the comments, and the Agency's response to them. Also, many minor recommendations, which do not warrant discussion here, were adopted by the Agency.

II. Recommended Procedures

A. Definitions

Several comments were received concerning the lack of definitions for certain key items and the general understandability of certain sections. Definitions have been rewritten for several terms and the text has been significantly rewritten to clarify the Agency's intent and meaning.

Several commentors noted the lack of a precise definition of "mixture," even though several classes of mixtures are discussed. In the field of chemistry, the term "mixture" is usually differentiated from true solutions, with the former defined as nonhomogeneous multicomponent systems. For these Guidelines, the term "mixture" is defined as ". . . any combination of two or more chemicals regardless of spatial or temporal homogeneity of source" (section 1). These Guidelines are intended to cover risk assessments for any situation where the population is exposed or potentially exposed to two or more compounds of concern. Consequently, the introduction has been revised to clarify the intended breadth of application.

Several commentors expressed concern that "sufficient similarity" was difficult to define and that the Guidelines should give more details concerning similar mixtures. The Agency agrees and is planning research projects to improve on the definition. Characteristics such as composition and toxic end-effects are certainly important, but the best indicators of similarity in terms of risk assessment have yet to be determined. The discussion in the Guidelines emphasizes case-by-case judgment until the necessary research can be performed. The Agency considered but rejected adding an example, because it is not likely that any single example would be adequate to illustrate the variety in the data and types of judgments that will be required in applying this concept. Inclusion of examples is being considered for the technical support document.

B. Mixtures of Carcinogens and Systemic Toxicants

The applicability of the preferred approach for a mixture of carcinogens and systemic (noncarcinogenic) toxicants was a concern of several public commentors as well as the SAB. The Agency realizes that the preferred approach of using test data on the mixture itself may not be sufficiently protective in all cases. For example, take a simple two-component mixture of one carcinogen and one toxicant. The preferred approach would lead to using toxicity data on the mixture of the two compounds. However, it is possible to set the proportions of each component so that in a chronic bioassay of such a mixture, the presence of the toxicant could mask the activity of the carcinogen. That is to say, at doses of the mixture sufficient for the carcinogen to induce tumors in the small

experimental group, the toxicant could induce mortality. At a lower dose in the same study, no adverse effects would be observed, including no carcinogenic effects. The data would then suggest use of a threshold approach. Since carcinogenicity is considered by the Agency to be a nonthreshold effect, it may not be prudent to construe the negative results of such a bioassay as indicating the absence of risk at lower doses. Consequently, the Agency has revised the discussion of the preferred approach to allow the risk assessor to evaluate the potential for masking of carcinogenicity or other effects on a case-by-case basis.

Another difficulty occurs with such a mixture when the risk assessment needs to be based on data for the mixture components. Carcinogens and systemic toxicants are evaluated by the Agency using different approaches and generally are described by different types of data: response rates for carcinogens vs. effect descriptions for toxicants. The Agency recognizes this difficulty and recommends research to develop a new assessment model for combining these dissimilar data sets into one risk estimate. One suggestion in the interim is to present separate risk estimates for the dissimilar end points, including carcinogenic, teratogenic, mutagenic, and systemic toxicant components.

III. Additivity Assumption

Numerous comments were received concerning the assumption of additivity, including:

a. the applicability of additivity to "complex" mixtures;

b. the use of dose additivity for compounds that induce different effects;

c. the intepretation of the Hazard Index; and

d. the use of interaction data.

Parts of the discussion in the proposed guidelines concerning the use of additivity assumptions were vague and have been revised in the final Guidelines to clarify the Agency's intent and position.

A. Complex Mixtures

The issue of the applicability of an assumption of additivity to complex mixtures containing tens or hundreds of components was raised in several of the public comments. The Agency and its reviewers agree that as the number of compounds in the mixture increases, an assumption of additivity will become less reliable in estimating risk. This is based on the fact that each component estimate of risk or an acceptable level is associated with some error and uncertainty. With current knowledge, the uncertainty will increase as the number of components increases. In any event, little experimental data are available to determine the general change in the error as the mixture contains more components. The Agency has decided that a limit to the number of components should not be set in these Guidelines. However, the Guidelines do explicitly state that as the number of compounds in the mixture increases, the uncertainty associated with the risk assessment is also likely to increase.

B. Dose Additivity

Commentors were concerned about what appeared to be a recommendation of the use of dose additivity for compounds that induce different effects. The discussion following the dose additivity equation was clarified to indicate that the act of combining all compounds, even if they induce dissimilar effects, is a screening procedure and not the preferred procedure in developing a hazard index. The Guidelines were further clarified to state that dose (or response) additivity is theoretically sound, and therefore best applied for assessing mixtures of similar acting components that do not interact.

C. Interpretation of the Hazard Index

Several comments addressed the potential for misinterpretation of the hazard index, and some questioned its validity, suggesting that it mixes science and value judgments by using "acceptable" levels in the calculation. The Agency agrees with the possible confusion regarding its use and has revised the Guidelines for clarification. The hazard index is an easily derived restatement of dose additivity, and is, therefore, most accurate when used with mixture components that have similar toxic action. When used with components of unknown or dissimilar action, the hazard index is less accurate and should be interpreted only as a rough indication of concern. As with dose addition, the uncertainty associated with the hazard index increases as the number of components increases, so that it is less appropriate for evaluating the toxicity of complex mixtures.

D. Use of Interaction Data

A few commentors suggested that any interaction data should be used to quantitatively alter the risk assessment. The Agency disagrees. The current information on interactions is meager, with only a few studies comparing response to the mixture with that predicted by studies on components. Additional uncertainties include exposure variations due to changes in composition, mixture dose, and species differences in the extent of the interaction. The Agency is constructing an interaction data base in an attempt to answer some of these issues. Other comments concerned the use of different types of interaction data. The Guidelines restrict the use of interaction data to that obtained from whole animal bioassays of a duration appropriate to the risk assessment. Since such data are frequently lacking, at least for chronic or subchronic effects, the issue is whether to allow for the use of other information such as acute data, *in vitro* data, or structure-activity relationships to quantitatively alter the risk assessment, perhaps by use of a safety factor. The Agency believes that sufficient scientific support does not exist for the use of such data in any but a qualitative discussion of possible synergistic or antagonistic effects.

IV. Uncertainties and the Sufficiency of the Data Base

In the last two paragraphs of section II of the Guidelines, situations are discussed in which the risk assessor is presented with incomplete toxicity, monitoring, or exposure data. The SAB, as well as several public commentors, recommended that the "risk management" tone of this section be modified and that the option of the risk assessor to decline to conduct a risk assessment be made more explicit.

This is a difficult issue that must consider not only the quality of the available data for risk assessment, but also the needs of the Agency in risk management. Given the types of poor data often available, the risk assessor may indicate that the risk assessment is based on limited information and thus contains no quantification of risk. Nonetheless, in any risk assessment, substantial uncertainties exist. It is the obligation of the risk assessor to provide an assessment, but also to ensure that all the assumptions and uncertainties are articulated clearly and quantified whenever possible.

The SAB articulated several other recommendations related to uncertainties, all of which have been followed in the revision of the Guidelines. One recommendation was that the summary procedure table also be presented as a flow chart so that all options are clearly displayed. The SAB further recommended the development of a system to express the level of confidence in the various steps of the risk assessment.

The Agency has revised the summary table to present four major options: risk assessment using data on the mixture

itself, data on a similar mixture, data on the mixture's components, or declining to quantify the risk when the data are inadequate. A flow chart of this table has also been added to more clearly depict the various options and to suggest the combining of the several options to indicate the variability and uncertainties in the risk assessment.

To determine the adequacy of the data, the SAB also recommended the development of a system to express the level of confidence associated with various steps in the risk assessment process. The Agency has developed a rating scheme to describe data quality in three areas: interaction, health effects, and exposure. This classification provides a range of five levels of data quality for each of the three areas. Choosing the last level in any area results in declining to perform a quantitative risk assessment due to inadequate data. These last levels are described as follows:

Interactions:

An assumption of additivity cannot be justified, and no quantitative risk assessment can be conducted.

Health effects:

A lack of health effects information on the mixture and its components precludes a quantitative risk assessment.

Exposure:

The available exposure information is insufficient for conducting a risk assessment.

Several commentors, including the SAB, emphasized the importance of not losing these classifications and uncertainties farther along in the risk management process. The discussion of uncertainties has been expanded in the final Guidelines and includes the recommendation that a discussion of uncertainties and assumptions be included at every step of the regulatory process that uses risk assessment.

Another SAB comment was that the Guidelines should include additional procedures for mixtures with more than one end point or effect. The Agency agrees that these are concerns and revised the Guidelines to emphasize these as additional uncertainties worthy of further research.

V. Need for a Technical Support Document

The third major SAB comment concerned the necessity for a separate technical support document for these Guidelines. The SAB pointed out that the scientific and technical background from which these Guidelines must draw their validity is so broad and varied that it cannot reasonably be synthesized within the framework of a brief set of guidelines. The Agency is developing a technical support document that will summarize the available information on health effects from chemical mixtures, and on interaction mechanisms, as well as identify and develop mathematical models and statistical techniques to support these Guidelines. This document will also identify critical gaps and research needs.

Several comments addressed the need for examples on the use of the Guidelines. The Agency has decided to include examples in the technical support document.

Another issue raised by the SAB concerned the identification of research needs. Because little emphasis has been placed on the toxicology of mixtures until recently, the information on mixtures is limited. The SAB pointed out that identifying research needs is critical to the risk assessment process, and the EPA should ensure that these needs are considered in the research planning process. The Agency will include a section in the technical support document that identifies research needs regarding both methodology and data.

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Part V

Environmental Protection Agency

Guidelines for the Health Assessment of Suspect Developmental Toxicants

ENVIRONMENTAL PROTECTION AGENCY

[FRL-2984-3]

Guidelines for the Health Assessment of Suspect Developmental Toxicants

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final Guidelines for the Health Assessment of Suspect Developmental Toxicants.

SUMMARY: The U.S. Environmental Protection Agency is today issuing five guidelines for assessing the health risks of environmental pollutants. These are:

Guidelines for Carcinogen Risk Assessment
Guidelines for Estimating Exposures
Guidelines for Mutagenicity Risk Assessment
Guidelines for the Health Assessment of Suspect Developmental Toxicants
Guidelines for the Health Risk Assessment of Chemical Mixtures

This notice contains the Guidelines for the Health Assessment of Suspect Developmental Toxicants; the other guidelines appear elsewhere in today's **Federal Register.**

The Guidelines for the Health Assessment of Suspect Developmental Toxicants (hereafter "Guidelines") are intended to guide Agency analysis of developmental toxicity data in line with the policies and procedures established in the statutes administered by the EPA. These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Office of Health and Environmental Assessment (OHEA) in the Agency's Office of Research and Development. They reflect Agency consideration of public and Science Advisory Board (SAB) comments on the Proposed Guidelines for the Health Assessment of Suspect Developmental Toxicants published November 23, 1984 (49 FR 46324).

This publication completes the first round of risk assessment guidelines development. These Guidelines will be revised, and new guidelines will be developed, as appropriate.

EFFECTIVE DATE: The Guidelines will be effective September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Dr. Carole A. Kimmel, Reproductive Effects Assessment Group, Office of Health and Environmental Assessment (RD-689), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202-382-7331.

SUPPLEMENTARY INFORMATION: In 1983, the National Academy of Sciences (NAS) published its book entitled *Risk Assessment in the Federal Government: Managing the Process.* In that book, the NAS 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. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

General

The guidelines published today are products of a two-year Agencywide effort, which has included many scientists from the larger scientific community. These guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments, and to inform Agency decision makers and the public about these procedures. In particular, the guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific information on each agent and use the most scientifically appropriate interpretation to assess risk. The guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Finally, the guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Guidelines for the Health Assessment of Suspect Developmental Toxicants

Work on the Guidelines for the Health Assessment of Suspect Developmental Toxicants began in January 1984. Draft guidelines were developed by Agency work groups composed of expert scientists from throughout the Agency. The drafts were peer-reviewed by expert scientists in the field of developmental toxicology from universities, environmental groups, industry, labor, and other governmental agencies. They were then proposed for public comment in the **Federal Register** (49 FR 46324). On November 9, 1984, the Administrator directed that Agency offices use the proposed guidelines in performing risk assessments until final guidelines become available.

After the close of the public comment period, Agency staff prepared summaries of the comments, analyses of the major issues presented by the commentors, and preliminary Agency responses to those comments. These analyses were presented to review panels of the SAB on March 4 and April 22-23, 1985, and to the Executive Committee of the SAB on April 25-26, 1985. The SAB meetings were announced in the **Federal Register** as follows: February 12, 1985 (50 FR 5811) and April 4, 1985 (50 FR 13420 and 13421).

In a letter to the Administrator dated June 19, 1985, the Executive Committee generally concurred on all five of the guidelines, but recommended certain revisions, and requested that any revised guidelines be submitted to the appropriate SAB review panel chairman for review and concurrence on behalf of the Executive Committee. As described in the responses to comments (see Part B: Response to the Public and Science Advisory Board Comments), each guidelines document was revised, where appropriate, consistent with the SAB recommendations, and revised draft guidelines were submitted to the panel chairmen. Revised draft Guidelines for the Health Assessment of Suspect Developmental Toxicants were concurred on in a letter dated July 26, 1985. Copies of the letters are available at the Public Information Reference Unit, EPA Headquarters Library, as indicated elsewhere in this notice.

Following this Preamble are two parts: Part A contains the Guidelines and Part B, the Response to the Public and Science Advisory Board Comments (a summary of the major public comments, SAB comments, and Agency responses to those comments).

The SAB suggested that the Agency pursue additional follow-up work on quantitative risk assessment. Several efforts are currently underway within the Agency on quantitative risk assessment models and procedures, the relationship of maternal and developmental toxicity, and the evaluation and interpretation of postnatal studies. In addition, a document addressing research needs is being prepared to highlight those areas that are in need of further study.

The Agency is continuing to study the risk assessment issues raised in the guidelines and will revise these guidelines in line with new information as appropriate.

References, supporting documents, and comments received on the proposed

guidelines, as well as copies of the final guidelines, are available for inspection and copying at the Public Information Reference Unit (202–382–5926), EPA Headquarters Library, 401 M Street, SW, Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m.

I certify that these Guidelines are not major rules as defined by Executive Order 12291, because they are nonbinding policy statements and have no direct effect on the regulated community. Therefore, they will have no effect on costs or prices, and they will have no other significant adverse effects on the economy. These Guidelines were reviewed by the Office of Management and Budget under Executive Order 12291.

Dated: August 22, 1986.

Lee M. Thomas,

Administrator.

CONTENTS

Part A: Guidelines for the Health Assessment of Suspect Developmental Toxicants

I. Introduction

These Guidelines describe the procedures that the U.S. Environmental Protection Agency will follow in evaluating potential developmental toxicity associated with human exposure to environmental toxicants. In 1980, the Agency sponsored a conference that addressed issues related to such evaluations (1) and provided some of the scientific basis for these risk assessment Guidelines. The Agency's authority to regulate substances that have the potential to interfere adversely with human development is derived from a number of statutes which are implemented through multiple offices within the Agency. Because many different offices evaluate developmental toxicity, there is a need for intra-Agency consistency in the approach to assess these types of effects. The procedures described here will promote consistency in the Agency's assessment of developmental toxic effects.

The developmental toxicity assessments prepared pursuant to these Guidelines will be utilized within the requirements and constraints of the applicable statutes to arrive at regulatory decisions concerning developmental toxicity. These Guidelines provide a general format for analyzing and organizing the available data for conducting risk assessments. The Agency previously has issued testing guidelines (2, 3) that provide protocols designed to determine the potential of a test substance to induce structural and/or other abnormalities in the developing conceptus. These risk assessment Guidelines do not change any statutory or regulatory prescribed standards for the type of data necessary for regulatory action, but rather provide guidance for the interpretation of studies that follow the testing guidelines, and in addition, provide limited information for interpretation of other studies (e.g., epidemiologic data, functional developmental toxicity studies, and short-term tests) which are not routinely required, but which may be encountered when reviewing data on particular agents. Moreover, risk assessment is just one component of the regulatory process and defines the adverse health consequences of exposure to a toxic agent. The other component, risk management, combines risk assessment with the directives of the enabling regulatory legislation, together with socioeconomic, technical, political, and other considerations, to reach a decision as to whether or how much to control future exposure to the suspected toxic agent. The issue of risk management will not be addressed in these Guidelines.

The background incidence of developmental defects in the human population is quite large. For example, approximately 50% of human conceptuses fail to reach term (4); approximately 3% of newborn children are found to have one or more significant congenital malformations at birth, and by the end of the first postnatal year, about 3% more are found to have serious developmental defects (5, 6). Of these, it is estimated that 20% of human developmental defects are of known genetic transmission, 10% are attributable to known environmental factors, and the remainder result from unknown causes (7). Approximately 7.4% of children are reduced in weight at birth (i.e., below 2500 g) (8). Exposure to agents affecting development can result in multiple manifestations (malformation, functional impairment, altered growth, and/or lethality). Therefore, assessment efforts should encompass a wide array of adverse developmental end points, such as spontaneous abortions, stillbirths, malformations, early postnatal mortality, and other adverse functional or physical changes that are manifested postnatally.

Numerous agents have been shown to be developmental toxicants in animal test systems (9). Several of them have also been shown to be the cause of adverse developmental effects in humans, including alcohol, aminopterin, busulfan, chlorobiphenyls, diethylstilbestrol, isotretinoin, organic mercury, thalidomide, and valproic acid (10, 11, 12, 13). Although a number of agents found to be positive in animal studies have not shown clear evidence of hazard in humans, usually the human data available are inadequate to determine a cause and effect relationship. Comparisons of human and animal data have been made for a limited number of agents that are positive in humans (13, 14). In these comparisons, there was almost always concordance of effects between humans and at least one species tested; also, the minimally effective dose (MED) for the most sensitive animal species was approximately 0.5 to 50 times the human

MED, not accounting for differences in the incidence of effect at the MED. Thus, there is some limited basis for estimating the risk of exposure to human development based on data from animal studies.

The National Research Council (15) has defined risk assessment as being comprised of some or all of the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization. In general, the process of assessing the risk of human developmental toxicity may be adapted to this format. However, due to special considerations in assessing developmental toxicity, which will be discussed later in these Guidelines, it is not always possible to follow the exact standards as defined for each component.

Hazard identification is the qualitative risk assessment in which all available experimental animal and human data are used to determine if an agent is likely to cause developmental toxicity. In considering developmental toxicity, these Guidelines will address not only malformations, but also fetal wastage, growth alteration, and functional abnormalities that may result from developmental exposure to environmental agents.

The dose-response assessment defines the relationship of the dose of an agent and the occurrence of developmental toxic effects. According to the National Research Council (15), this component would usually include the results of an extrapolation from high doses administered to experimental animals or noted in epidemiologic studies to the low exposure levels expected for human contact with the agent in the environment. Since at present there are no mathematical extrapolation models that are generally accepted for developmental toxicity, the Agency, for the most part, uses uncertainty (safety) factors and margins of safety, which will be discussed in these Guidelines. Appropriate models are being sought by the Agency for application to data in this area.

The exposure assessment identifies populations exposed to the agent, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the agent.

In risk characterization, the exposure assessment and the dose-response assessment are combined to estimate some measure of the risk of developmental toxicity. As part of risk characterization, a summary of the strengths and weaknesses in each component of the assessment are presented along with major assumptions, scientific judgments, and, to the extent possible, estimates of the uncertainties.

II. Definitions and Terminology

The Agency recognizes that there are differences in the use of terms in the field of developmental toxicology. For the purposes of these Guidelines the following definitions and terminology will be used.

Developmental Toxicology—The study of adverse effects on the developing organism that may result from exposure prior to conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Adverse developmental effects may be detected at any point in the life span of the organism. The major manifestations of developmental toxicity include: (1) death of the developing organism, (2) structural abnormality, (3) altered growth, and (4) functional deficiency.

Embryotoxicity and Fetotoxicity—Any toxic effect on the conceptus as a result of prenatal exposure; the distinguishing feature between the two terms is the stage of development during which the injury occurred. The terms, as used here, include malformations and variations, altered growth, and *in utero* death.

Altered Growth—An alteration in offspring organ or body weight or size. Changes in body weight may or may not be accompanied by a change in crown-rump length and/or in skeletal ossification. Altered growth can be induced at any stage of development, may be reversible, or may result in a permanent change.

Functional Developmental Toxicology—The study of the causes, mechanisms, and manifestations of alterations or delays in functional competence of the organism or organ system following exposure to an agent during critical periods of development pre- and/or postnatally.

Malformations and Variations—A malformation is usually defined as a permanent structural change that may adversely affect survival, development, or function. The term *teratogenicity*, which is used to describe these types of structural abnormalities, will be used in these Guidelines to refer only to structural defects. A variation is used to indicate a divergence beyond the usual range of structural constitution that may not adversely affect survival or health. Distinguishing between variations and malformations is difficult since there exists a continuum of responses from the normal to the extreme deviant. There is no generally accepted classification of malformations and variations. Other terminology that is often used, but no better defined, includes anomalies, deformations, and aberrations.

III. Qualitative Assessment (Hazard Identification of Developmental Toxicants)

Developmental toxicity is expressed as one or more of a number of possible end points that may be used for evaluating the potential of an agent to cause abnormal development. The four types of effects on the conceptus that may be produced by developmental exposure to toxicants include death, structural abnormality, altered growth, and functional deficits. Of these, the first three types of effects are traditionally measured in laboratory animals using the conventional developmental toxicity (also called teratogenicity or Segment II) testing protocol as well as in other study protocols, such as the multigeneration study. Functional deficits are seldom evaluated in routine studies of environmental agents. This section will discuss the end points examined in routinely used protocols as well as the evaluation of data from other types of studies, including functional studies and short-term tests. Transplacental carcinogenesis, another type of developmental effect, will not be discussed in detail here since, at present, it is considered more appropriate to use the Guidelines for Carcinogen Risk Assessment (16) for assessing the human risk for these types of effects. Also, mutational events may occur as part of developmental toxicity, and in practice, are difficult to discriminate from other possible mechanisms of developmental toxicity. The Guidelines for Mutagenicity Risk Assessment (17) should be consulted in cases where genetic damage is suspected.

A. Laboratory Animal Studies of Developmental Toxicity: End Points and Their Interpretation

The most commonly used protocol for assessing developmental toxicity in laboratory animals involves the administration of a test substance to pregnant animals (usually mice, rats, or rabbits) during the period of major organogenesis, evaluation of maternal responses throughout pregnancy, and examination of the dam and the uterine contents just prior to term (2, 3, 18, 19, 20). Other protocols may use exposure periods of one to a few days to investigate periods of particular sensitivity for induction of anomalies in specific organs or organ systems (21). In

addition, developmental toxicity may be evaluated in studies involving exposure of one or both parents prior to conception, of the conceptus during pregnancy and over several generations, or of offspring during the late prenatal and early postnatal periods. These Guidelines are intended to provide information for interpreting developmental effects related to any of these types of exposure. Since many of the end points evaluated also are related to effects on the parental reproductive systems, these Guidelines will be used in conjunction with those to be published in the future by EPA on male and female reproductive toxicity.

Study designs should include a high dose, which produces some maternal or adult toxicity (i.e., a level which at the least produces marginal but significantly reduced body weight, weight gain, or specific organ toxicity, and at the most produces no more than 10% mortality); a low dose, which demonstrates a no observed effect level (NOEL) for adult and offspring effects; and at least one intermediate dose level. A concurrent control group treated with the vehicle used for agent administration should be included. The route of exposure should be based on expected human exposure considerations, although data from other routes may sometimes be useful, especially if supported by pharmacokinetic information. Test animals should be selected based on considerations of species, strain, age, weight, and health status, and should be randomized to dose groups in order to reduce bias and provide a basis for performing valid statistical tests.

The next three sections discuss individual end points of maternal and developmental toxicity as measured in the conventional developmental toxicity study, the multigeneration study, and, on occasion, in postnatal studies. Other end points specifically related to reproductive toxicity will be covered in the relevant reproductive toxicity guidelines. The fourth section deals with the integrated evaluation of all data, including the relative effects of exposure on maternal animals and their offspring, which is important in assessing the level of concern about a particular agent.

1. *End Points of Maternal Toxicity.* A number of end points that may be observed as possible indicators of maternal toxicity are listed in Table 1. Maternal mortality is an obvious end point of toxicity; however, a number of other end points can be observed which may give an indication of the subtle effects of an agent. For example, in well-conducted studies, the fertility and gestation indices provide information on the general fertility rate of the animal stock used and are important indicators of toxic effects if treatment begins prior to mating or implantation. Changes in gestation length may indicate effects on the process of parturition.

Table 1.—End Points of Maternal Toxicity

- Mortality
- Fertility Index (no. with seminal plugs or sperm/no. mated)
- Gestation Index (no. with implants/no. with seminal plugs or sperm)
- Gestation Length (when allowed to deliver pups)
- Body Weight
  - Treatment days (at least first, middle, and last treatment days)
  - Sacrifice day
- Body Weight Change
  - Throughout gestation
  - During treatment (including increments of time within treatment period)
  - Post-treatment to sacrifice
  - Corrected maternal (body weight change throughout gestation minus gravid uterine weight or litter weight at sacrifice)
- Organ Weights (in cases of suspected specific organ toxicity)
  - Absolute
  - Relative to body weight
- Food and Water Consumption (where relevant)
  - Clinical Evaluations (on days of treatment and at sacrifice)
  - Types and incidence of clinical signs
  - Enzyme markers
  - Clinical chemistries
- Gross Necropsy and Histopathology

Body weight and the change in body weight are viewed collectively as indicators of maternal toxicity for most species, although these end points may not be as useful in rabbits, because body weight changes in rabbits are not good indicators of pregnancy status. Body weight changes may provide more information than a daily body weight measured during treatment or during gestation. Changes in weight during treatment could occur that would not be reflected in the total weight change throughout gestation, because of compensatory weight gain that may occur following treatment but before sacrifice. For this reason, changes in weight during treatment can be examined as another indicator of maternal toxicity.

Changes in maternal body weight corrected for gravid uterine weight at sacrifice may indicate whether the effect is primarily maternal or fetal. For example, there may be a significant reduction in weight gain throughout gestation and in gravid uterine weight, but no change in corrected maternal weight gain which would indicate primarily an intrauterine effect. Conversely, a change in corrected weight gain and no change in gravid uterine weight suggests primarily maternal toxicity and little or no intrauterine effect. An alternate estimate of maternal weight change during gestation can be obtained by subtracting the sum of the weights of the fetuses. However, this weight does not include the uterine tissue, placental tissue, or the amniotic fluid.

Changes in other end points should also be determined. For example, changes in relative and absolute organ weights may be signs of a maternal effect when an agent is suspected of causing specific organ toxicity. Food and water consumption data are useful, especially if the agent is administered in the diet or drinking water. The amount ingested (total and relative to body weight) and the dose of the agent (relative to body weight) can then be calculated, and changes in food and water consumption related to treatment can be evaluated along with changes in body weight and body weight gain. Data on food and water consumption are also useful when an agent is suspected of affecting appetite, water intake, or excretory function. Clinical evaluations of toxicity may also be used as indicators of maternal toxicity. Daily clinical observations may be useful in describing the profile of maternal toxicity. Enzyme markers and clinical chemistries may be useful indicators of exposure but must be interpreted carefully as to whether or not a change constitutes toxicity. Gross necropsy and histopathology data (when specified in the protocol) may aid in determining toxic dose levels.

2. *End Points of Developmental Toxicity.* Because the maternal animal, and not the conceptus, is the individual treated during gestation, data generally should be calculated as incidence per litter or as number and percent of litters with particular end points. Table 2 indicates the way in which offspring and litter end points may be expressed.

Table 2.—End Points of Developmental Toxicity

- *Litters with implants*
  - No. implantation sites/dam
  - No. corpora lutea (CL)/dam *
  - Percent preimplantation loss

$$\frac{(CL - \text{implantations}) \times 100}{CL} *$$

  - No. and percent live offspring/litter
  - No. and percent resorptions/litter
  - No. and percent litters with resorptions

No. and percent late fetal deaths/litter
No. and percent nonlive (late fetal deaths + resorptions) implants/litter
No. and percent litters with nonlive implants
No. and percent affected (nonlive + malformed) implants/litter
No. and percent litters with affected implants
No. and percent litters with total resorptions
No. and percent stillbirths/litter

Litters with live offspring [b]

No. and percent litters with live offspring
No. and percent live offspring/litter
Viability of offspring [c]
Sex ratio/litter
Mean offspring body weight/litter [c]
Mean male body weight/litter [c]
Mean female body weight/litter [c]
No. and percent externally malformed offspring/litter
No. and percent viscerally malformed offspring/litter
No. and percent skeletally malformed offspring/litter
No. and percent malformed offspring/litter
No. and percent litters with malformed offspring
No. and percent malformed males/litter
No. and percent malformed females/litter
No. and percent offspring with variations/litter
No. and percent litters having offspring with variations
Types and incidence of individual malformations
Types and incidence of individual variations
Individual offspring and their malformations and variations (grouped according to litter and dose)
Clinical signs [c]
Gross necropsy and histopathology

[a] Important when treatment begins prior to implantation. May be difficult in mice.

[b] Offspring refers both to fetuses observed prior to term or to pups following birth. The end points examined depend on the protocol used for each study.

[c] Measured at selected intervals until termination of the study.

When treatment begins prior to implantation, an increase in preimplantation loss could indicate an adverse effect either on the developing blastocyst or on the process of implantation itself. If treatment begins around the time of implantation (i.e., day 6 of gestation in the mouse, rat, or rabbit), an increase in preimplantation loss probably reflects normal variability in the animals being used, but the data should be examined carefully to determine whether or not the effect is dose related. If preimplantation loss is related to dose in either case, further studies would be necessary to determine the mechanism and extent of such effects.

The number and percent of live offspring per litter, based on all litters, may include litters that have no live implants. The number and percent resorptions or late fetal deaths per litter gives some indication of when the conceptus died, and the number and percent nonlive implants per litter (postimplantation loss) is a combination of resorptions and late fetal deaths. The number and percent of litters showing an increased incidence for these end points is generally useful but may be less useful than incidence per litter because, in the former case, a litter is counted whether it has one or all resorbed, dead, or nonlive implants.

If a significant increase in postimplantation loss is found after exposure to an agent, the data may be compared not only with concurrent controls, but also with recent historical control data, since there is considerable interlitter variability in the incidence of postimplantation loss (22). If a given study control group exhibits an unusually high or low incidence of postimplantation loss compared to historical controls, then scientific judgment must be used to determine the adequacy of the studies for risk assessment purposes.

The end point for affected implants (i.e., the combination of nonlive and malformed conceptuses) gives an indication of the total intrauterine response to an agent and sometimes reflects a better dose-response relationship than does the incidence of nonlive or malformed offspring taken individually. This is especially true at the high end of the dose-response curve in cases when the incidence of nonlive implants per litter is greatly increased. In such cases, the malformation rate may appear to decrease because only unaffected offspring have survived. If the incidence of prenatal death or malformation is unchanged, then the incidence of affected implants will not provide any additional dose-response information. In studies where maternal animals are allowed to deliver pups normally, the number of stillbirths per litter should also be noted.

The number of live offspring per litter, based on those litters that have one or more live offspring, may be unchanged even though the incidence of nonlive in all litters is increased. This could occur either because of an increase in the number of litters with no live offspring, or an increase in the number of implants per litter. A decrease in the number of live offspring per litter should be accompanied by an increase in the incidence of nonlive implants per litter, unless the implant numbers differ among dose groups. In postnatal studies, the viability of live born offspring should be determined at selected intervals until termination of the study.

The sex ratio per litter, as well as the body weights of males and females, can be examined to determine whether or not one sex is preferentially affected by the agent. However, this is an unusual occurrence.

A change in offspring body weight is a sensitive indicator of developmental toxicity, in part because it is a continuous variable. In some cases, offspring weight reduction may be the only indicator of developmental toxicity; if so, there is always a question remaining as to whether weight reduction is a permanent or transitory effect. A permanent weight change may be considered more severe than a transitory change, although little is known about the long-term consequences of short-term fetal or neonatal weight changes. When fetal or neonatal weight reduction is the only indicator of developmental toxicity, data from the two-generation reproduction study (2), if available, may be useful for evaluating these parameters. Ideally, follow-up studies to evaluate postnatal viability, growth, and survival through weaning should be conducted. There are other factors that should be considered in the evaluation of fetal or neonatal weight changes. For example, in polytocous animals, fetal and neonatal weights are usually inversely correlated with litter size, and the upper end of the dose-response curve may be confounded by smaller litters and increased fetal or neonatal weight. Additionally, the average body weight of males is greater than that of females in the more commonly used laboratory animals.

Live offspring should be examined for external, visceral, and skeletal malformations. If only a portion of the litter is examined, then it is preferable that those examined be randomly selected from each litter. An increase in the incidence of malformed offspring may be indicated by a change in one or more of the following end points: the incidence of malformed offspring per litter, the number and percent of litters with malformed offspring, or the number of offspring or litters with a particular malformation that appears to increase with dose as indicated by the incidence of individual types of malformations.

Other ways of examining the data include the incidence of external, visceral, and skeletal malformations which may indicate which general systems are affected. A listing of individual offspring with their malformations and variations may give an indication of the pattern of developmental deviations. All of these methods of expressing and examining the data are valid for determining the effects of an agent on structural development. However, care must be taken to avoid counting offspring more than once in evaluating any single end point based on number or percent of offspring or litters. The incidence of individual types of malformations and variations should be examined for significant changes which may be masked if the data on all malformations and variations are pooled. Appropriate historical control data are helpful in the interpretation of malformations and variations, especially those that normally occur at a low incidence apparently unrelated to dose in an individual study. Although a dose-related increase in malformations is interpreted as an adverse developmental effect of exposure to an agent, the significance of anatomical variations is more difficult to determine, and must take into account what is known about developmental stage (e.g., with skeletal ossification), background incidence of certain variations (e.g., 12 or 13 pairs of ribs in rabbits), or other strain- or species-specific factors. However, if variations are significantly increased in a dose-related manner, these should also be evaluated as a possible indication of developmental toxicity. The Interagency Regulatory Liaison Group noted that dose-related increases in defects, which may occur spontaneously, are as relevant as dose-related increases in any other developmental toxicity end points (23).

3. *Functional Developmental Toxicology.* Developmental effects, which are inducible by exogenous agents, are not limited to death, structural abnormalities, and altered growth. Rather, it has been demonstrated in a number of instances that subtle alterations in the functional competence of an organ or a variety of organ systems may result from exposure during critical developmental periods that may occur between conception and sexual maturation. Often, these functional defects are observed at dose levels below those at which gross malformations are evident (24). At present, such testing is not routinely required in the United States. However, data from postnatal studies, when available, are considered very useful for the assessment of the relative importance and severity of findings in the fetus and neonate. Often, the long-term consequences of adverse developmental outcomes at birth are unknown, and further data on postnatal development and function may contribute valuable information. When regulatory statutes permit, studies designed to evaluate adverse fetal or neonatal outcomes have been requested (e.g., the Office of Pesticide Programs has sometimes requested postnatal studies where the reversibility of study findings were at issue). In some cases, useful data can be derived from well-executed multigeneration studies.

Much of the early work in functional developmental toxicology was related to behavioral evaluations, and the term "behavioral teratology" became prominent in the mid 1970s. Less work has been done on other functional systems, but sufficient data have accumulated to indicate that the cardiopulmonary, immune, endocrine, digestive, urinary, nervous, and reproductive systems are subject to alterations in functional competence (25, 26). Currently, there are no standard testing procedures, although some attempts are being made to standardize and evaluate tests and protocols (27). The functional evaluation of specific systems often involves highly specialized training and equipment. The routine use of such test procedures may not always be practical, but may be extremely important in determining the nature of a suspected alteration in terms of its biological significance and dose-response relationship.

The interpretation of data from functional developmental toxicology studies is limited due to the lack of knowledge about the underlying toxicological mechanisms and their significance. However, since such data are sometimes encountered in the risk assessment of particular agents, some guidance is provided here concerning general concepts of study design and evaluation.

a. Several aspects of study design are similar to those important in standard developmental toxicity studies (e.g., a dose-response approach with the highest dose producing minimal overt maternal or perinatal toxicity, number of litters large enough for adequate statistical power, randomization of animals to dose groups, litter generally considered the statistical unit, etc.).

b. A replicate study design provides added confidence in the interpretation of data.

c. Use of a pharmacological challenge may be valuable in evaluating function and "unmasking" effects not otherwise detectable, particularly in the case of organ systems that are endowed with a reasonable degree of functional reserve capacity.

d. Use of functional tests with a moderate degree of background variability may be more sensitive to the effects of an agent than are tests with low variability that may be impossible to disrupt without being life-threatening. Butcher et al. (28) have discussed this with relation to behavioral end points.

e. A battery of functional tests usually provides a more thorough evaluation of the functional competence of an animal; tests conducted at several ages may provide more information about maturational changes.

f. Critical periods for the disruption of functional competence include both the prenatal and the postnatal periods to the time of sexual maturation, and the effect is likely to vary depending on the time and degree of exposure.

Although interpretation of functional data may be difficult at present, there are at least three ways in which the data from these studies may be useful for risk assessment purposes: (1) to help elucidate the long-term consequences of fetal and neonatal findings; (2) to indicate the potential for an agent to cause functional alterations, and the effective doses relative to those that produce other forms of toxicity; and (3) for existing environmental agents, to focus on organ systems to be evaluated in exposed human populations.

4. *Overall Evaluation of Maternal and Developmental Toxicity.* As discussed previously, individual end points are evaluated in developmental toxicity studies, but an integrated evaluation must be done considering all maternal and developmental end points in order to interpret the data fully. Developmental toxicity is considered to be an increase in the incidence of malformed offspring, decreased viability (prenatal or postnatal), altered growth, and/or functional deficits.

The level of concern for a developmental toxic effect is related to several issues, including the relative toxicity of an agent to the offspring versus the adult animal, and the long-term consequences of findings in the fetus or neonate. Those agents which produce developmental toxicity at a dose that is not toxic to the maternal animal are of greatest concern because the developing organism appears to be selectively affected or more sensitive than the adult. However, when developmental effects are produced only

at maternally toxic doses, the types of developmental effects should be examined carefully, and not discounted as being secondary to maternal toxicity. Current information is inadequate to assume that developmental effects at maternally toxic doses result only from the maternal toxicity; rather, when the lowest observed effect level is the same for the adult and developing organisms, it may simply indicate that both are sensitive to that dose level. Moreover, the maternal effects may be reversible while effects on the offspring may be permanent. These are important considerations for agents to which humans may be exposed at minimally toxic levels either voluntarily or in the workplace, since several agents are known to produce adverse developmental effects at minimally toxic doses in adult humans (e.g., smoking, alcohol).

Approaches for ranking agents for their selective developmental toxicity are being developed; Schardein (10) has reviewed several of these. Of current interest are approaches that develop ratios relating an adult toxic dose to a developmental toxic dose (29, 30, 31, 32). Ratios near unity indicate that developmental toxicity occurs only at doses producing maternal toxicity; as the ratio increases, there is a greater likelihood of developmental effects occurring without maternal manifestations. Although further exploration and validation are necessary, such approaches may ultimately help in identifying those agents that pose the greatest threat and should be given higher priority for further testing (33).

5. *Short-term Testing in Developmental Toxicity.* The need for short-term tests for developmental toxicity has arisen from the large number of agents in or entering the environment, the interest in reducing the number of animals used for routine testing, and the expense of testing. Two approaches are considered here in terms of their contribution to the overall testing process: (1) An *in vivo* mammalian screen, and (2) a variety of *in vitro* systems. Currently, neither approach is considered as a replacement for routine *in vivo* developmental toxicity testing in experimental animals, and should not be used to make the final decision as to whether an agent is a positive or negative developmental toxicant; rather, such tests may be useful as tools for assigning priorities for further, more extensive testing. Although such short-term tests are not routinely required, data are sometimes encountered in the review of chemicals; the comments are provided here for guidance in the evaluation of such data.

a. *In Vivo* Mammalian Developmental Toxicity Screen. The most widely studied *in vivo* approach is that developed by Chernoff and Kavlock (34) which uses the pregnant mouse. This approach is based on the hypothesis that a prenatal injury, which results in altered development, will be manifested postnatally as reduced viability and/or impaired growth. In general, the test substance is administered over the period of major organogenesis at a single dose level that will elicit some degree of maternal toxicity. A second lower dose level may be used which potentially will reduce the chances of false positive results. The pups are counted and weighed shortly after birth, and again after 3–4 days. End points that are considered in the evaluation include: general maternal toxicity (including survival and weight gain), litter size, and viability, weight, and gross malformations in the offspring. Basic priority-setting categories for more extensive testing have been suggested: (1) agents that induce perinatal death should receive highest priority, (2) agents inducing perinatal weight changes should be ranked lower in priority, and (3) agents inducing no effect should receive the lowest priority (34). Another scheme that has been proposed applies a numerical ranking to the results as a means of prioritizing agents for further testing (35, 36).

The mouse was chosen originally for this test because of its low cost, but the procedure should be easily applicable to other species. However, the test will only predict the potential for developmental toxicity of an agent in the species utilized and does not improve the ability to extrapolate risk to other species, including humans. The Office of Toxic Substances has developed testing guidelines for this procedure (37). Although the testing guidelines are available, such procedures are not routinely required, and further validation is currently being carried out (38).

b. *In Vitro* Developmental Toxicity Screens. Test systems that fall under the general heading of *"in vitro"* developmental toxicity screens include any system that employs a test subject other than the intact pregnant mammal. These systems have long been used to assess events associated with normal and abnormal development, but only recently have they been considered for their potential as screens in testing (39, 40, 41). Many of these systems are now being evaluated for their ability to predict the developmental toxicity of various agents in intact mammalian systems. This validation process requires certain considerations in study design, including defined end points for toxicity and an understanding of the system's ability to handle various test agents (40, 42). A list of agents for use in such validation studies has been developed (43).

6. *Statistical Considerations.* In the assessment of developmental toxicity data, statistical considerations require special attention. Since the litter is generally considered the experimental unit in most developmental toxicity studies, the statistical analyses should be designed to analyze the relevant data based on incidence per litter or on the number of litters with a particular end point. The analytical procedures used and the results, as well as an indication of the variance in each end point, should be clearly indicated in the presentation of data. Analysis of variance (ANOVA) techniques, with litter nested within dose in the model, take the litter variable into account but allow use of individual offspring data and an evaluation of both within and between litter variance as well as dose effects. Nonparametric and categorical procedures have also been widely used for binomial or incidence data. In addition, tests for dose-response trends can be applied. Although a single statistical approach has not been agreed upon, a number of factors important in the analysis of developmental toxicity data have been discussed (23, 44).

Studies that employ a replicate experimental design (e.g., two or three replicates with 10 litters per dose per replicate rather than a single experiment with 20–30 litters per dose group) allow for broader interpretation of study results since the variability between replicates can be accounted for using ANOVA techniques. Replication of effects due to a given agent within a study, as well as between studies or laboratories, provides added strength in the use of data for the estimation of risk.

An important factor to determine in evaluating data is the power of a study (i.e., the probability that a study will demonstrate a true effect), which is limited by the sample size used in the study, the background incidence of the end point observed, the variability in the incidence of the end point, and the analysis method. As an example, Nelson and Holson (45) have shown that the number of litters needed to detect a 5 or 10% change was dramatically lower for fetal weight (a continuous variable with low variability) than for resorptions (a binomial response with high variability). With the current recommendation in

testing protocols being 20 rodents per dose group (2, 3), it is possible to detect an increased incidence of malformations in the range of 5 to 12 times above control levels, an increase of 3 to 6 times the *in utero* death rate, and a decrease of 0.15 to 0.25 times the fetal weight. Thus, even within the same study, the ability to detect a change in fetal weight is much greater than for the other end points measured. Consequently, for statistical reasons only, changes in fetal weight are often observable at doses below those producing other signs of developmental toxicity. Any risk assessment should present the detection sensitivity for the study design used and for the end point(s) evaluated.

Although statistical analyses are important in determining the effects of a particular agent, the biological significance of data should not be overlooked. For example, with the number of end points that can be observed in developmental toxicity studies, a few statistically significant differences may occur by chance. On the other hand, apparent trends with dose may be biologically relevant even though statistical analyses do not indicate a significant effect. This may be true especially for the incidence of malformations or *in utero* death where a relatively large difference is required to be statistically significant. It should be apparent from this discussion that a great deal of scientific judgment based on experience with developmental toxicity data and with principles of experimental design and statistical analysis may be required to adequately evaluate such data.

B. Human Studies

Because of the ethical considerations involved, studies with deliberate dosing of humans are not done. Therefore, dose-effect developmental toxicity data from humans are limited to those available from occupational, environmental, or therapeutic exposures. While animal studies provide dose-response data that can be used in the extrapolation of risk to humans, good epidemiologic data provide the best information for assessing human risk.

The category of "human studies" includes both epidemiologic studies and other reports of cases or clusters of events. While case reports have been important in identifying several human teratogens, they are potentially of greater value in identifying topics for further investigation (46). The data from case reports are often of an anecdotal or highly selected nature, and thus are of limited usefulness for risk assessment except when a unique defect is produced, as with thalidomide, or when the agent is so potent as to greatly increase the incidence of a particular defect(s).

As there are many different designs for epidemiologic studies, simple rules for their evaluation do not exist. The assessment of epidemiologic studies requires a sophisticated level of understanding of the appropriate epidemiologic and statistical methods and interpretation of the findings. Factors that increase a study's usefulness for risk assessment include such things as the examination of multiple end points and exposure levels, the validity of the data, and proper control of other risk factors, effect modifiers, and confounders in the study design and/or analysis. A more in-depth discussion can be found elsewhere (47).

As described earlier, a single developmental toxicant can result in multiple end points (malformations, functional impairment, altered growth, and/or lethality). These end points can be thought of as sequential competing risks. For example, a malformed fetus spontaneously aborted would not be observed in a study of births with malformations (48). Very early conceptus losses may not be identified in human populations, whereas in most laboratory animal studies, all resorption sites can be identified. Many epidemiologic studies, especially of the case-control design, have focused on one end point, possibly missing a true effect of exposure. Furthermore, some studies have selected one type or class of malformations to study. Since an agent can result in different spectra of malformations following exposure at different times in the pregnancy (49), limiting a study to one class of malformation may give misleading results. Malformations can be meaningfully grouped only if there is a logical underlying teratogenic mechanism or pathogenetic pathway. As a minimum, malformations, deformations, and disruptions should be separated.

The power, or probability of a study to detect a true effect, is dependent upon the size of the study group, the frequency of the outcome in the general population, and the level of excess risk to be identified. Rarer outcomes, such as malformations, require thousands of pregnancies to have a high probability of detecting an increase in risk. More common outcomes, such as fetal loss, require hundreds of pregnancies to have the same probability (8, 23, 50, 51, 52, 53). The confidence one has in the results of a study with negative findings is directly related to the power of the study to detect clinically meaningful differences in incidence for the end points studied.

As in animal studies, pregnancies within the same family (or litter) are not independent events. In animal studies, the litter is generally used as the unit of measure. This approach is difficult in humans since the pregnancies are sequential, with the risk factors changing for the different pregnancies (23, 51, 54). If more than one pregnancy per family is included, and this is often necessary due to small study groups, the use of non-independent observations overestimates the true size of the population at risk and artificially increases the significance level (54).

Other criteria for evaluating epidemiologic studies include the following (23, 50, 52, 55, 56, 57, 58):

1. The potential for complete or relatively complete ascertainment of events for study. This can vary by outcome and by data source; for example, if hospital records are used, early fetal losses will be underascertained, but a more complete list of pregnancies could be obtained by interviewing the women. Congenital malformations can be more completely ascertained using hospital records than birth certificates. Studies with relatively complete ascertainment of events, or at least low probability of unbiased ascertainment, should carry more weight.

2. Validity (accuracy) of the data. Recall of past events in interviews may be faulty, while hospital files contain data recorded at the time of the event (but may be incomplete). Validation of interview data with an independent source, where possible, increases confidence in the results of the study.

3. Collection of data on other risk factors, effect modifiers, and confounders. Data on smoking, alcohol consumption, drug use, and environmental and occupational exposure, etc., during pregnancy should be examined and controlled for in the study design and/or analysis where appropriate. The analytic techniques used to control these factors require careful consideration in their application and interpretation.

C. Other Considerations

1. *Pharmacokinetics.* Extrapolation of data between species can be aided considerably by the availability of data on the pharmacokinetics of a particular agent in the species tested and, if possible, in humans. Information on half-lives, placental metabolism and transfer, and concentrations of the parent compound and metabolites in the

maternal animal and conceptus may be useful in predicting risk for developmental toxicity. Such data may also be helpful in defining the dose-response curve, developing a more accurate comparison of species sensitivity including that of humans (59, 60), determining dosimetry at target sites, and comparing pharmacokinetic profiles for various dosing regimens or routes of exposure. Pharmacokinetic studies in developmental toxicology are most useful if conducted in pregnant animals at the stage when developmental insults occur. The correlation of pharmacokinetic parameters and developmental toxicity data may be useful in determining the contribution of specific pharmacokinetic parameters to the effects observed (61).

2. *Comparisons of Molecular Structure.* Comparisons of the chemical or physical properties of an agent with those of known developmental toxicants may provide some indication of a potential for developmental toxicity. Such information may be helpful in setting priorities for testing of agents or for evaluation of potential toxicity when only minimal data are available. Structure/activity relationships have not been well studied in developmental toxicology, although data are available that suggest structure-activity relationships for certain classes of chemicals (e.g., glycol ethers, steroids, retinoids). Under certain circumstances (e.g., in the case of new chemicals), this is one of several procedures used to evaluate the potential for toxicity when little or no data are available.

D. Weight-of-Evidence Determination

Information available from studies discussed previously, whether indicative of potential concern or not, must be evaluated and factored into the risk assessment. The types of data may vary from chemical to chemical, and certain types of data may be more relevant than other types in performing developmental toxicity assessments. The primary considerations are the human data (which are seldom available) and the experimental animal data. The qualitative assessment for developmental toxicity should include statements concerning the quality of the data, the resolving power of the studies, the number and types of end points examined, the relevance of route and timing of exposure, the appropriateness of the dose selection, the replication of the effects, the number of species examined, and the availability of human case reports, case series, and/or epidemiologic study data. In addition, pharmacokinetic data and structure-activity considerations, as well as other factors that may affect the quality, should be taken into account. Therefore, all data pertinent to developmental toxicity should be examined in the evaluation of a chemical's potential to cause developmental toxicity in humans, and sound scientific judgment should be exercised in interpreting the data in terms of the risk for adverse human developmental health effects.

IV. Quantitative Assessment

Risk assessment involves the description of the nature and often the magnitude of potential human risk, including a description of any attendant uncertainty. In the final phase of the risk assessment (risk characterization), the results of the qualitative evaluation (hazard identification), the dose-response, and the exposure assessments are combined to give qualitative and/or quantitative estimates of the developmental toxicity risk. A summary of the strengths and weaknesses of the hazard identification, dose-response assessment, and exposure assessment should be discussed. Major assumptions, scientific judgments, and, to the extent possible, estimates of the uncertainties in the assessment also should be presented.

A. Dose-Response Assessment

When quantitative human dose-effect data are available and with sufficient range of exposure, dose-response relationships may be examined. However, such data have rarely been available; thus, other methods have been used in developmental toxicology for estimating exposure levels that are unlikely to produce adverse effects in humans. The dose-response assessment is usually based on the evaluation of tests performed in laboratory animals. Evidence for a dose-response relationship is an important criterion in the assessment of developmental toxicity, although this may be based on limited data from standard three-dose studies. As mentioned earlier (section III. A. 2.), however, traditional dose-response relationships may not always be observed for some end points. For example, as the exposure level rises, embryo/fetolethal levels may be reached, resulting in an observed decrease in malformations with increasing dose (49, 51). The potential for this relationship indicates that dose-response relationships for individual end points as well as combinations of end points (e.g., dead and malformed combined) must be carefully examined and interpreted.

Although dose-response data are important in this area, the approaches frequently employed in attempts to extrapolate to humans has involved simply the use of uncertainty (safety) factors and margins of safety, which in some respects are conceptually similar. However, uncertainty factors and margins of safety are computed differently and are often used in different regulatory situations. The choice of approach is dependent upon many factors, including the statute involved, the situation being addressed, the data base used, and the needs of the decision-maker. The final uncertainty factor used and the acceptability of the margin of safety are risk management decisions, but the scientific issues that must be taken into account are addressed here.

The uncertainty factor approach results in a calculated exposure level believed to be unlikely to cause any toxic developmental response in humans. The size of the uncertainty factor will vary from agent to agent and will require the exercise of scientific judgment (10, 62), taking into account interspecies differences, the nature and extent of human exposure, the slope of the dose-response curve, the types of developmental effects observed, and the relative dose levels for maternal and developmental toxicity in the test species. The uncertainty factor selected is then divided into the NOEL for the most sensitive end point obtained from the most appropriate and/or sensitive mammalian species examined to obtain an acceptable exposure level. Currently, there is no one laboratory animal species that can be considered most appropriate for predicting risk to humans (10). Each agent should be considered on a case-by-case basis.

The margin of safety approach derives a ratio of the NOEL from the most sensitive species to the estimated human exposure level from all potential sources (63). The adequacy of the margin of safety is then considered, based on the weight of evidence, including the nature and quality of the hazard and exposure data, the number of species affected, dose-response relationships, and other factors such as benefits of the agent.

Although the standard study design for a developmental toxicity study calls for a low dose that demonstrates a NOEL, there may be circumstances where a risk assessment is based on the results of a study in which a NOEL for developmental toxicity could not be identified. Rather, the lowest dose administered caused significant effect(s) and was identified as the lowest observed effect level (LOEL). In circumstances where only a LOEL is available, it may be appropriate to apply

an additional uncertainty factor. The magnitude of this additional factor is dependent upon scientific judgment. In some instances, additional studies may be needed to strengthen the confidence in this additional uncertainty factor.

B. Exposure Assessment

The results of the dose-response assessment are combined with an estimate of human exposure in order to obtain a quantitative estimate of risk. The Guidelines for Estimating Exposures are published separately (64) and will not be discussed in detail here. In general, the exposure assessment describes the magnitude, duration, schedule, and route of exposure. This information is developed from monitoring data and from estimates based on modeling of environmental exposures. Unique considerations relevant to developmental toxicity are duration and period of exposure as related to stage of development (i.e., critical periods), and the possibility that a single exposure may be sufficient to produce adverse developmental effects (i.e., chronic exposure is not a necessary prerequisite for developmental toxicity to be manifested). Also, it should be recognized that exposure of almost any segment of the human population (i.e., fertile men and women, the conceptus, and the child up to the age of sexual maturation) may lead to risk to the developing organism.

Data on exposure to humans may be qualitative or quantitative. The qualitative data could be surrogate data, such as employment or residence histories; quantitative or dose data are frequently not available. Exposures at different stages of the reproductive process can result in different outcomes (49). In laboratory studies, these time periods can be carefully controlled. In human studies, especially retrospective ones, linking of specific time periods and specific exposures, even on a qualitative level, may be difficult due to errors of recall or record keeping (where records are available). The increased probability of misclassification of exposure status may affect the ability of a study to recognize a true effect (8, 23, 52, 65, 66).

Exposure may be defined at a specific point in time, or the cumulative lifetime exposure up to a specific point in time. Each of these definitions carries an implicit assumption about the underlying relationship between exposure and outcome. For example, a cumulative exposure measure assumes that total lifetime exposure is important, with a greater probability of effect with greater total exposure; a dichotomous exposure measure (ever exposed versus never exposed) assumes an irreversible effect of exposure; and exposure at a specific time in the reproductive process assumes that only concurrent exposure is important. The appropriate exposure depends on the outcome(s) studied, the biologic mechanism affected by exposure, and the half-life of the exposure. Unbiased misclassification of exposure, due either to poor data or to an inappropriate exposure variable, may result in missing an effect of the agent under study.

C. Risk Characterization

Many uncertainties have been pointed out in these Guidelines which are associated with the toxicological and exposure components of risk assessments in developmental toxicology. In the past, these uncertainties have often not been readily apparent or consistently presented. The presentation of any risk assessment for developmental toxicity should be accompanied by statements concerning the strength of the hazard evaluation (see section III. D. for more detail) as well as dose-response relationships, estimates of human exposure, and any other factors that affect the quality and precision of the assessment. The dose-response and exposure data are combined to estimate risk based on a NOEL for any adverse developmental effect. The uncertainty factor selected or margin of safety calculated should be sufficiently qualified as to the assumptions used and the accuracy of the estimates.

At present, there are no mathematical models that are generally accepted for estimating developmental toxicity responses below the applied dose range. This is due primarily to a lack of understanding of the biological mechanisms underlying developmental toxicity, intra/interspecies differences in the types of developmental events, the influence of maternal effects on the dose-response curve, and whether or not a threshold exists below which no effect will be produced by an agent. Many developmental toxicologists assume a threshold for most developmental effects; this assumption is based largely on the biological rationale that the embryo is known to have some capacity for repair of the damage or insult (49), and that most developmental deviations are probably multifactorial in nature (67). The existence of a NOEL in an animal study does not prove or disprove the existence or level of a true threshold; it only defines the highest level of exposure under the conditions of the test that are not associated with a significant increase in effect. The use of NOELs and uncertainty factors or margins of safety are attempts to ensure that the allowable levels are below those that will produce a significant increase in developmental effects.

Discussions of risk extrapolation procedures have noted that further work is needed to improve mathematical tools for developing estimates of potential human developmental risk (62, 68). Gaylor (69) has suggested an approach for controlling risk that combines the use of mathematical models for low-dose estimation of risk with the application of an uncertainty factor based on a preselected level of allowable risk. This approach is similar to approaches proposed for carcinogenesis, but does not preclude the possibility of a threshold, and may provide a more quantitative approach to controlling risk. Several such approaches are being examined. For the most part, the Agency will continue to use uncertainty factors and margins of safety as described above. Other appropriate methods for expressing risk are being sought and will be applied if considered acceptable.

These Guidelines summarize the procedures that the U.S. Environmental Protection Agency will follow in evaluating the potential for agents to cause developmental toxicity. These Guidelines will be reviewed and updated as advances are made in the field, since it is evident that our ability to evaluate and predict human developmental toxicity is imprecise. Further studies that (1) delineate the mechanisms of developmental toxicity and pathogenesis, (2) provide comparative pharmacokinetic data, and (3) elucidate the functional modalities that may be altered by exposure to toxic agents will aid in the interpretation of data and interspecies extrapolation. These types of studies, along with further evaluation of the relationship between maternal and fetal toxicity and the concept of a threshold in developmental toxicity, will provide for the development of improved mathematical models to more precisely assess risk.

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Part B: Response to Public and Science Advisory Board Comments

I. Introduction

This section summarizes some of the issues raised in public comments on the Proposed Guidelines for the Health Assessment of Suspect Developmental Toxicants published November 23, 1984 (49 FR 46324). Comments were received from 44 individuals or organizations. The Agency's initial summary of comments was presented to the Developmental Toxicity Guidelines Panel of the Science Advisory Board (SAB) at its organizational meeting on March 4, 1985. At its April 22–23, 1985, meeting, the Panel provided the Agency with its suggestions and recommendations concerning the Guidelines.

The SAB and public comments were diverse and addressed issues from a variety of perspectives. In general, the comments were favorable and in support of the Guidelines. The SAB Panel noted that the field of developmental toxicology is particularly weak with respect to quantitative assessment and recommended that further efforts be given to developing alternative methods for quantitative estimates of risk for developmental toxicity. They also indicated that further discussion of the relationship of maternal toxicity to fetal toxicity could be added. Concern was expressed that these Guidelines be coordinated with the reproductive toxicity guidelines which are currently being developed.

In response to the comments, the Agency has modified or clarified many sections of the Guidelines. For purposes of this discussion, only the most significant issues reflected by the public and SAB comments are discussed. Several minor recommendations, which do not warrant discussion here, were considered by the Agency in the revision of these Guidelines.

II. Coordination With Other Guidelines

A. Other Risk Assessment Guidelines

Several commentors raised concerns about aspects of developmental toxicity (e.g., paternally-mediated effects, effects of subchronic exposures, transplacental carcinogenesis, etc.) that were not covered in these Guidelines, and how these Guidelines will integrate with those on male and female reproductive toxicity which are still under development.

The Guidelines have been revised to indicate that developmental toxicity may result from several different types of exposure, including parental exposure prior to conception, acute or subacute exposure during organogenesis, perinatal and postnatal development to the time of sexual maturation, or subchronic exposure as would be the case in multigeneration studies. These Guidelines provide information for interpreting developmental effects related to any of the types of exposure mentioned above. End points of developmental toxicity, which are measured in multigeneration studies, have been added to Table 2 and discussed in the text. Transplacental carcinogenesis, although considered a developmental effect, will be evaluated and assessed in terms of human risk according to the Guidelines for Carcinogen Risk Assessment. Careful attention will be paid to integrating these developmental toxicity risk assessment Guidelines and the male and female reproductive toxicity risk assessment guidelines, which are currently being written, so that overlapping material is not in conflict, and no pertinent information is overlooked. Since the developmental and reproductive toxicity guidelines are being developed by Agency committees that have overlapping membership within the Agency, such integration will be ensured.

B. Coordination With Testing Guidelines

Several commentors indicated that these Guidelines did not make clear enough the fact that testing guidelines are already in place and that these guidelines were intended only for the purposes of risk assessment.

The Guidelines have been revised to indicate that they do not constitute any changes in current testing guidelines, but rather they are intended to provide guidance for the interpretation of studies that follow the testing guidelines. In addition, limited information is provided for interpretation of other studies (e.g., functional developmental toxicity studies and short-term tests) which are not routinely required or for which there are no current testing guidelines, but which may be encountered when reviewing data on particular agents.

III. Definitions

Several questions were raised about definitions of terminology, due to lack of clarity or inconsistency with other parts of these Guidelines or the testing guidelines.

As indicated in the Guidelines, there are differences in the use of terms in the field of developmental toxicology, and the terms have been defined so that the reader may understand how the terms are being used. Several minor changes in the definitions have been made to

make them more consistent. For example, the definition for developmental toxicology has been expanded to include the wide range of exposure situations that may result in developmental effects. The term functional teratology has been changed to functional developmental toxicology, and the term teratogenicity has been discussed in the section on malformations and variations.

IV. Qualitative Assessment

A. Maternal and Developmental Toxicity

Several commentors noted the need for a better discussion of how maternal toxicity affects the evaluation of developmental toxic effects.

The Agency has taken the approach in these Guidelines of discussing in detail the individual end points of maternal and offspring toxicity, then giving guidance relating to an overall evaluation of the data in Part A, section III.A.4. This approach is consistent with the philosophy reflected in the Guidelines as follows: Those agents that cause developmental effects at doses lower than those causing maternal toxicity are of greatest concern, but developmental effects at doses that also produce maternal toxicity shoud not be discounted as secondary to maternal effects. Rather, when the lowest observed effect level (LOEL) is the same for maternal and developmental toxicity, it may indicate similar sensitivities to the agent, and maternal effects may be reversible while developmental effects may be permanent.

B. Functional Developmental Toxicity

Several commentors raised concern about the premature use of functional data in the risk assessment process. On the other hand, the SAB Panel felt that these tests were very valuable in assessing developmental toxicity.

The Agency does not routinely require such testing, and these Guidelines do not suggest requirements. However, in the review of data on existing chemicals, such data are sometimes encountered and must be evaluated by the Agency. The discussion in the Guidelines is intended to delineate the current state of the art, and to indicate to what extent the data currently may be used for risk assessment purposes.

C. Short-Term Testing

Several commentors stressed the need for further refinement, validation, and comparative testing to determine the credibility of short-term tests for developmental toxicity. The appropriateness of single dose level screens for the purpose of prioritization was endorsed by the SAB Panel with the reservation that too many false positives might occur, and that positive agents in these screens would be permanently labelled as positive developmental toxicants.

Since data from these types of test procedures may be encountered in the assessment of chemicals, the Agency felt it appropriate to give guidance as to how these should be evaluated. The Guidelines have been revised to clearly indicate that these tests are not routinely required, should not be considered as a replacement for routine *in vivo* developmental toxicity testing in mammals, and should not be used to make the final decision as to whether an agent is a positive or negative developmental toxicant.

D. Comparisons of Molecular Structure

Comments suggested that not much is known about structure-activity relationships for developmental toxicants, and that this procedure should not be used except in the case of hormone analogs.

A statement has been added to indicate that structure-activity relationships have not been well-studied in developmental toxicology, but under certain circumstances, e.g., in the case of the premanufacturing notice process (TSCA, section 5), the evaluation of molecular structure is one of several procedures used by the Agency to evaluate potential toxicity and to support requests for testing of new chemicals.

V. Quantitative Assessment

Most comments related to the appropriateness of using uncertainty (safety) factors, margins of safety, and no observed effect levels (NOELs). Some commentors felt that the concept of threshold was not adequately discussed in the Guidelines.

These Guidelines are intended to reflect current Agency policy and practice. Although more quantitative assessment of developmental toxicity data are desirable, and efforts are currently ongoing within the Agency to evaluate other approaches, the current practice is to use the NOEL (or the LOEL if a NOEL is not available), and to apply an uncertainty factor or to calculate the margin of safety. This practice is based in large part on the lack of understanding of the biological mechanisms involved. The uncertainty factor used or acceptability of the margin of safety are considered risk management decisions, but the scientific issues that must be taken into account are discussed in these Guidelines. An experimentally determined NOEL does not prove or disprove the existence of a threshold, although many developmental toxicologists assume a threshold for most developmental effects because of known repair capabilities in developing systems and the fact that many developmental alterations are multifactorial in nature.

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Part VI

Environmental Protection Agency

Guidelines for Exposure Assessment

ENVIRONMENTAL PROTECTION AGENCY

[FRL-2984-4]

Guidelines for Estimating Exposures

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final Guidelines for Estimating Exposures.

SUMMARY: The U.S. Environmental Protection Agency is today issuing five guidelines for assessing the health risks of environmental pollutants. These are:

Guidelines for Carcinogen Risk Assessment
Guidelines for Estimating Exposures
Guidelines for Mutagenicity Risk Assessment
Guidelines for the Health Assessment of Suspect Developmental Toxicants
Guidelines for the Health Risk Assessment of Chemical Mixtures

This notice contains the Guidelines for Estimating Exposures; the other guidelines appear elsewhere in today's Federal Register.

The Guidelines for Estimating Exposures (hereafter "Guidelines") are intended to guide Agency analysis of exposure assessment data in line with the policies and procedures established in the statutes administered by the EPA. These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Office of Health and Environmental Assessment (OHEA) in the Agency's Office of Research and Development. They reflect Agency consideration of public and Science Advisory Board (SAB) comments on the Proposed Guidelines for Exposure Assessment published November 23, 1984 (49 FR 46304).

This publication completes the first round of risk assessment guidelines development. These Guidelines will be revised, and new guidelines will be developed, as appropriate.

EFFECTIVE DATE: The Guidelines will be effective September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Dr. Richard V. Moraski, Exposure Assessment Group, Office of Health and Environmental Assessment (RD-689), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, 202-475-8923.

SUPPLEMENTARY INFORMATION: In 1983, the National Academy of Sciences (NAS) published its book entitled *Risk Assessment in the Federal Government: Managing the Process.* In that book, the NAS 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. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

General

The guidelines published today are products of a two-year Agencywide effort, which has included many scientists from the larger scientific community. These guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments, and to inform Agency decision makers and the public about these procedures. In particular, the guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific information on each agent and use the most scientifically appropriate interpretation to assess risk. The guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Finally, the guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Guidelines for Estimating Exposures

Work on the Guidelines for Estimating Exposures began in January 1984. Draft guidelines were developed by Agency work groups composed of expert scientists throughout the Agency. The drafts were peer-reviewed by expert scientists in the field of exposure assessment from universities, environmental groups, industry, labor, and other governmental agencies. They were then proposed for public comment in the **Federal Register** (49 FR 46304). On November 9, 1984, the Administrator directed that Agency offices use the proposed guidelines in performing risk assessments until final guidelines become available.

After the close of the public comment period, Agency staff prepared summaries of the comments, analyses of the major issues presented by the commentors, and preliminary Agency responses to those comments. These analyses were presented to review panels of the SAB on March 4 and April 22-23, 1985, and to the Executive Committee of the SAB on April 25-26, 1985. The SAB meetings were announced in the **Federal Register** as follows: February 12, 1985 (50 FR 5811) and April 4, 1985 (50 FR 13420 and 13421).

In a letter to the Administrator dated June 19, 1985, the Executive Committee generally concurred on all five of the guidelines, but recommended certain revisions, and requested that any revised guidelines be submitted to the appropriate SAB review panel chairman for review and concurrence on behalf of the Executive Committee. As described in the responses to comments (see Part B: Response to the Public and Science Advisory Board Comments), each guidelines document was revised, where appropriate, consistent with the SAB recommendations, and revised draft guidelines were submitted to the panel chairmen. Revised draft Guidelines for Estimating Exposures were concurred on in a letter dated January 13, 1986. Copies of the letters are available at the Public Information Reference Unit, EPA Headquarters Library, as indicated elsewhere in this notice.

Following this Preamble are two parts: Part A contains the Guidelines and Part B, the Response to the Public and Science Advisory Board Comments (a summary of the major public comments, SAB comments, and Agency responses to those comments).

The SAB requested that the Agency develop guidelines on the principles for the measurement of pollutant concentrations in the various environmental media and for the uses of environmental measurements for exposure assessment. This effort is currently underway.

The Agency also will provide technical support documents that contain detailed technical information needed to implement the Guidelines. Two of these technical reports entitled "Development of Statistical Distributions or Ranges of Standard Factors Used in Exposure Assessments" (available from the National Technical Information Service, PB85-242667) and "Methodology for Characterization of Uncertainty in Exposure Assessments" (available from the National Technical Information Service, PB85-240455) are currently available. Technical support documents will be revised periodically to reflect improvements in exposure assessment methods and new information or experience.

The Agency is continuing to study the risk assessment issues raised in the Guidelines and will revise these Guidelines in line with new information, as appropriate.

References, supporting documents, and comments received on the proposed guidelines, as well as copies of the final guidelines, are available for inspection and copying at the Public Information Reference Unit (202–382–5926), EPA Headquarters Library, 401 M Street, SW, Washington, DC, between the hours of 8:00 a.m. and 4:30 p.m.

I certify that these Guidelines are not major rules as defined by Executive Order 12291, because they are nonbinding policy statements and have no direct effect on the regulated community. Therefore, they will have no effect on costs or prices, and they will have no other significant adverse effects on the economy. These Guidelines were reviewed by the Office of Management and Budget under Executive Order 12291.

Dated: August 22, 1986.

Lee M. Thomas,

Administrator.

Contents

Part A: Guidelines for Estimating Exposures

I. Introduction

These Guidelines provide the Agency with a general approach and framework for carrying out human or nonhuman exposure assessments for specified pollutants. The Guidelines have been developed to assist future assessment activities and encourage improvement in those EPA programs that require, or could benefit from, the use of exposure assessments. The Guidelines are procedural. They should be followed to the extent possible in instances where exposure assessment is a required element in the regulatory process or where exposure assessments are carried out on a discretionary basis by EPA management to support regulatory or programmatic decisions.

This document, by laying out a set of questions to be considered in carrying out an exposure assessment, should help avoid inadvertent mistakes of omission. Ideally, exposure assessments are based on measured data. EPA recognizes that gaps in data will be common, but the Guidelines will nevertheless serve to assist in organizing the data that are available, including new data developed as part of the exposure assessment. In the absence of sufficient reliable data and the time to obtain appropriate measurements, exposure assessments may be based on validated mathematical models. Whenever possible, exposure assessments based on modeling should be complemented by reliable measurements. Furthermore, it is understood that the level of detail found in the exposure assessments depends on the scope of the assessment.

These Guidelines should also promote consistency among various exposure assessment activities that are carried out by the Agency. Consistency with respect to common physical, chemical, and biological parameters, with respect to assumptions about typical exposure situations, and with respect to the characterization of uncertainty of estimates, will enhance the comparability of results and enable the Agency to improve the state-of-the-art of exposure assessment over time through the sharing of common data and experiences.

It is recognized that the main objective of an exposure assessment is to provide reliable data and/or estimates for a risk assessment. Since a risk assessment requires the coupling of exposure information and toxicity or effects information, the exposure assessment process should be coordinated with the toxicity/effects assessment. This document provides a common approach to format, which should simplify the process of reading and evaluating exposure assessments and thereby increase their utility in assessing risk.

As the Agency performs more exposure assessments, the Guidelines will be revised to reflect the benefit of experience.

II. General Guidelines and Principles

A. Exposure and Dose

Exposure has been defined by Committee E–47, Biological Effects and Environmental Fate, of the American Society for Testing and Materials, as the contact with a chemical or physical agent. The magnitude of the exposure is determined by measuring or estimating the amount of an agent available at the exchange boundaries, i.e., lungs, gut, skin, during some specified time. Exposure assessment is the determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure. Exposure assessments may consider past, present, and future exposures with varying techniques for each phase, e.g., modeling of future exposures, measurements of existing exposure, and biological accumulation for past exposures. Exposure assessments are generally combined with environmental and health effects data in performing risk assessments.

In considering the exposure of a subject to a chemical agent, there are several related processes. The contact between the subject of concern and the agent may lead to the intake of some of the agent. If absorption occurs, this constitutes an uptake (or an absorbed dose). When biological tissue or fluid measurements indicate the presence of a chemical, exposures may be estimated from these data. Presence of a chemical in such biological samples is the most direct indication that an exposure has occurred. The route of exposure generally impacts the extent of absorption and should be considered in performing risk assessments.

B. Decision Path To Determine Scope of the Assessment

The first step in preparing an exposure assessment should be the circumscription of the problem at hand to minimize effort by use of a narrowing process. A decision path that describes this process is shown in Figure 1. As illustrated in Figure 1, the preliminary assessment and the in-depth assessment are two major phases in this logic path.

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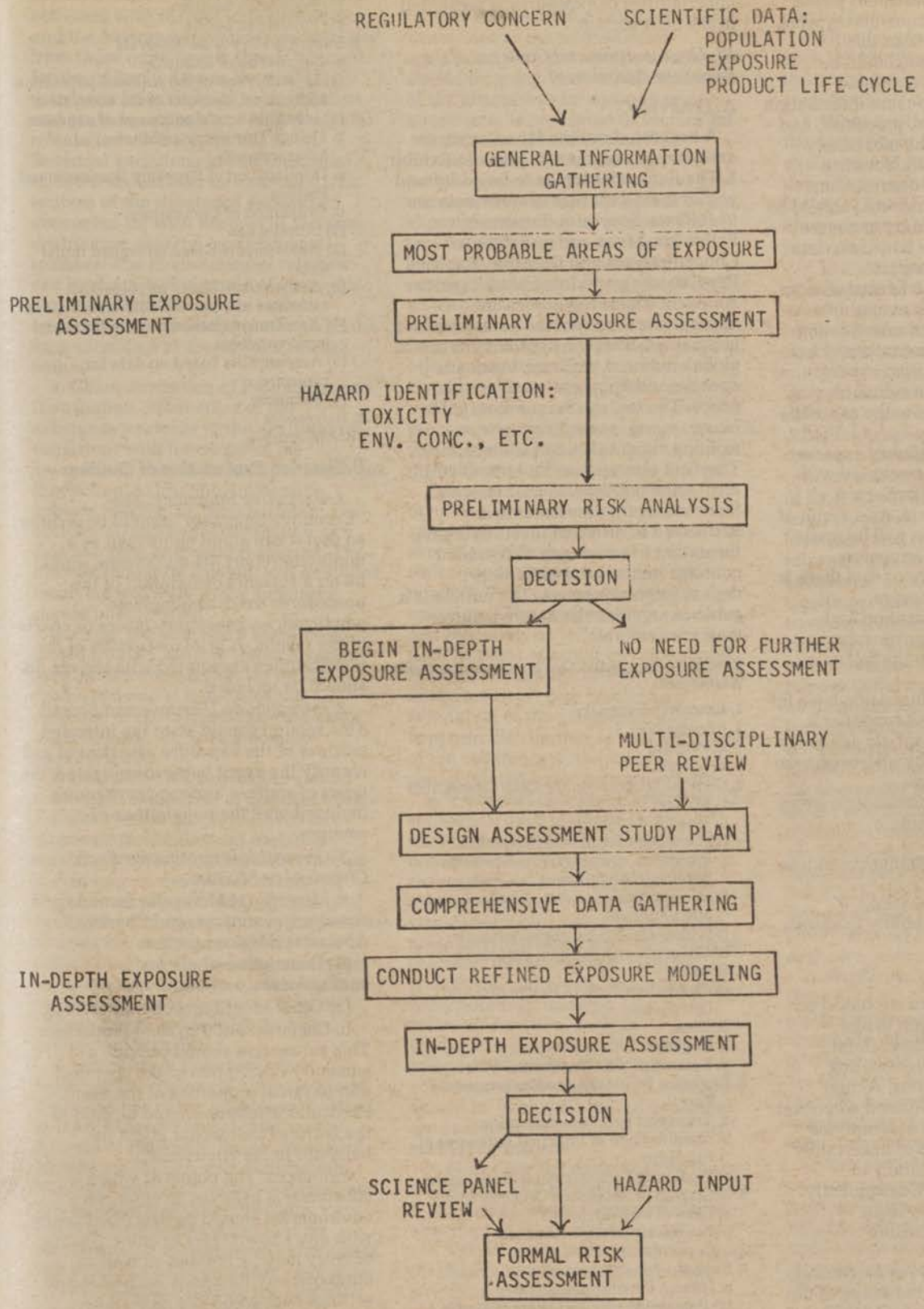

Figure 1. Decision path for exposure assessment.

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The preliminary assessment phase should commence by considering what risk is under study. Within this framework, a data base should be compiled from readily available scientific data and exposure information based on manufacturer, processor, and user practices. Next, the most likely areas of exposure (manufacturing, processing, consumer, distribution, disposal, water and food, etc.) should be identified. The preliminary exposure assessments should be based on data derived from environmental measurements. When a limited amount of measurement data is available, estimates may be based on modeling. Since a complete data search may not be possible, well identified assumptions and order of magnitude estimates may be used to further narrow the exposure areas of concern.

Data from this preliminary exposure assessment can then be coupled with toxicity information to perform a preliminary risk analysis. As a result of this analysis, a decision will be made that either an in-depth exposure assessment is necessary or that there is no need for further exposure information. The organization and contents of an in-depth exposure assessment are given in the following section.

In assembling the information base for either a preliminary assessment or a more detailed assessment, its adequacy should be ascertained by addressing the following considerations:

- Availability of information in every area needed for an adequate assessment;
- Quantitative and qualitative nature of the data;
- Reliability of information;
- Limitations on the ability to assess exposure.

C. Uncertainty

Exposure assessments are based on measurements, simulation model estimates, and assumptions about parameters used in approximating actual exposure conditions. Actual measurements should be used whenever possible. Both data and assumptions contain varying degrees of uncertainty which influence the accuracy of exposure assessments. Consequently, evaluation of uncertainty is an important part of all exposure assessments.

The uncertainty analyses performed will vary depending on the scope of the assessment, the quantity and quality of measurements, and the type and complexity of mathematical models used. A discussion of the types of analyses used for quantifying uncertainties in exposures is presented in the next section.

III. Organization and Contents of an Exposure Assessment

A. Overview

A suggested outline for an exposure assessment document is given in Exhibit 1. The five major topics to be addressed within most exposure assessments are as follows: Source(s), Exposure Pathways, Measured or Estimated Concentrations and Duration, Exposed Population(s), and Integrated Exposure Analysis. These five topics are appropriate for exposure assessments in general, whether the assessments are of global, national, regional, local, site specific, workplace related, or other scope. The topics are appropriate for exposure assessments on new or existing chemicals and radionuclides. They are also applicable to both single media and multimedia assessments. Since exposure assessments are performed at different levels of detail, the extent to which any assessment contains items listed in Exhibit 1 depends upon its scope. The outline is a guide to organize the data whenever they are available.

Exhibit 1—Suggested Outline for an Exposure Assessment

1. Executive Summary
2. Introduction
   a. Purpose
   b. Scope
3. General Information for Each Chemical or Mixture
   a. Identity
   (1) Molecular formula and structure, synonyms, and Chemical Abstracts Service (CAS) number
   (2) Description of grades, contaminants, and additives
   (3) Other identifying characteristics
   b. Chemical and Physical Properties
4. Sources
   a. Characterization of Production and Distribution
   b. Uses
   c. Disposal
   d. Summary of Environmental Releases
5. Exposure Pathways and Environmental Fate
   a. Transport and Transformation
   b. Identification of Principal Pathways of Exposure
   c. Predicting Environmental Distribution
6. Measured or Estimated Concentrations
   a. Uses of Measurements
   b. Estimation of Environmental Concentrations
7. Exposed Populations
   a. Human Populations
   (1) Population size and characteristics
   (2) Population location
   (3) Population habits
   b. Nonhuman Populations (where appropriate)
   (1) Population size and characteristics
   (2) Population location
   (3) Population habits
8. Integrated Exposure Analysis
   a. Calculation of Exposure
   (1) Identification of the exposed population and critical elements of the ecosystem
   (2) Identification of pathways of exposure
   b. Human Dosimetry and Biological Measurements
   c. Development of Exposure Scenarios and Profiles
   d. Evaluation of Uncertainty
   (1) Introduction
   (2) Assessments based on limited initial data
   (3) Assessments based on subjective estimates of input variable distributions
   (4) Assessments based on data for model input variables
   (5) Assessments based on data for exposure
   (6) Summary
9. References
10. Appendices

B. Detailed Explanation of Outline

1. Executive Summary. The "Executive Summary" should be written so that it can stand on its own as a miniature report. Its main focus should be on a succinct description of the procedures used, assumptions employed, and summary tables or charts of the results. A brief discussion of the uncertainties associated with the results should be included.

2. Introduction (Purpose and Scope). This section should state the intended purpose of the exposure assessment and identify the agent being investigated, the types of sources and exposure routes included, and the populations of concern.

3. General Information for Each Chemical or Mixture.

a. Identity. (1) Molecular formula and structure, synonyms, and Chemical Abstracts Service number.

(2) Description of grades, contaminants, and additives.

(3) Other identifying characteristics.

b. Chemical and Physical Properties. This subsection should provide a summary description of the chemical and physical properties of the agent. Particular attention should be paid to the features that would affect its behavior in the environment.

4. Sources. The points at which a substance is believed to enter the environment should be described, along with any known rates of entry. (Points of entry may be indoors as well as outdoors; environments include indoor settings such as offices as well as outdoor environments.) A detailed exposure assessment should include a study of sources, production, uses, destruction/disposal, and environmental release of a substance. The studies

should include a description of human activities with respect to the substance and the environmental releases resulting from those activities. It should account for the controlled mass flow of the substance from creation to destruction and provide estimates of environmental releases at each step in this flow. Seasonal variations in environmental releases should also be examined. All sources of the substance should be accounted for with the sum of the uses, destruction, and the environmental releases. The environmental releases can be described in terms of geographic and temporal distribution and the receiving environmental media, with the form identified at the various release points.

a. Characterization of Production and Distribution. All sources of the substance's release to the environment, consistent with the scope of the assessment, should be included, such as production, extraction, processing, imports, stockpiles, transportation, accidental/incidental production as a side reaction, and natural sources. The sources should be located, and activities involving exposure to the substance should be identified.

b. Uses. The substance should be traced from its sources through various uses (with further follow-up on the products made to determine the presence of the original material as an impurity), e.g., exports, stockpile increases, etc.

c. Disposal. This subsection should contain an evaluation of disposal sites and destruction processes, such as incineration of industrial chemical waste, incineration of the substance as part of an end-use item in municipal waste, landfilling of wastes, biological destruction, or destruction in the process of using the end product. Hazardous contaminants of the substance may be included, and products containing the substance as a contaminant may be followed from production through destruction/disposal.

d. Summary of Environmental Releases. Estimates should be made of the quantities of the substance released to the various environmental media. Sources of release to the environment include production, use, distribution/transport, natural sources, disposal, and contamination of other products. Environmental releases should be presented at a reasonable level of detail. Extremely detailed exposure estimates would attempt to specify the following information for each significant emission source: location, amount of the substance being released as a function of time to each environmental medium, physical characteristics of the emission source, and the physical and chemical form of the substance being released. Evaluation of the uncertainties associated with the emission estimates should be given. A detailed discussion of the procedures for estimating uncertainty is presented in section 8.d.

5. Exposure Pathways and Environmental Fate. The exposure pathways section should address how an agent moves from the source to the exposed population or subject. For a less detailed assessment, broad generalizations on environmental pathways and fate may be made. In the absence of data, e.g., for new substances, fate estimates may have to be predicted by analogy with data from other substances. Fate estimates may also be made by using measurements and/or models and laboratory-derived process rate coefficients. At any level of detail, certain pathways may be judged insignificant and not pursued further.

For more detailed assessments involving environmental fate, the analysis of sources described previously should provide the amount and rate of emissions to the environment, and possibly the locations and form of the emissions. The environmental pathways and fate analysis follows the substance from its point of initial environmental release, through the environment, to its ultimate fate. It may result in an estimation of the geographic and temporal distribution of concentrations of the substance in the various contaminated environmental media.

a. Transport and Transformation. The substance, once released to the environment, may be transported (e.g., convected downstream in water or on suspended sediment, through the atmosphere, etc.) or physically transformed (e.g., volatilized, melted, absorbed/desorbed, etc.); may undergo chemical transformation, such as photolysis, hydrolysis, oxidation, and reduction; may undergo biotransformation, such as biodegradation; or may accumulate in one or more media. Thus, the environmental behavior of a substance should be evaluated before exposures are assessed. Factors that should be addressed include:

- How does the agent behave in air, water, soil, and biological media? Does it bioaccumulate or biodegrade? Is it absorbed or taken up by plants?
- What are the principal mechanisms for change or removal in each of the environmental media?
- Does the agent react with other compounds in the environment?
- Is there intermedia transfer? What are the mechanisms for intermedia transfer? What are the rates of the intermedia transfer or reaction mechanisms?
- How long might the agent remain in each environmental medium? How does its concentration change with time in each medium?
- What are the products into which the agent might degrade or change in the environment? Are any of these degradation products ecologically or biologically harmful? What is the environmental behavior of the harmful products?
- Is a steady-state concentration distribution in the environment, or in specific segments of the environment, achieved? If not, can the nonsteady-state distribution be described?
- What is the resultant distribution in the environment—for different media, different types or forms of the agent, for different geographical areas, at different times or seasons?

b. Identification of Principal Pathways of Exposure. The principal pathway analysis should evaluate the sources, locations, and types of environmental releases, together with environmental behavioral factors, to determine the significant routes of human and environmental exposure to the substance. Thus, by listing the important characteristics of the environmental release (entering media, emission rates, etc.) and the agent's behavior (intermedia transfer, persistence, etc.) after release to each of the entering media, it should be possible to follow the movement of the agent from its initial release to its subsequent fate in the environment. At any point in the environment, human or environmental exposure may occur. Pathways that result in major concentrations of the agent and high potential for human or environmental contact are the principal exposure pathways.

c. Predicting Environmental Distribution. Models may be used to predict environmental distributions of chemicals. Model estimates of environmental distribution of chemicals are based on measurements whenever feasible. In predicting environmental distributions of chemicals, available measurements must be considered.

In this section an estimation is made, using appropriate models, of representative concentrations of the agent in different environmental media, and its time-dependence in specific geographical locations (e.g., river basins, streams, etc.).

6. Measured or Estimated Concentrations.

a. Uses of Measurements. Measurements are used to identify releases (source terms) and, in the

exposure pathways and fate assessments, to quantitatively estimate both release rates and environmental concentrations. Some examples of uses of measurements are: sampling of stacks or discharge pipes for emissions to the environment, testing of products for chemical or radionuclide content, testing of products for chemical or radioactive releases, sampling of appropriate points within a manufacturing plant to determine releases from industrial processes or practices, sampling of potentially exposed populations using personal dosimeters, and sampling of solid waste for chemical or radionuclide content. These data should be characterized as to accuracy, precision, and representativeness. If actual environmental measurements are unavailable, concentrations can be estimated by various means, including the use of fate models (see previous section) or, in the case of new chemicals, by analogy with existing chemicals.

Measurements are a direct source of information for exposure analysis. Furthermore, reliable measurements can be used to calibrate or extrapolate models or calculations to assess environmental distributions. However, environmental pathway and fate analysis may be needed in addition to the measured data for the following reasons: for most pollutants, particularly organic and new chemicals, measurements are limited; analysis of measured data does not often yield relationships between environmental releases and environmental concentration distribution in media or geographic locations that have not been measured; analysis of measurements does not provide information on how and where biota influence the environmental distribution of a pollutant; and measured concentrations may not be traceable to individual sources.

b. Estimation of Environmental Concentrations. Concentrations of agents should be estimated for all environmental media that might contribute to significant exposures. Generally, the environmental concentrations are estimated from measurements, mathematical models, or a combination of the two. If environmental measurements are not limited by sample size or inaccuracies, then exposure assessments based on measurements have precedence over estimates based on models.

The concentrations must be estimated and presented in a format consistent with available dose-response information. In some cases an estimate of annual average concentration will be sufficient, while in other cases the temporal distribution of concentrations may be required. Future environmental concentrations resulting from current or past releases may also be projected. In some cases, both the temporal and geographic distributions of the concentration may be assessed. Moreover, if the agent has natural sources, the contribution of these to environmental concentrations may be relevant. These "background" concentrations may be particularly important when the results of tests of toxic effects show a threshold or distinctly nonlinear dose-response.

The uncertainties associated with the estimated concentrations should be evaluated by an analysis of the uncertainties of the model parameters and input variables. When the estimates of the environmental concentrations are based on mathematical models, the model results must be compared to available measurements, and any significant discrepancies should be discussed. Reliable, analytically-determined values must be given precedence over estimated values whenever significant discrepancies are found.

7. Exposed Populations. Populations selected for study may be done *a priori*, but frequently the populations will be identified as a result of the sources and fate studies. From an analysis of the distribution of the agent, populations and subpopulations (i.e., collections of subjects) at potentially high exposure can be identified, which will then form the basis for the populations studied. Subpopulations of high sensitivity, such as pregnant women, infants, chronically ill, etc., may be studied separately.

Census and other survey data may be used to identify and describe the population exposed to various contaminated environmental media. Depending on the characteristics of available toxicological data, it may be appropriate to describe the exposed population by other characteristics such as species, subspecies-age-sex distribution, and health status.

In many cases, exposed populations can be described only generally. In some cases, however, more specific information may be available on matters such as the following:

a. *Human Populations*

(1) Population size and characteristics (e.g., trends, sex/age distribution)

(2) Population location

(3) Population habits—transportation habits, eating habits, recreational habits, workplace habits, product use habits, etc.

b. *Nonhuman Populations (where appropriate)*

(1) Population size and characteristics (e.g., species, trends)

(2) Population location

(3) Population habits

8. *Integrated Exposure Analysis.* The integrated exposure analysis combines the estimation of environmental concentrations (sources and fate information) with the description of the exposed population to yield exposure profiles. Data should be provided on the size of the exposed populations; duration, frequency, and intensity of exposure; and routes of exposure. Exposures should be related to sources.

For more detailed assessments, the estimated environmental concentrations should be considered in conjunction with the geographic distribution of the human and environmental populations. The behavioral and biological characteristics of the exposed populations should be considered, and the exposures of populations to various concentration profiles should be estimated. The results can be presented in tabular or graphic form, and an estimate of the uncertainty associated with them should be provided.

a. Calculation of Exposure. The calculation of exposure involves two major aspects:

(1) Identification of the exposed population and critical elements of the ecosystem.

The estimate of environmental concentrations also should give the geographical areas and environmental media contaminated. The stated purpose of the assessment should have described the human and environmental subjects for which exposures are to be calculated. If the subjects are not listed, the contaminated geographical areas and environmental media can be evaluated to determine subject populations. The degree of detail to be used in defining the exposed population distribution depends on the concentration gradient over geographic areas.

(2) Identification of pathways of exposure:

(a) Identification and description of the routes by which the substances travel from production site, through uses, through environmental releases/sources, through transport and fate processes, to the target population.

(b) Quantitative estimates of the amounts of the chemical following each exposure pathway. Such estimates allow the various pathways to be put in the perspective of relative importance.

From the geographic and temporal distribution of environmental

concentrations, the exposed population, the behavioral characteristics, and the critical elements of the ecosystem, exposure distributions can be estimated. The results of exposure calculation should be presented in a format that is consistent with the requirements of the dose-response functions which may later be used in a risk assessment. For example, when health risks caused by exposure over extended durations are considered, average daily exposure over the duration of exposure usually is calculated. When lifetime risks are considered, average daily exposure over a lifetime usually is calculated. In contrast, when health risks caused by exposures over short durations are considered, exposure rates are calculated over short time intervals to ensure that peak risks are defined. Many exposure assessments are based on the average exposure occurring over the exposure period. The range of possible exposures is usually divided into intervals, and the exposures within each interval are counted. The results can be presented in tabular form or as a histogram.

The population residing in a specific geographic area may be exposed to a substance from several exposure routes. For each exposure route, exposure of individuals in these populations may be determined by summing the contribution of all sources to the exposure route. When exposures involve more than one exposure route, the relative amounts of a substance absorbed is usually route dependent. Consequently, total absorbed dose estimates must account for these differences. Because EPA regulates sources of releases, the contribution to exposures from each type of source being considered should be displayed. Exposure estimates should be presented for each significant exposure route, and the results should be tabulated in such a way that total externally applied and absorbed dose can be determined.

b. Human Dosimetry and Biological Measurements. Biological measurements of human body fluids and tissues for substances or their metabolites can be used to estimate current or past exposure to chemicals. When analytical methods are available, chemicals that have been absorbed into the body can be measured in body tissue and fluid. Such measurements may be used to estimate human exposure if the chemical substances leave in the body reliable indicators of exposure. Furthermore, although a compound may be relatively easy to detect in body tissue, for some compounds, attributing body burdens to specific environmental releases may be difficult because of limited ability to obtain environmental measurements or appropriate metabolic data.

c. Development of Exposure Scenarios and Profiles. Depending on the scope of the exposure assessment, the total exposure may be fractionated into one or more "exposure scenarios" to facilitate quantification. As an example, Table 1 lists seven very broad scenarios: Occupational, Consumer, Transportation, Disposal, Food, Drinking Water, and Ambient. For each of the scenarios, the major topics necessary to quantify exposure include sources, pathways, measurements, and population characteristics. Investigation of only one scenario may be necessary for the scope of some assessments. For example, a pesticide application exposure assessment may consider the occupational scenario which would address the exposure to applicators and populations in the vicinity of the site. An exposure assessment around a hazardous waste site may focus on the disposal scenario. The exposure assessment also may consider other scenarios. The more extensive and comprehensive the scope, the more scenarios are usually involved.

TABLE 1.—EXPOSURE ASSESSMENT INFORMATION NEEDS FOR VARIOUS EXPOSURE SCENARIOS

Exposure scenario	Sources	Fate	Population characteristics	Measurement
Occupational (chemical production).	Site/plant locations, in-plant/on-site materials balance.	Physical and chemical properties models.	Workers, families, population around sites/plants.	In-plant/on-site releases, ambient levels surrounding site/plants; human dosimetry.
Consumer (direct use of chemical or inadvertent use).	Consumption rates, distribution pattern amounts in products.	Physical and chemical properties, shelf life release rates, models.	Consumers	Levels in products releases.
Transportation/storage/spills.	Patterns of distribution and transportation; models for spills.	Physical and chemical properties, environmental fate models.	Storage, transportation workers, general population in area.	Releases, ambient levels.
Disposal (include incineration, landfill).	Materials balance around disposal method, efficiency, releases to environment.	Fate within disposal process; environmental fate of releases; models.	Workers at site of disposal, general population around site.	Releases, levels at various points within process, ambient levels.
Food	Food chain, packaging, additives	Food chain models, fate during preparation or processing of food.	General population, nonhuman population.	Levels in food, feedstuff; food chain sampling.
Drinking water	Groundwater, surface water, distribution system.	Leach rates from pipes, chlorination processes, fate in water; models.	General population	Levels in drinking water, groundwater, surface water, treatment plants.
Ambient	Releases to environment; air, land, water.	Environmental fate models	General population, nonhuman population.	Ambient air, water, soil, etc.; human dosimetry.

It will usually be advantageous in performing an exposure assessment to identify exposure scenarios, quantify the exposure in each scenario, and then integrate the scenarios to estimate total exposure. In this "integrated exposure analysis," the summation of independent exposures from different scenarios (keeping exposure routes separate) often will result in a breakout of exposure by subpopulations, since the individual scenarios usually treat exposure by subpopulation. Therefore, the integration of the scenarios, or integrated exposure analysis, will often result in an exposure profile.

For each exposed subpopulation, exposure profiles should include the size of the group, the make-up of the group (age, sex, etc.), the source of the agent, the exposure pathways, the frequency and the intensity of exposure by each route (dermal, inhalation, etc.), the duration of exposure, and the form of the agent when exposure occurs. Assumptions and uncertainties associated with each scenario and profile should be clearly discussed.

d. Evaluation of Uncertainty.

(1) Introduction. Often an exposure assessment progresses through several stages of refinement. The purpose of these Guidelines is to present methods appropriate for characterization of uncertainty for assessments at various stages of refinement, from assessments based on limited initial data to those based on extensive data.

The appropriate method for characterizing uncertainty for an exposure assessment depends upon the underlying parameters being estimated, the type and extent of data available, and the estimation procedures utilized.

The uncertainty of interest is always with regard to the population characteristic being estimated. For example, when the population distribution of exposures is being estimated, characterization of uncertainty addresses the possible differences between the estimated distribution of exposure and the true population distribution of exposure.

An exposure assessment quantifies contact of a substance with affected population members (human or nonhuman subjects). The measure of contact (e.g., environmental level or absorbed dose) depends upon what is needed to predict risk. An integrated exposure assessment quantifies this contact via all routes of exposure (inhalation, ingestion, and dermal) and all exposure pathways (e.g., occupational exposure, exposure from consumption of manufactured goods, etc.). The exposed population generally is partitioned into subpopulations such that the likely exposure of all members of a subpopulation is attributable to the same sources. The exposure for each member of a subpopulation is then the sum of exposures over a fixed set of sources and pathways. The measured or estimated exposures for members of a subpopulation are ideally used to estimate the subpopulation distribution of exposure or characteristics thereof. However, a lack of sufficient information sometimes precludes estimation of the subpopulation distributions of exposure and only summary measures of this distribution, such as the mean, minimum, maximum, etc., are estimated. In each case, characterization of uncertainty for the exposure assessment primarily addresses limitations of the data and the estimation procedures. The proportions of the population members in the individual subpopulations are usually estimated and can be used (by combining estimated distributions for the subpopulations) to estimate the distribution of exposure for the total population. Uncertainty concerning the sizes of the subpopulations should be addressed by discussing limitations of the data and estimation methods as well as by tabulating confidence interval estimates for the population sizes whenever possible.

(2) Assessments based on limited initial data. The initial exposure assessment for a substance may be based on limited data for exposure and/or input variables for an exposure prediction model (i.e., an equation that expresses exposure as a function of one or more input variables). These data might be either extant data or data produced by an initial small-scale study. The limited initial data frequently are insufficient to permit estimation of the entire distribution of exposure. Instead, summary measures of this distribution, such as the mean, minimum, and maximum, are usually estimated.

If the assessment is based on measured exposures, the methods used to characterize uncertainty depend mainly upon whether or not the data result from a probability sample for which the probability of inclusion is known for each sample member. Characterization of uncertainty for an assessment based on a probability sample of exposures is discussed later in section 8.d.(5). If the measured exposures are not based on a probability sample, acknowledgement that no strictly valid statistical inferences can be made beyond the units actually in the sample is one aspect of the characterization of uncertainty. If inference procedures are implemented, the assumptions upon which these inferences are based (e.g., treatment of the sample as if it were a simple random sample, or assumption of an underlying model) should be explicitly stated and justified. The data collection methods and inherent limitations of the data should also be discussed.

An initial exposure assessment also may be based on limited data, such as estimated ranges, for input variables for an exposure prediction model. The exposure prediction model would be derived from a postulated exposure scenario that describes the pathways from sources to contact with population members. If the data were only sufficient to support estimates of the ranges of the input variables, the exposure assessment might be limited to a sensitivity analysis. The purpose of the sensitivity analysis would be to identify influential model input variables and develop bounds on the distribution of exposure. A sensitivity analysis would estimate the range of exposures that would result as individual model input variables were varied from their minimum to their maximum possible values with the other input variables held at fixed values, e.g., their midranges. The overall minimum and maximum possible exposures usually would be estimated also. For an exposure assessment of this type, the uncertainty would be characterized by describing the limitations of the data used to estimate possible ranges of model input variables and by discussing justification for the model. Justification of the model should include a description of the exposure scenario, choice of model input variables, and the functional form of the model. Sensitivity to the model formulation also can be investigated by replicating the sensitivity analysis for plausible alternative models.

The sensitivity analysis can be enhanced by computing the predicted exposures that result from all possible input variable combinations. If each input variable has only a finite set of possible values, the set of all possible combinations of the input variables can be formed, and the predicted exposure can be computed for each combination. These exposure predictions can be used to form a distribution of exposures by counting the number of occurrences at each exposure level or interval of exposures. This is equivalent to estimating the distribution of exposures that results from treating all input variable combinations as equally likely. This procedure can also be applied by transforming continuous input variables into discrete ones and representing them by equally spaced points. In the limit, as the equal spaces become small and the number of points becomes large, the distribution of exposure that results from counting occurrences of exposure levels is equivalent to estimating the distribution of exposures that results from statistically independent, continuous input variables with uniform distributions on the estimated ranges. This estimated distribution of exposure values can be produced by Monte Carlo simulation, one of the methods of mathematical statistics. The Monte Carlo method consists of randomly generating input variate values and using these to compute corresponding exposure levels, generating an exposure distribution via many iterations. Interpretation of statistics based on this exposure distribution would be in terms of the equally likely input variable combinations. For example, the 95th percentile of this distribution would be the exposure level exceeded by on1y 5% of the exposures resulting from treating all combinations of input variable values as equally likely. Although this distribution of exposures cannot be interpreted as an estimate of the population distribution (unless the input variables actually are statistically independent and uniformly distributed), it provides additional information for making regulatory decisions. Characterization of uncertainty would include a discussion of limitations of the data and justification for the model as discussed above. Sensitivity to model formulation could also be investigated by estimating the distribution of exposure that results from using the

same uniform input variable distributions with plausible alternative models and comparing the estimated percentiles.

(3) Assessments based on subjective estimates of input variable distributions. If a model has been formulated that expresses exposure as a function of one or more input variables, the methods of mathematical statistics, such as Monte Carlo simulation, can be used to estimate the population distribution of exposure from an estimate of the joint distribution of the model input variables. Ideally, model input variables should be represented by empirically-validated probability distributions. In some cases, it may be possible to formulate an estimate of the joint distribution of model input variables from discussions with subject matter experts (e.g., via histograms for statistically-independent input variables). The estimated population distribution of exposure will be equivalent to the distribution discussed in section 8.d.(2) for equally likely combinations of input variable values only when the input variable distributions supported are independent uniform distributions. When qualitative knowledge of input variable distributions is used to estimate the population distribution of exposure, uncertainty is characterized by discussing justification for the presumed model and input variable distributions. Alternative models and/or alternative input variable distributions also should be discussed. Sensitivity to these alternatives can be investigated by estimating the distributions of exposure that result from plausible alternatives and comparing the percentiles of the estimated exposure distributions. All available data, even if data are limited, should be used to validate the presumed input variable distributions and the predicted distribution of exposure.

(4) Assessments based on data for model input variables. The exposure assessment based on an estimate of the joint probability distribution for model input variables can be refined by collecting sample survey data for model input variables for a sample of population members. The population distribution of exposure can then be estimated by computing the expected exposure for each sample member based on the model. These expected exposures can be used to directly compute confidence interval estimates for percentiles of the exposure distribution. Alternatively, the sample survey data can be used to compute joint confidence interval estimates for percentiles of the input variable distribution, which can then be used to generate confidence interval estimates for percentiles of the exposure distribution. In either case, the interval estimates for percentiles of the exposure distribution are a useful quantitative characterization of uncertainty.

Characterization of uncertainty for the exposure assessment would contain a thorough discussion of limitations of the data and justification for the model used to compute expected exposures. The design of the sample survey used to produce the data base should also be discussed. If a probability sample were not used, the lack of a probability sample would be an additional source of uncertainty. Any assumptions used in computing the confidence interval estimates, such as independence of model input variables, should be explicitly stated and justified. Sensitivity to model formulation can be investigated by estimating the distribution of exposure for plausible alternative models and comparing the estimated percentiles, if sample survey data have been collected for the input variables of the alternative models. Appropriate available data for exposure should be used to validate the predicted distribution of exposure. If specific probability distributions have been presumed for any model input variables, the data for these variables should be used to test for goodness of fit for these distributions.

(5) Assessments based on data for exposure. A major reduction in the uncertainty associated with an exposure assessment can be achieved by directly measuring the exposure for a sufficiently large sample of members of the affected population. This reduction in uncertainty is achieved by eliminating the use of a model to predict exposure. The measured exposure levels can be used to directly estimate the population distribution of exposure and confidence interval estimates for percentiles of the exposure distribution. Direct confidence interval estimates also can be computed for other characteristics of the exposure distribution, such as the mean exposure.

These confidence interval estimates are then the primary characterization of uncertainty for the exposure assessment. Limitations of the data and design of the sample survey used to collect the data also should be discussed. If the sample was not a probability sample, this would again be an additional source of uncertainty.

(6) Summary. A summary of the primary methods recommended for characterizing uncertainty in exposure assessments is presented in Table 2. Virtually all exposure assessments, except those based on measured exposure levels for a probability sample of population members, rely upon a model to predict exposure. The model may be any mathematical function, simple or complex, that expresses an individual's exposure as a function of one or more input variables. Whenever a model that has not been validated is used as the basis for an exposure assessment, the uncertainty associated with the exposure assessment may be substantial. The primary characterization of uncertainty is at least partly qualitative in this case, i.e., it includes a description of the assumptions inherent in the model and their justification. Plausible alternative models should be discussed. Sensitivity of the exposure assessment to model formulation can be investigated by replicating the assessment for plausible alternative models.

TABLE 2.—SUMMARY OF PRIMARY METHODS FOR CHARACTERIZING UNCERTAINTY FOR ESTIMATING EXPOSURES

Type and extent of data	Population characteristic being estimated	Primary methods for characterizing uncertainty	
		Qualitative methods	Quantitative methods
Measured exposures for a large sample of population members.	Distribution of exposure	1. Limitations of the survey design and measurement techniques.	1. Confidence interval estimates for percentiles of the exposure distribution. 2. Goodness of fit for exposure models, if any have been postulated.
Measured exposures for a small sample of population members.	Summary parameter(s) of the exposure distribution, e.g., mean or a percentile.	1. Limitations of the survey design and measurement techniques.	1. Confidence interval estimate for the summary parameter(s). 2. Goodness of fit for exposure models, if any have been postulated.
Measured model input variables for a large sample of population members.	Distribution of exposure	1. Limitations of the survey design and measurement techniques.	1. Confidence interval estimates for percentiles of the exposure distribution.

TABLE 2.—SUMMARY OF PRIMARY METHODS FOR CHARACTERIZING UNCERTAINTY FOR ESTIMATING EXPOSURES—Continued

Type and extent of data	Population characteristic being estimated	Primary methods for characterizing uncertainty	
		Qualitative methods	Quantitative methods
		2. Validity of the exposure model.	2. Goodness of fit for input variable distribution functions, if any have been postulated. 3. Estimated distribution of exposure based on alternative models.
Estimated distributions of model input variables.	Distribution of exposure	1. Validity of the exposure model. 2. Limitations of the data or other basis for the input variable distributions.	1. Confidence interval estimates for percentiles of the exposure distribution. 2. Goodness of fit for input variable distributions, if input variable data are available. 3. Estimated distribution of exposure based on alternative models.
Limited data for model input variables.	Minimum, maximum, and range of the exposure distribution.	1. Limitations of the data..... 2. Validity of the exposure model.	If input variable data are very limited, e.g., some extant data collected for other purposes, quantitative characterization of uncertainty may not be possible.

When an exposure assessment is based on directly measured exposure levels for a probability sample of population members, uncertainty can be greatly reduced and described quantitatively. In this case, the primary sources of uncertainty are measurement errors and sampling errors. The effects of these sources of error are measured quantitatively by confidence interval estimates of percentiles of the exposure distribution. Moreover, the sampling errors can be limited by taking a large sample.

Whenever it is not feasible to take a large sample, it is sometimes possible to obtain at least some data for exposure and model input variables. These data should be used to assess goodness of fit of the model and/or presumed distributions of input variables. This substantially reduces the amount of quantitative uncertainty for estimation of the distribution of exposure and is strongly recommended. It is recognized, however, that it may not be feasible to collect such data.

9. *References.* The references should contain a listing of all reports, documents, articles, memoranda, contacts, etc. that have been cited in the report.

10. *Appendices.* The appendices may contain such items as memoranda and letters that are not readily accessible, other tables of measurements, detailed lists of emission sources, detailed tables of exposures, process flow diagrams, mathematical model formulations, or any other item that may be needed to describe or document the exposure assessment.

Part B: Response to Public and Science Advisory Board Comments

I. Introduction

This section summarizes some of the issues raised in public comments on the Proposed Guidelines for Exposure Assessment published November 23, 1984 (49 FR 46304). Comments were received from 29 individuals or organizations. The Agency's initial summary of comments was presented to the Exposure Assessment Guidelines Review Group of the Science Advisory Board (SAB) on March 4, 1985. At its April 22–23, 1985, meeting, the panel provided the Agency with suggestions and recommendations concerning the Guidelines.

The SAB and public commentors expressed diverse opinions and addressed issues from a variety of perspectives. While most commentors supported the Guidelines, two urged withdrawal of the document. The SAB Panel recommended that supplementary guidelines be written on the use of measurements in preparing exposure assessments. In addition, the Panel wished to see a greater emphasis in the current Guidelines on the use of measured data rather than models in generating exposure assessments. The Panel recommended that the technical support document entitled "Methodology for Characterization of Uncertainty in Exposure Assessments" be expanded with additional examples.

In response to the comments, the Agency has modified or clarified many sections of the Guidelines, and is planning to develop supplementary guidance in line with the SAB recommendations. The discussion that follows highlights significant issues raised in the comments, and the Agency's response to them. Also, many minor recommendations, which do not warrant discussion here, were adopted by the Agency.

II. General Information

A. Acceptable Latitude of Approach

Some commentors believe the Guidelines are too general and allow too much latitude in choice of approach and do not assure that "all" data, sources, limitations, etc. are considered before an exposure assessment is conducted. Others suggested that the Agency specify models to be used while others thought that only measured data should be allowed.

The Guidelines were developed to provide assistance in carrying out exposure assessments. The approach suggested is deliberately general in order to accommodate the development of exposure assessments with different levels of detail depending on the scope of the assessment. The Agency does not agree with the inclusion of such restrictive terminology as "in all cases." We cannot foresee all possible cases. We believe reasonable flexibility is a necessary ingredient for the proper implementation of the Guidelines while relying on uncertainty and sensitivity analyses to put the quality of the approach in perspective.

B. Technical Nature of Guidelines

Some commentors believe the language of the document is too technical for the lay person to understand; one commentor expressed misgivings concerning the "state-of-the-art" methods available for conducting exposure assessments.

While the Agency recognizes that the public has an interest in the Guidelines and invites comments from the public, the Guidelines are intended for use by technical/professional people. Providing guidelines written in lay terms would result in insufficient technical specifications to the professionals in the development of scientifically acceptable exposure assessments.

The Agency believes that the suggested procedures and methods in the Guidelines are commonly accepted. The Guidelines do not suggest the use of ad hoc, untested, and unvalidated procedures, but stress the use of the best scientific methods available with maximum analysis of existing data. This is both a scientific and practical approach that reflects the level of consensus within the Agency.

C. Measurements vs. Modeling

Some commentors support the use of measurements alone to develop an exposure assessment. Some believed there should be no data restraints; others thought all data should be validated. Other commentors argued for the use of simulation model estimates without measurements. One commentor objected to the use of unvalidated models to perform exposure assessments. In its review, the SAB strongly encouraged the Agency to develop a supplement to the current Guidelines on the development and use of measurements for exposure assessments.

The Agency encourages the use of validated measurements when available. The Guidelines specifically state that "Reliable, analytically determined values should be given precedence over estimated values . . ." and analytically determined values ". . . can be used to calibrate . . . models . . . to assess environmental distribution." Furthermore, in practice, exposure assessments performed by the Agency use published models with varying degrees of testing and validation. It is our belief that transport process models have been adequately validated over many years in most cases.

Furthermore, the Agency has revised the Guidelines to reflect the SAB suggestions that exposure assessments based on reliable measured data are preferred over model estimates whenever feasible.

III. Data Availability and Uncertainty Analysis

A. Information Uses

Some commentors asked for guidance in the use of information that may be false and how to deal with the potential situation when different models give different results. Others asked for model selection criteria.

The Guidelines clearly state the considerations that need to be addressed when assembling information bases for exposure assessments. Two considerations are: qualitative and quantitative nature of the data and the reliability of the information. Whether the exposure assessment is based on measurements or simulation model estimates, an evaluation of uncertainties associated with the data including source data and assumptions is necessary and important.

When there is uncertainty in the scientific facts, it is Agency policy to err on the side of public safety. The Agency intends to be realistic, but will not arbitrarily select midranges of environmental distributions that may compromise human health. In addition, quality assurance is an important matter that requires detailed attention. The collection of measured data and the development of methods to collect measurements are done by another office within the EPA. These issues will be handled by the Office of Acid Deposition, Environmental Monitoring, and Quality Assurance as they develop the supplemental guidelines for measurement of exposure.

Substantial work is currently being done on the development of mathematical model selection criteria. Results of these efforts will be published as a technical support document containing detailed information to further implement the Guidelines.

B. Worst-Case Estimates

A few commentors were concerned that worst-case estimates would be used when data are nonexistent or limited. The Guidelines do not encourage the use of worst-case assessments, but rather the development of realistic assessments based on the best data available.

A technical support document and a substantial section of the Guidelines currently discuss evaluation of uncertainty in order to produce objective assessments using the best (not worst-case) estimates available either for preliminary or in-depth exposure assessments. However, the Agency will err on the side of public health when evaluating uncertainties when data are limited or nonexistent.

IV. Evaluation of Uncertainties

A. Uncertainty Analysis

Many commentors felt that the sections of the Guidelines that dealt with uncertainty needed amplification while some sections as written were confusing. Some urged that uncertainty evaluation be presented and documented for each section within a specific exposure scenario in order to judge the overall plausibility of the assessment in reaching regulatory decisions.

Since the accuracy of an exposure assessment is influenced by the degrees of uncertainty contained in both data and assumptions, the Guidelines call for the evaluation of these uncertainties. The technical support document, Methodology for Characterization of Uncertainty in Exposure Assessments (available from the National Technical Information Service, PB85–240455), describes in detail how such analyses can be performed. The Guidelines suggest that the uncertainty characterization include a discussion of the limitations of the data and estimation procedures as the justification for the model chosen. A sensitivity analysis of the exposure assessment is appropriate if the data were only able to support the estimates of ranges of the input variables. By identifying model input variables that determine the bounds on the distribution of exposure, the range of exposure, which results as individual model input variables are varied from minimum to maximum possible values as other variables remain constant, constitutes the sensitivity analysis. Further sensitivity of model formulation can be examined by repeating the sensitivity analysis for plausible alternative models.

Nothing in the Guidelines precludes estimation of uncertainty for each specific exposure scenario. The Agency has encouraged the evaluation of uncertainty in each aspect of the exposure assessment, which could impact the total risk estimate. It is important to estimate the level of uncertainty in risk assessments so that decisions based on risk assessment will reflect total uncertainty. The information presented in the Guidelines or the technical support documents properly and adequately describes the extent and quality of appropriate uncertainty analysis. Recognizing that the basis for the decision to refine a preliminary exposure assessment involves risk management, the Agency, at the suggestion of many commentors, decided to strike from the Guidelines the paragraph beginning "If the maximum possible exposure . . . ." in section III.B.8.d.(2).

B. Population Characterization

The Guidelines state that identification of populations and subpopulations at potentially high exposure forms the basis of the populations to be studied. Separate studies of sensitive subpopulation can also be included. Population characteristics, such as age and/or sex distributions, can be derived from the use of geographic and activity-specific data. Uncertainty related to estimation of a population characteristic include a discussion of the data limitations and the estimation procedures. In addition, uncertainty in estimating sizes of sensitive subpopulations should include estimates of confidence intervals.

Some commentors suggested the inclusion of additional characteristics, such as occupational and life style factors, and the inclusion of additional guidance concerning potential pitfalls when conducting population exposure

assessments. Others expressed concern that the exposure of a particular subpopulation would be combined with other exposures to produce an average exposure level for the general population.

The section describing population characterization encompasses, in general terms, the many characteristics that may be available, including life style factors, to describe exposed populations. The Agency agrees that there are difficulties associated with epidemiologic studies. The relationship between exposure assessments and epidemiologic studies is currently being investigated and will be the subject of a future technical support document and the further refinement of the Guidelines.

V. Clarification of Terminology

A. Exposure vs. Dose

Commentors expressed concern with the American Society for Testing and Materials (ASTM) definition of exposure. Concern was also raised about the assertion that exposures can be estimated when biological tissues for fluid measurements indicate the presence of a chemical. Some commentors found difficulty in the wording of the last sentence in section II.A., specifically "The route of exposure . . . impacts . . . the overall exposure . . . ."

It is the Agency's opinion that the members who served on the ASTM Committee E-47 had expertise in exposure assessment. The scientists and engineers cumulatively possessed many years of experience in exposure assessment. In addition, no technical society has presented an alternate definition of exposure. The Agency will consider changing the definition if a reasonable alternate definition is written and agreed upon by the scientific community.

The Agency agrees with the commentors who were concerned that the wording provided in the Guidelines that the presence of a chemical in biological tissue can be used to estimate exposure is not correct in all cases. Consequently, the word "can" was changed to "may" to reflect the current level of understanding between tissue residue and exposure (II.A., 2nd paragraph, 4th sentence). The Agency agrees with several commentors' concerns that the route of exposure impacts the overall absorbed dose, not the overall exposure, and the Guidelines reflect this change (II.A., last sentence).

B. Mixtures and Synergism

Some commentors thought more discussion was necessary on the effect of chemical mixtures and potential synergistic effect on exposure. The Guidelines for the Health Risk Assessment of Chemical Mixtures includes a discussion of chemical synergism. The Agency recognizes the need to do further work in the area of exposure to mixtures. It is recommended that this be identified as an area requiring further research.

These Guidelines stress the need to determine the products into which the chemical might degrade or react in the environment and to determine if any of these products are ecologically or biologically harmful.

C. Removal and Creation Steps

Some commentors urged that more emphasis be placed on changes that occur once the materials have entered the ambient environment. Other commentors argued that our current understanding will not allow a comprehensive treatment, particularly for metabolic processes.

These Guidelines state the need to address how a chemical agent moves from the source to the exposed population, which may result in the estimation of geographic and temporal distributions in various environmental media. The Guidelines also state the need to know such factors as, for example, whether the chemical agent bioaccumulates or by what mechanism the agent is removed from each medium and the role of any degradation products on ecological safety. We have already stated that guidance for analysis of metabolism data is an area of ongoing research which includes consideration of metabolism data in the calculation of whole organism dose from one species to another.

VI. Purpose, Philosophy, and Results

Several commentors raised questions related to the basic style of the Guidelines. Among the issues raised were:

- the role of exposure assessment in risk assessment/risk management (many comments directed to appropriateness of Figure 1);
- statutory/regulatory authority and uses of results; and
- the need for peer review of assessments and periodic updating of Guidelines.

A deliberate effort to separate risk assessment from risk management has been made. The management of complex issues such as procedural issues, which include coordination or linkage among divisions in the Agency, are best dealt with by management and not in Guidelines.

The decision pathway (Figure 1) was included in the Guidelines at the recommendation of the SAB. It has drawn many comments. The changes suggested would include additional detail and steps that would diminish the value of the graphic. However, the figure has been truncated to remove risk management steps.

In order to remain consistent with the separation of risk assessment and risk management, any directions to consider applicable laws or regulatory decisions have been stricken from the Guidelines.

The Agency agrees that peer review is an important aspect of the assessment process. However, emergency cases may not allow peer review in preliminary assessments. All nonemergency exposure assessments have been peer reviewed and will continue to be peer reviewed. Finally, it is clearly stated in the Guidelines that periodic revision of the document will be done to reflect the benefit of experience and knowledge.

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Part VII

Environmental Protection Agency

40 CFR Part 61

National Emission Standards for Hazardous Air Pollutants (NESHAPs); Standards for Radon-222 Emission From Licensed Uranium Mill Tailings; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[AO-FR-3060-7]

National Emission Standards for Hazardous Air Pollutants (NESHAPs); Standards for Radon-222 Emissions From Licensed Uranium Mill Tailings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule establishes work practices that apply to tailings at licensed uranium mill sites. Radon-222 is emitted from these tailings in amounts sufficient to produce a risk to public health. The work practices established here will limit the emissions of radon-222 in accordance with Section 112 of the Clean Air Act.

EFFECTIVE DATE: The final rule is effective on September 24, 1986.

ADDRESSEES: The rulemaking record is contained in Docket No. A-79-11. This docket is available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery One, Waterside Mall, 401 M Street, SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Terrence A. McLaughlin, Chief, Environmental Standards Branch, Criteria and Standards Division (ANR-460), Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC 20460, (202) 475-9610.

SUPPLEMENTARY INFORMATION:

I. Supporting Documents

The draft background information document and draft economic analysis issued in support of the proposed rule have been revised in response to public comments and are now issued in final form titled, respectively, "Background Information Document—Final Rule for Radon-222 Emissions from Licensed Uranium Mill Tailings" (EPA 520/1-86-009) and "Economic Analysis—Final Rule for Radon-222 Emissions from Licensed Uranium Mill Tailings" (EPA 520/1-86-010).

The documents contain projections of radon emissions and the resulting risks to nearby individuals and to populations due to the operation of the uranium milling industry, a description of radon control technology and associated costs, and an environmental and economic analysis of the effects of alternative control strategies on the industry.

In addition, the Agency's summary of public comments on the proposed rule, together with the Agency's reply to these comments, are contained in the document "Response to Comments—Final Rule for Radon-222 Emissions from Licensed Uranium Mill Tailings" (EPA 520/1-86-011).

Single copies of these documents may be obtained from the Program Management Office (ANR-459), Office of Radiation Programs, Environmental Protection Agency, Washington, DC 20460, (202) 475-8386.

II. Basic Terms Used in the Notice

Definitions of basic terms used in this notice are given below:

1. *ALARA*—A practice in radiation protection that encourages radionuclide emissions to be kept "as low as reasonably achievable."

2. *Continuous disposal*—A method of tailings management and disposal in which tailings are dewatered by mechanical methods soon after generation. The dried tailings are then placed in trenches or other disposal areas and immediately covered.

3. *Covered*—Disposal of tailings in accordance with specifications required by regulations appearing at 40 CFR Part 192 and issued under the Uranium Mill Tailings Radiation Control Act (UMTRCA).

4. *Mill tailings*—The waste resulting from conventional milling of uranium ore. Tailings are classified as either sands or slimes depending on particle size. Processing 1 ton of ore produces approximately 1 ton of tailings.

5. *Phased disposal*—A method of tailings management and disposal that uses a series of small impoundments. Tailings are pumped to one impoundment until it is filled and then pumped to the next impoundment. The filled impoundment is actively dewatered, or allowed to dry naturally, and then immediately reclaimed.

6. *Radon*—Radon-222; an inert radioactive gas.

7. *Radon decay products*—The seven principal radionuclides that are produced as radon-222 decays to nonradioactive lead. Radon-222 short-lived decay products means the four radionuclides with half-lives less than 20 minutes produced as radon-222 decays to lead-210.

8. *Single cell disposal*—A method of tailings management that uses a large impoundment designed to contain all tailings generated during the lifetime of the mill. At the end of the mill life the impoundment is actively dewatered or allowed to dry and is then immediately reclaimed.

9. *Tailings pile*—The on-site waste impoundment in which tailings are deposited.

III. Background

A. Industry Description

Uranium milling involves the handling of large quantities of ore containing uranium and its decay products. In this ore, the concentration of uranium and its decay products is about one thousand times greater than in other rocks and soils. Uranium milling recovers the uranium in the ore by mechanical and chemical processes that generate waste tailings. The ore is first crushed, blended, and ground to the proper size for the leaching process, which extracts uranium. Several leaching processes are used, including the use of acid, alkali, and a combination of the two. After uranium is leached from the ore, it is concentrated from the leachate through ion exchange or solvent extraction. The concentrated uranium is then extracted from the concentrating medium, precipitated, dried, and packaged. The depleted ore, in the form of tailings, is pumped to a tailings pile as a slurry.

Since ore generally contains less than 0.5 percent uranium by weight, every ton of ore processed results in almost a ton of tailings. The tailings contain virtually all of the uranium decay products present in the ore, including thorium-230 and radium-226, which decay to radon. Previous risk analyses have shown that radon presents the highest risk of any radionuclide released to air at uranium mills and that the tailings pile is the most significant source of radon.

The 26 licensed uranium mills in the United States are located in Colorado, New Mexico, South Dakota, Texas, Utah, Washington, and Wyoming. In addition, four mills have been licensed but not built. The milling industry is depressed due to a decline in the demand for uranium and competition from low-cost foreign sources. Three mills are actively processing ore, 17 are on standby and could process ore in the future if market conditions improve, and 6 are being decommissioned and will no longer process ore. The 20 licensed mills that are actively processing ore or on standby were considered in the analyses reported in the supporting documentation. These 20 mills have about 35 tailings impoundments associated with them. Recently, three of these mills have indicated to the NRC that they will no longer process ore and intend to reclaim the sites.

Past milling activities have generated about 200 million tons of tailings. Production at conventional mills peaked

in 1980, when 21 mills recovered more than 17 thousand tons of uranium and generated more than 14 million tons of tailings. The industry is currently operating at about 10 percent of capacity due to the depressed market. At this level of production, the industry is recovering about 1.8 thousand tons of uranium and generating about 1.4 million tons of new tailings annually. At full capacity, the industry could generate approximately 14 million tons of tailings a year.

B. Estimates of Exposure and Risk

Exposure estimates are based on radon emissions from tailings piles, since emissions and risks from other parts of a uranium mill are small in comparison. Radon emission rate estimates are based on the radium-226 concentration in the tailings using the relationship of 1 picocurie of radon emitted per square meter per second for each picocurie of radium-226 per gram of tailings. It is assumed that the radium-226 is evenly mixed throughout the tailings and that radon is emitted from all dry exposed surfaces of tailings. The radium-226 content of the tailings is derived from the relationship of one-tenth of one percent of uranium in ore equalling 280 picocuries of radium-226 per gram of ore and the assumption that all the radium-226 in the ore finds its way into the tailings pile.

Standard meteorological transport models are used to estimate radon concentrations in air at various distances from the piles. Exposure to radon decay products is then estimated from the radon concentration in air. The final risk estimates are a product of the units of radon decay product exposure levels and a risk factor that relates risk to a single unit of exposure.

Two measures of human exposure are of particular interest: "nearby individual risk" and "total population impact". The former refers to the estimated increased lifetime risk to individuals who spend their entire life at the location of existing residences where predicted concentrations of the pollutant are highest. Nearby individual risk is expressed as a probability; for example, a risk of one in one thousand means that a person spending his lifetime at the point of maximum exposure has an estimated increased risk of one in one thousand of developing a fatal cancer. Estimates of nearby individual risk are best estimates, and are not upper bound estimates.

The second measure, "total population impact", considers people exposed at all concentrations, low as well as high, and it considers people exposed throughout the United States, as appropriate. It is expressed in terms of annual number of fatal cancer cases and provides a measure of the overall impact on public health. For example, a total population impact of 0.5 fatal cancer cases per year means that emissions of the specific pollutant are predicted to cause one case of cancer every 2 years. As distance from a source increases, risks to specific persons decrease and become extremely small; but, considering the total population exposed, the sums of these risks may be significant.

The two estimates together provide a better description of the magnitude and distribution of risk than either number alone. "Nearby individual risk" gives an estimate of the highest risk, but not how many people may bear that risk. "Total population impact" describes the overall estimated health impact on the entire exposed population, but not how much risk the most exposed persons may bear. For example, two sources of radionuclide or chemical emissions could have similar population impacts but very different maximum individual risks, or vice versa. Both estimates are important and both are used in making risk management decisions. The risk estimates should not be viewed as precise determinations of likely health damage, but rather as a general indication of estimated health risk.

EPA's analysis of risks due to radon emissions from existing uranium tailings piles concluded:

1. Lung cancer, which is caused by the short-lived decay products of radon, is the dominant health hazard from tailings. Estimated effects of gamma radiation and of long-lived decay products of radon are less significant, although high gamma radiation exposures may sometimes occur.

2. Individuals living near an uncontrolled tailings pile are subject to high risks due to radon emitted from tailings. Radon contained in the ambient air enters homes and other structures built near the mill through doors and other openings in the structure. The resulting radon decay products tend to concentrate indoors, thus exposing the occupants to potentially harmful levels of these radionuclides. The EPA estimates that, at present, some persons may be exposed to risks that are as high as one in one hundred. This estimate is based on median risk estimates and an assumed exposure of 70-years during which emission levels remain the same as present values. Of course, this time period is longer than assumed in EPA's "40-year" analysis. Using the 40-year analysis, an exposure posing this level of risk could only occur if an individual remained at that location for the full 70-year period, and the pile presenting that risk was replaced after closure by another pile presenting the same risk factors.

3. Based on models for the risk to all exposed populations (local, regional, and national), about one to five fatal cancers per year are estimated from emissions of radon from tailings at the 20 mill sites being considered here, if no controls are present. If the tailings at all sites were to dry out, it is estimated that the risk could rise to about two to nine fatal cancers per year. However, not all of the piles are expected to dry out at the same time. Approximately one half of these deaths are estimated to occur within 80 kilometers of the tailings piles.

There is substantial uncertainty in these estimates because of uncertainties in the emission rates of radon from tailings sites, in the exposure people will receive from its decay products, and from incomplete knowledge of the effects on people due to these exposures. The values presented here represent best estimates based on current knowledge. Examples of factors leading to possible underestimation of risk include: the use of median rather than upper bound risk factors, ignoring radon sources at a mill site other than the tailings pile, and not considering piles where owners have indicated intent to reclaim their pile but have not done so for long periods. Risks could be overestimated if owners reclaim piles faster than EPA assumes, if radon emissions are smaller due to less radium-226 in a pile than is estimated, or if the radon emanation rate is lower than EPA estimates it to be. Additionally, since these estimates are based on current pile sizes and population distributions, as nearby populations increase or decrease in the future, the estimated impacts would vary. If specific information indicates radon emissions rates were lower, then risk estimates could be lower.

In general, much more is known about the risks from exposure to radiation than exposure to most chemicals. While there is uncertainty in risk estimates from assessments of chemical emissions and radionuclide emissions, there is much less uncertainty in estimates of risk from radionuclide emissions because of the extensive data base on the effects of human exposure to radiation. Therefore, a risk estimate resulting from exposure to radionuclides is likely to be more accurate than the same estimate for chemical exposures.

C. History of Standard Development

The Agency's standards for Nuclear Power Operation (40 CFR Part 190)

issued under the Atomic Energy Act (42 FR 2858 (January 13, 1977)) limit the total individual radiation dose caused by emissions from facilities that make up the uranium fuel cycle, including licensed uranium mills. However, when 40 CFR Part 190 was promulgated, considerable uncertainty existed about the public health impact of existing levels of radon in the air, as well as uncertainty about the best method for management of new man-made sources of radon. The EPA exempted radon from coverage under 40 CFR Part 190 since the problems associated with emissions of this radionuclide were sufficiently different from those of other radioactive materials associated with the fuel cycle to warrant separate consideration.

EPA has also issued standards (48 FR 45926 (October 7, 1983)) for uranium and thorium mill tailings at commercial processing licensed sites under the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), which amends the Atomic Energy Act (AEA). These standards for disposal of tailings require stabilization of tailings on final disposal so that the associated health hazards will be controlled and limited for 1000 years to the extent reasonably achievable, in any case, for at least 200 years. The standards limit releases of radon to the air after disposal, and require measures to limit releases of radionuclides and other hazardous substances to water (40 CFR Part 192, Subparts D and E). In the preamble to these standards, the Agency discussed the relationship between UMTRCA and the Clean Air Act (CAA) and indicated its intent to publish an Advanced Notice of Proposed Rulemaking (ANPR) to consider additional control of radon emissions during the operational phase of mills.

Section 122 of the CAA required EPA to determine whether or not to regulate radioactive pollutants based on an assessment of risks to public health. After seeking public comment (44 FR 21704 (April 11, 1979)), EPA listed airborne emissions of radionuclides as hazardous air pollutants under section 112 of the CAA (44 FR 76738 (December 27, 1979)). Based on that listing, EPA subsequently promulgated standards under section 112 for Department of Energy (DOE) facilities, Nuclear Regulatory Commission (NRC) licensed facilities and non-DOE Federal facilities, elemental phosphorus plants, and underground uranium mines (50 FR 5190 (February 6, 1985 and 50 FR 15386 (April 17, 1985)).

On October 31, 1984, EPA issued its ANPR to inform interested parties that the Agency was considering issuing standards under the CAA to limit radon emissions from licensed uranium mills (49 FR 43916 (October 31, 1984)). Subsequently, EPA entered into a stipulation with the Sierra Club to promulgate such standards, or delist radionuclides, by May 1, 1986. This agreement was entered as a consent order by the United States District Court for the Northern District of California (Civil No. C–84–0656 WHO).

On February 21, 1986, EPA issued proposed standards for radon emissions from licensed uranium mills and announced a public hearing (51 FR 6382 (February 21, 1986)). The hearing was held in Denver, Colorado, on March 25, 1986 (51 FR 8205 (March 10, 1986)). A transcript of the hearing was placed in the Docket and the comment period was extended to April 28, 1986.

Due to the complexity of the proposed rule and the need for an extended comment period, EPA and the Sierra Club entered into a second stipulation to extend the deadline to August 15, 1986. The district court granted the extension on motion of the parties.

IV. Summary of Proposed Standards

As noted earlier, EPA published a proposed rulemaking regarding control of radon-222 emissions from tailings piles at licensed sites on February 21, 1986 (51 FR 6382). That notice announced that EPA was considering various work practice standards for limiting such emissions based on its preliminary conclusions that it is not feasible to set an emissions standard, and that the nature of the risk involved warrants a regulatory response.

In its proposal, EPA presented three work practices, including improved methods for disposal of newly generated tailings, various timing requirements for use of these improved methods, and interim covers. The improved methods of disposal of newly generated tailings were a large, single pile with immediate closure, phased disposal, and continuous disposal involving dewatering and covering of tailings. EPA also stated it was considering alternatives of allowing new tailings to be added to existing piles over a range of times, including 5 years, 10 years, 15 years and an undefinite period of time into the future. (An exception from the latter requirements was proposed where existing tailings impoundments were lined.)

That proposal also discussed two available options for controlling radon-222 emissions from existing piles. It concluded that earthen covers might be placed over dry tailings beaches and embankments constructed of sand tailings. It noted that dry beaches typically cover 60 percent of the total tailings area during the operational phase of a mill and that this percentage could be significantly larger during periods of extended shutdown. It also noted that use of existing tailings piles could be terminated. While a dry out period would ensue during which emissions would unavoidably increase prior to disposal in accordance with Federal standards under UMTRCA, this is an unavoidable result of disposal.

V. Summary of Responses To Comment

The Agency has reviewed all submittals to the docket and testimony given at the public hearing. A complete discussion of all substantive comments and the Agency's response to them appears in "Response to Comments—Proposed Rule for Radon-222 Emissions from Licensed Uranium Mills Tailings" (EPA 500/1–86–011); the document may be obtained from the Program Management Office (ANR–459), Office of Radiation Programs, Environmental Protection Agency, Washington, DC 20460. A summary of major concerns, together with the Agency's responses, are presented below.

Legal and Procedural

Many commenters stated that there is no need for regulation under the CAA because existing regulations developed under the AEA and the UMTRCA and license conditions administered by the NRC and its agreement States adequately protect the public from risk due to radon. The Agency estimates the individual lifetime risk may be as high as 1 in 100, assuming 70 years of exposure. The population risk is estimated to be 1 to 5 deaths per year under current industry and regulatory conditions. The Agency believes that these risks are significant and that there is a need for standards under the CAA to protect public health with an ample margin of safety.

A number of commenters addressed ground water quality and stated that it should not be considered in regulating radon under the CAA. The Agency has not developed this rule to regulate ground water. Ground water protection standards are currently in force and being implemented under the UMTRCA standards (40 CFR Part 192). However, potential effects of various alternatives on ground water were considered as part of the analysis of the impacts of this rule, since EPA has a responsibility to consider the impacts that its rules may have on the total environment. In part, this is done to ensure that regulations do not control pollution in one environmental medium only to degrade

another. Consequently, there may be some additional ground water protection incidental to these standards.

Some commenters stated that EPA should not consider cost and technical feasibility of regulation under section 112 of the CAA. They maintain that the Congressional mandate directs EPA to adopt standards based exclusively on protection of public health. The EPA interprets the requirement of section 112 to establish emission standards at a level which "provides an ample margin of safety" as not implying that these standards must ensure that there is no remaining level of risk. Consequently, the standard being adopted today requires the use of work practices that will reduce radionuclide emissions and therefore risks to the practical minimum. The standard reflects consideration of the magnitude of the risks, the costs and availability of further controls and associated risk reduction potential, and the potential societal impacts of regulatory alternatives. The Agency, in considering the impacts, weighed the estimated risks achieved by and remaining after application of controls and their uncertainties against the costs to achieve the emission reduction and the potential for widespread closure.

Some commenters stated that the Agency must promulgate an emission standard to be consistent with the mill tailings disposal standards (40 CFR Part 192), which are partly in the form of a design standard; an emission rate limit per square meter of pile surface. These comments are based on a misconception of the disposal standards. The disposal standards had multiple environmental goals including preventing misuse of tailings, reducing radon emissions for a long period of time, and protecting ground water. The Agency determined that the best way to accomplish these goals is through the use of a design standard based on a thick barrier. The Agency found that a design standard limiting the rate of radon release was most appropriate given the many variables of location, tailings and earth characteristics. For example, a minimum thickness of barrier might not provide adequate protection under all conditions. The prescribed standard, which requires the release of radon not to exceed an average of 20 picocuries per square meter per second, is a design standard requiring a certain effectiveness from a cover. The Agency stated that the standard was not to be construed as an emission standard, "(T)he standard applies to design. Monitoring for radon after installation of an appropriately designed cover is not required," making it analogous to a work practice standard or design standard authorized under section 112(e). The Agency, thus, finds no inconsistency between the work practice standards for operations and the design standards for disposal.

The NRC questioned why EPA did not issue an emission standard, such as already exists in NRC and State regulations, instead of proposing a work practice standard. The Agency judges that it is not feasible to prescribe an emission standard since most of the radon emitted by a uranium mill comes from the surface of mill tailings piles. A typical pile may be from a few to hundreds of acres in area, and emissions from its surface cannot be controlled through a conveyance designed and constructed to emit or capture radon. It is also not practical to accurately and consistently measure emissions because of the large size of the tailings pile and the continued modifications of the pile that take place during operations. For these and other reasons, a work practice standard is being promulgated. It should be noted that the NRC and State regulations establish a concentration limit at the site boundary in units of quantity per cubic meter of air, but do not directly limit the quantity or rate of radon emissions.

A commenter argued that EPA may not use a phased application of the work practice requirements, since section 112 of the CAA permits only a two-year compliance waiver for the installation of technology to meet an emission standard. However, the two-year compliance waiver discussed by the commenter is not applicable to the standard adopted in this rulemaking. The Administrator has concluded that neither of the available interim work practices, wetting or interim cover, is an appropriate measure to be imposed generally under section 112. Also, as discussed in this notice, the requirements for new tailings impoundments cannot be implemented within two years. Consequently, the two-year period that section 112(c)(1)(b)(ii) provides "for the installation of controls" has no meaning or applicability here. As a result, the Agency has adopted a comprehensive set of risk management requirements for limiting radon emissions that fall under the general category of "design, equipment, work practice, or operational standard[s] . . ." section 112(e). These requirements were designed as an integrated program to require the maximum reduction of long-term cancer incidence attributable to uranium mill tailings piles that can be reasonably achieved. These standards operate in phases. During the first six-year phase, the operator may continue to place tailings on existing piles. In the second phase, this practice is terminated except for certain small piles and for those operators that make a satisfactory, individualized showing of low interim risk. In the third phase, without exception, tailings may only be placed in impoundments meeting size and operating limitations designed to minimize exposed area and associated radon emissions. Taken as a whole, this scheme provides protection of public health that meets the Act's requirements of "an ample margin of safety".

Technical

Several commenters, in commenting on the continuous disposal method, stated that the industry has minimal experience with dewatering sands and no experience with dewatering slimes. The Agency has found that although continuous disposal has never been actually practiced on uranium mill tailings in the United States, it has been proposed by industry as the preferred method of tailings disposal at three sites. These proposals were never put into practice because of the downturn in uranium production. The EPA believes that these proposals, submitted by industry, adequately demonstrate that continuous disposal can be a viable option. It should be noted that the method has been included as an allowable alternative for industry, but is not the sole practice required for new piles. It was included to provide industry with flexibility in the management of new tailings.

Several commenters said that technology to dewater tailings exists, but increased energy and manpower to accomplish this are probably not economically feasible. The Final Background Information Document and the Economic Analysis reflect the additional costs and uncertainties in dewatering tailings for the continuous disposal option. The method has been selected as a suitable work practice that an operator may choose in lieu of phased disposal.

Several commenters stated that EPA's assumption of 40 years of standby is excessive. One commenter stated that the assumption of a 40-year period between the end of an impoundment's useful life and compliance with UMTRCA requirements is reasonable. The EPA judges that a 40-year standby period (which in practice could be several different periods totaling 40 years) before reclamation to Federal standards is a "worst-case" scenario. The Agency has estimated the fatal lung

cancers committed under this scenario to serve as a point of reference and has also evaluated a 20-year standby period scenario. Both periods were considered when the final rule was selected.

Several commenters stated that it would take about 6 years to design, license and construct a new tailings management process. One commenter said it could take more than 10 years, and one commenter said 5 years was sufficient. The EPA agrees that, based on the comments received from the NRC, States, and individual companies, a 3-year period to design, license, and construct a new tailings impoundment is unrealistically short. The Agency judges that a period of 6 years is the time needed to design, permit, and construct a new tailings impoundment. Extensions to allow more time will be available, if due to circumstances beyond their control, mill operators are unable to complete a new impoundment within that period.

Several commenters stated that more accurate site-specific emanation factors should be used as opposed to using the relationship of 1 pCi/m^2-s per pCi Ra-226/g tailings. The Agency used a factor of 1 pCi/m^2-s per pCi Ra-226/g of tailings for all dry areas and a factor of zero for wet areas. This same factor was used for the UMTRCA rulemaking and is the factor used by NRC. An attempt was made to develop a formula, using site specific characteristics, that would provide a more precise estimate of emissions. However, the formula has not been verified by the Agency's internal review process or by independent experts and data on the site-specific characteristics needed to derive such estimates are not available. For these reasons, the Agency decided to continue the use of the previously accepted factor.

The NRC stated that recent literature indicates that a water cover may not be as effective in reducing radon emissions as previously thought. Recent technical assessments of radon emissions from tailings covered with water are less than 2 percent of emissions from dry tailings. The Agency believes that assuming no emissions from wet tailings as compared to the more accurate 2 percent emission rate is an insignificant error in the context of this rulemaking. The Agency assumed an emission rate of zero for all tailings covered with water or saturated with water in estimating radon emissions.

Risk

A commenter stated that a site-specific rule based on a lifetime risk of one in a million should be set for each mill to determine the allowable exposed surface area. The EPA has not accepted the proposition that the standard must reduce risk to a predefined value, such as a level of one in a million. The EPA believes that it must protect the public with an ample margin of safety and that this requirement provides the Agency with flexibility to consider the magnitude of the risks, the practicality of measures to reduce risks, and other relevant factors. This is a judgment based on many factors specific to the source category under consideration.

Several commenters stated that radon exposure from mill tailings on a regional and national level is overshadowed by background radon sources. Therefore, regional and national risk estimates are meaningless. The EPA agrees that radon exposures due to mill tailings, at locations distant from mill tailings sites, are small compared to exposures from some other large sources. However, it does not follow that it is meaningless to calculate exposure and risk due to emissions from such sites. These calculations are based on procedures generally regarded as sufficiently accurate to support the setting of regulatory standards. The significance of the risk is judged based on the value of the individual and population risk, and the regulatory options are assessed based on the degree of risk reduction and the practicality and reasonableness of control measures.

Many commenters stated that the significance of effects of radon from mill tailings on total population is negligible because there are no proven adverse health effects. The Agency agrees that the adverse health effects due to radon emissions from mill tailings piles cannot be directly measured due to the high incidence of lung cancer from other causes. However, it would be imprudent to use this as a reason not to regulate exposure to carcinogens. The risk estimates were derived from relative risk coefficients, the use of which was recommended by the Agency's Science Advisory Board and represent current scientific knowledge. It is EPA's position that, based on current scientific evidence, excess lung cancers result from radon emitted by tailings piles and that the projected numbers of cancers calculated in the support documents are sufficient to support a rulemaking.

Economic

Several commenters said that the proposed rules will have significant adverse effects on industry's ability to contain costs and will threaten the industry's future. EPA's analysis shows that the control measures for new tailings disposal practices required in this rulemaking are similar in cost to alternative practices already required by existing regulations and, therefore, the control measures required by this rule are not expected to affect the industry's viability. With respect to existing tailings, the major cost of this rule to industry is moving the timetable for final cover for existing piles forward in time because the sooner new work practices are implemented, the sooner industry must undertake the expense of reclamation. Additional costs may arise in those cases where new capacity for tailings disposal will have to be created to replace the capacity lost during disposal of the existing piles. As indicated in the Economic Analysis for this rulemaking, EPA projects that this impact will not threaten the viability of this industry. The Agency concluded that the costs are reasonable in relation to the benefits derived and that this action is consistent with previous Agency actions.

VI. Summary and Rationale of Final Rule

A. Summary

Based on currently available information, EPA has determined that it is not feasible to prescribe an emission standard for radon emissions from uranium mills. Radon is emitted from the surfaces of tailings piles in a manner analogous to fugitive dust emissions and cannot be emitted through a conveyance designed and constructed to capture such radon emissions. Instead, EPA is requiring an improved work practice for the disposal of newly generated tailings and is specifying a date by which all newly generated tailings must be managed by this work practice.

EPA expects that, when tailings can no longer be placed on an existing pile, Federal and State regulatory agencies will promptly move to require disposal of the piles to Federal standards established by the EPA and implemented by the NRC under the AEA as amended by UMTRCA.

This work practice requires that new tailings be disposed of either in impoundments that are no larger than 40 acres or by the use of continuous disposal in which no more than 10 acres of tailings are exposed at any one time. All new tailings impoundments must be designed and constructed to meet this work practice. Using the first alternative would require a series of impoundments, each constructed with earthen dikes or in a excavated pit and each having a liner as required by 40 CFR 192. As each impoundment is filled, it would be dried out and covered with earthen materials immediately. This design permits the use

of a water cover over all tailings during operations without risk of contaminating ground water. The water cover seals in the radon, greatly reducing radon emissions to air. Also, a series of impoundments significantly reduces the amount of unreclaimed tailings at the end of a mill's lifetime because only one or two impoundments would still require closure. By making final reclamation easy, the potential for larger areas of dry tailings to remain uncovered is avoided, and this too, greatly reduces radon emissions.

The second procedure, continuous disposal, is similarly effective. If tailings are dewatered and immediately buried on a continuous basis, radon emissions during the operational phase of the mill are greatly reduced. At the end of the mill's lifetime, only about 10 acres of tailings require final reclamation. There is, thus, no potential for large areas of tailings to remain dry and uncovered as a source of radon emissions. A liner is used to protect ground water.

At mill sites where there are existing tailings piles, this work practice is to be phased in on a reasonable schedule. No later than 2 years after the effective date of this rule, all owners will either certify to the Administrator that they do not intend to build a new tailings impoundment, or if they wish to build new tailings impoundments they must apply to the Administrator for approval to construct. Within 60 days following the Administrator's approval, the owner must apply to the NRC for a license to construct. Following the granting of a license by NRC, construction must begin promptly and must be completed in not less than 30 months. The entire process must be completed by December 31, 1992. If the owner is in compliance with this schedule, new tailings can continue to be placed on existing piles until the new impoundments are ready. Those owners not building new impoundments may also continue to use their existing piles until December 31, 1992.

An exception from the preceding schedule allowing for continued use of an existing tailings pile will be granted upon petition to the Administrator, provided the existing pile meets one of the following conditions: (1) The existing pile is 40 acres or less and is lined or, (2) the combined area of all piles at the site is less than 20 acres. Each exception will last for five years, at which time the owner may request a new exception.

A discretionary extension for all or some of the milestones on the preceding schedule, allowing for continued use of an existing tailings pile, may be granted upon application to the Administrator for one of the following reasons: (1) The owner demonstrates it cannot, due to circumstances beyond its control, complete a new impoundment before a construction schedule milestone date or (2) the owner or operator demonstrates that an extension is consistent with the CAA. To make such a demonstration, the owner must certify that the mill is in compliance with applicable EPA standards and NRC regulations and license conditions, and makes a submittal showing that the public is protected with an ample margin of safety taking into account the size and condition of the pile, risks to nearby individuals and population, length of extension requested, risk reduction practices in effect, and the expected level of future mill activity. An extension may be granted for a period not to exceed 5 years, although the mill owner will be able to apply for more than one extension.

No exception or extension is effective after December 31, 2001 and no new tailings may be placed on any existing tailings pile after that date.

B. Options Considered

In developing this rule, EPA reviewed a variety of options in the light of comments received on its proposal. A fundamental step in this process was recognizing that the opportunities for regulatory response to the risks involved were different for existing tailings and for new tailings. EPA's analysis of regulatory options proceeded on the basis of this recognition.

With respect to tailings that would be generated in the future, EPA recognizes that improved work practices were available that could limit the period during which tailings were exposed prior to disposal. Limiting this exposure would correspondingly limit risk to health. The work practices that EPA examined reduced this exposure in two ways: first, by placing the tailings on sites smaller than is now the practice; second, by placing cover on the tailings continuously or at intervals. EPA analyzed options for new tailings that varied both as a function of size and as a function of time.

With respect to tailings that already existed, EPA's ability to identify work practice improvements that would limit emissions was more limited. The most direct means for reducing exposures, i.e., a permanent thick earth cover or water cover, could conflict with continued use of the pile or exacerbate ground water problems. Measures involving interim or partial use of earth or water covers were also evaluated. These options are described elsewhere in this notice. Indirect means of reducing exposures were also explored. These basically involve limiting the use of the existing pile for deposition of new tailings by limiting the period during which new tailings could be placed on the piles. On analysis, EPA concluded that volume restrictions would prove difficult to administer and that a more feasible approach would be to limit the future use of existing piles. In the end, EPA decided that risk reductions should be reconciled with continuity of mill operations by phasing in the transition to new disposal methods. The best currently available information indicates that it will require about six years for a source to phase in new capacity. The specific options considered are discussed below.

Interim Cover for Existing Piles

The Agency's proposed rule contained an alternative work practice for existing tailings piles consisting of interim earth covers placed on the sides and tops of dry tailings piles. An interim cover on dry tailings acts to reduce emissions of radon. In a wet pile, water acts to prevent radon emissions so that interim covers are not needed for the wet surfaces. Upon reexamination of the interim cover alternatives and after consideration of the comments received on that issue, the Agency has determined that such covers are not an appropriate work practice to be required under this generally applicable rule.

EPA's model of the interim cover alternative used in the analysis of the proposed rule was overly simplistic. Sources of error included the following factors:

1. The model did not consider tailings piles that go on and off standby repeatedly. In these situations, the interim cover is buried under new tailings followed by application of a new interim cover.

2. The model assumed the dry areas of the pile are covered immediately and that the pile remained on standby for an extended period of time. This is unlikely, because regulatory agencies would require the operator to reclaim sooner than 40 years.

3. Maintenance costs for interim covers were ignored.

4. Covering high, steep slopes with 1 meter of earth is a difficult engineering feat and may be more expensive and impractical than the model assumed it to be, and in practice may endanger workers.

5. Slimes may underlie tailings considered to be dry, making such tailings uncoverable because heavy equipment necessary to apply the cover would sink into the pile. If dry tailings cannot be covered, this would reduce benefits.

The Final Background Information Document and Economic Assessment contains a revised model that attempts to account for these factors. The Agency now believes that interim cover is inappropriate as a generally applicable work practice.

The appropriateness of interim cover can only be evaluated on a site-by-site basis. Though its use in some cases would be practicable and could lead to significant risk reduction, in others it would have dubious risk reduction benefits, costs that appear unwarranted in relation to those benefits, and would present hazards to the safety of workers. Moreover, enforcement of a requirement for interim covers would be difficult and controversial because it would not be obvious which parts of the pile are dry enough to cover and whether future operational plans are firm enough so that it is reasonable to delay application of an interim cover.

The Agency believes that in establishing generally applicable standards it should seek permanent solutions rather than temporary ones. Interim earth covers are temporary because they are often covered by new tailings when the mill returns to operation. The new tailings on top of the interim cover release radon, removing the beneficial effect of the cover. The value of the interim earth cover is also lost when the final cover required by Federal Regulations is put in place. Final reclamation normally requires piles with steep sand dams to be recontoured to a more stable shape. Any interim cover would be lost due to mixing with the tailings during the recontouring. A better use for the limited resources available to the producers of uranium would be final disposal consistent with federal standards.

The State of New Mexico expressed concern about severe additional environmental impacts due to the disruption of many additional acres of land to obtain cover material. The NRC raised serious safety concerns for interim covers. The NRC stated that interim covers on dams would interfere with important safety practices, such as movement monitors for tailings dams. They also stated that covering of certain drain portions of the dams could seriously reduce their stability.

In summary, the Agency concluded that requiring operators of existing tailings piles to immediately add and maintain interim earth covers on all dry surfaces is not an appropriate generally applicable work practice.

Phased Disposal

The Agency is selecting phased disposal for new tailings impoundments as one of two alternative work practices required by the final rule because it reduces health risks due to radon from tailings, providing public health protection with an ample margin of safety during the operating lifetime of a uranium mill tailings impoundment. In this disposal scheme, a series of small impoundments is constructed over the lifetime of a mill. Each small impoundment would be constructed with earthen dikes or in an excavated pit and, under existing Federal regulations, must be lined to prevent ground water contamination. After each impoundment fills, it will be dried out and covered with earth as soon as practical. Disposal costs will be spread over the operating life of the mill. The design permits the use of a water cover over most of the tailings, with only a small risk of contaminating ground water.

An important benefit of phased disposal is that it eliminates the difficulties and expense of reclaiming large tailings piles at the end of the impoundment life. By limiting the size of the piles, very large areas of tailings are prevented from becoming exposed to air, drying out, and emitting radon during extended standby periods. At the end of the mill's lifetime, only one or two impoundments will still require reclamation.

These characteristics of phased disposal combine to reduce radon emissions. The liner under the tailings pile helps maintain wetness of the tailings by preventing water from leaching into the ground. This not only protects ground water, but also greatly reduces radon emissions by keeping the tailings wet. Experience with phased disposal shows that the tailings often stay so wet that water must be pumped out of the impoundments.

Since control of radon emissions is achieved by keeping the tailings saturated or covered with water, it is important that impoundment liners have water retention capability. In most cases eligible for this exception, impermeable synthetic liners will be required. However, UMTRCA standards (40 CFR Part 192) allow an exception from the synthetic liner requirement if it is demonstrated that ground water contamination will not occur.

The size of the pile also helps reduce emissions. It does so by reducing the time for the dry out and standby periods that precede final closure, when radon emissions are at their highest. Since the piles are smaller, they dry sooner, and the exposed surface area is reduced. Closure is relatively easy and inexpensive, reducing the incentive for the owner to delay disposal. To further reduce the time before closure, this rule allows a company to operate a maximum of two tailings impoundments at once. Companies can legitimately need two operating piles to work most efficiently (especially when one pile is almost full), but by limiting an owner to only two operating piles, an owner must close its first pile before it opens its third pile (or close its second before it opens the fourth, etc.). This incentive will work to reduce standby periods.

Phased disposal, therefore, is a tailings management system in which tailings are kept wet until they are dried and disposed. Radon emissions are reduced while the pile is in use and while the pile is on standby. This results in a large reduction of the total emissions from mill tailings pile and, therefore, protects public health with an ample margin of safety.

Constructing, filling, and reclaiming tailings impoundments in series costs less than using a single, large impoundment when a reasonable (5%) discount rate is used. This lower cost reflects the lower initial capital expenditures for phased disposal. Further cost savings may be realized in phased disposal by using excavated earth from future impoundments to reclaim filled, dry impoundments.

Phased disposal is the best available demonstrated technology for uranium mill tailings management. The two mills most recently licensed by the Nuclear Regulatory Commission use phased disposal designs.

The Agency also considered a 20-acre limit for each phased disposal impoundment in the proposal (51 FR 6382). One commenter found a 20-acre limit acceptable but stressed the need for economic assessment of size limits. Several commenters argued that the Agency should allow flexibility for site-specific considerations and should not dictate a specific limitation. The Agency evaluated both 20- and 40-acre phased disposal options. It found that the 40-acre impoundment provides about the same health protection as the 20-acre impoundment, but at a slightly lower cost. The Agency concludes that a 40-acre size limit for phased disposal protects health with an ample margin of safety, as required by section 112. The 40-acre impoundment is the maximum size allowed under the rule; an operator can choose to build a smaller one.

The 40-acre phased disposal work practice provides considerable flexibility for construction and operation of tailings impoundments, although all existing rules (including 10 CFR Part 40 and 40 CFR Part 192) must still be followed. For example, under this work

practice, impoundments can be constructed in hollows by building a dam across the hollow and storing the tailings on the upstream side. The standard only limits the total area of any impoundment used for storage of uranium mill tailings; other site-specific design considerations are not affected.

Liners are required at all new uranium tailings impoundments under existing rules (40 CFR Part 192). The tradeoffs between potential problems and the advantages of liners were considered in that previous rulemaking (48 FR 45926).

Continuous Disposal

The Agency selected continuous disposal as an alternative work practice under the final rule because it reduces health risks from radon from tailings to the same extent as phased disposal and provides quick reclamation of the site. This disposal method calls for tailings to be dewatered as they are generated, placed in pits or on pads, and covered with about 3 meters of earthen materials on a continuous basis. Disposal pits or pads would be constructed with impermeable liners. This method would rely on a thick earth cover to reduce radon emissions rather than on water as in the phased method disposal. During operation, no more than 10 acres of tailings could be uncovered at any given time. To assure that the water remaining in the tailings after dewatering (which is never completely effective) and rain water does not seep through the tailings and contaminate ground water, a continuous disposal impoundment is lined in accordance with 40 CFR 192.32. The potential for ground water contamination is negligible.

A second important benefit of continuous disposal is that it would eliminate the difficulties of reclaiming large tailings piles at the end of the impoundment life. By requiring disposal of tailings as they are generated, very large areas of tailings are prevented from being exposed to air, drying out, and emitting radon during extended standby periods.

The technology of continuous disposal has not been demonstrated for uranium mill tailings in the United States. However, the industry has proposed this method for use at three sites. The decline in uranium demand is one of the major reasons why none of these proposals was put into practice. Tailings dewatering systems have been used successfully at nonferrous ore beneficiation mills. The Agency believes that these proposals and experiences demonstrate that continuous disposal can be a viable work practice.

Flexibility is provided to allow designs that can take advantage of site-specific characteristics. For example, there is no requirement that tailings be disposed of below surface level and no restrictions that limit the use of topographical features of a site as tailings dams. However, all existing regulations still apply.

Although the industry commented that continuous disposal is not practical, this is not a persuasive argument, since at least three companies have chosen this method as their preferred disposal method in detailed site design plans and applications. Also, as noted above, dewatering tailings has been performed in other extraction industries. The Agency decided to allow the industry to select either continuous or phased disposal because both methods provide similar levels of radon reduction and either method could be preferable to the other, depending on the specific physical, environmental, or economic conditions that exist at the site.

C. Existing Piles

The regulation of uranium mill tailings disposal piles requires different approaches to new and existing tailings impoundments. From the standpoint of risk reduction, new impoundments can readily be designed and operated in order to achieve substantial reduction of risk at a reasonable cost. EPA, thus, has adopted standards that have the effect of limiting the total exposed surface area during the active phase of an impoundment's existence. Existing impoundments present more difficult regulatory problems. They were constructed over a thirty year period, range in size from a few acres to several hundred acres, and are located in different areas with different topography, soil characteristics, tailings characteristics, and other factors affecting health risks. Consequently, they are not susceptible to a single regulatory scheme of the sort adopted here for new impoundments. In addition, the NRC and their agreement States regulate practices at these sites on a site-by-site basis. For example, the NRC has stated in comments that it typically requires interim cover for the purpose of dust control on appropriate portions of existing piles.

EPA investigated work practices that might be imposed generally upon existing tailings piles that would reduce risks until they are closed and replaced with new piles. As discussed previously, the Agency found that the two principal options, wetting and interim cover, made no sense to impose as across-the-board requirements. While interim cover has theoretical applicability, its risk reduction is not great in many situations, and costs are disproportionate to that limited reduction of risk. Wetting, particularly in unlined impoundments in arid areas of the Southwest, yields some risk reduction but again at a disproportionate cost. Moreover, wetting at unlined impoundments can lead to ground water contamination, exacerbating a problem that several operators are now trying to remedy.

EPA believes that the reasonable course to deal with these impoundments is to adopt requirements that will encourage their closure, in the long term, in accordance with requirements set by EPA and the NRC. At the same time, these requirements must be tempered with flexibility for the particular circumstances of individual impoundments. It is reasonable to do this in light of the wide disparity in risk from different existing impoundments, and the small number of those impoundments.

Accordingly, the final rule generally requires the cessation of disposal of tailings at existing impoundments six years after promulgation of these regulations. The requirement for cessation of disposal will remove any obstacle for the NRC or an agreement state to require, after an appropriate dry out period, final closure of the impoundment, since it can no longer be used for disposal of newly generated tailings. In EPA's view, the risk that will result from this phase in period of continued disposal at existing impoundments is consistent with the protection of public health with an ample margin of safety.

Exception for Existing Lined Impoundments

The Agency has determined that certain existing tailings management impoundments presently meet the requirements of the new work practice standards. Therefore, the Agency is providing an exception from the schedule requirements, which are specified below, for impoundment designs that are no larger than 40 acres and have a liner meeting the specifications of 40 CFR 192.32. This requirement assures that the impoundment has the capability to retain water, thereby keeping tailings wet and greatly reducing radon emissions.

Exception for Small Tailings Piles

The Agency, in its examination of the uranium milling industry, has discovered that each mill is unique and that not all mills present a significant health risk to the public. The Agency found that one of the most important mill characteristics

that affect risk is the size of the mill tailings pile. The Agency also found that mills having combined pile areas smaller than 20 acres have very small radon emissions. The Agency believes that such a mill does not threaten public health. Therefore, the Agency has decided to except them from the 6-year schedule. Such an exception is consistent with protection of public health with an ample margin of safety.

D. Schedule for Standards Implementation

The Agency is requiring that all tailings generated at existing mill sites after December 31, 1992, be managed by one of the work practices specified in the final rule. By phasing out existing tailings piles and requiring new tailings generated at existing mill sites to be placed in impoundments subject to the new work practice, risks to individuals and populations are reduced and the public is protected with an ample margin of safety. The Agency is assuming that, when tailings can no longer be placed on existing piles, Federal and State regulatory agencies will promptly move to require reclamation of the piles to Federal standards established under the AEA through UMTRCA.

The Agency is aware that section 112 has provided for only a 2-year compliance waiver. However, it is impossible to design, license, and build a new tailings impoundment in that short period of time. The operators of existing mills are given the time necessary to install new impoundments. To assure that new tailings impoundments are built and used as soon as practical, the Agency has established a strict schedule with milestones for meeting regulatory requirements and construction of the facility. Industry is provided with sufficient time to prepare new impoundments while, simultaneously, there is a strict timetable that must be met. This timetable is designed to be flexible to assure that if time is saved in one part of the process the impoundment will be ready sooner. The rule also provides an extension mechanism to give operators a chance to have more time if, due to circumstances beyond their control, they are unable to meet the schedule.

The Agency has examined the effect from the continued use of existing piles during the 6 years required for the construction of new tailings impoundments. In performing the analysis of the effect of allowing all mills to operate for 6 years, relevant radon emissions come only from some of the mills. Since EPA's original analysis, 3 of the 20 mills have stated an intent to go to closure and, therefore, are not effected by this standard. The resulting risk from radon emissions in allowing all other mills to operate for 6 years is not significant. The use of these mills for this short time period represents a marginal risk that does not justify the economic waste of requiring a mill owner to build an impoundment that the owner has no intention of using. Because of these low risks, operators of existing piles who want to continue to use their existing piles may do so for the 6-year period.

Any owner or operator of a licensed uranium mill who wishes to continue to use existing tailings impoundments must submit an application to the Administrator for approval to construct a new impoundment or certify that they do not intend to build a new impoundment. This should be done as soon as possible, but no later than 2 years after the effective date of this rule. This period is necessary to provide the time needed for owners to decide whether or not to build a new impoundment and, if they decide to build a new impoundment, it also provides the time needed for the purchase of a site, for the collection of site data and for the design and preparation of licensing material for EPA and NRC. Owners not building new impoundments may continue to use their existing piles until December 31, 1992.

The Agency anticipates an internal review and decision period following submittal of a complete application. After the Agency's approval to construct, the owner or operator must apply to the NRC within 60 days for a license to construct a new tailings impoundment under 10 CFR 40. The Agency anticipates that NRC will act promptly on the application. Following the receipt of a license from the NRC, the owner or operator must then start construction of an impoundment within 90 days, weather permitting, and must complete construction within 30 months.

The Agency proposed alternative schedules of immediate, 10 years, 15 years, and no time limit for mandatory use of work practice standards. Comments from the NRC and the industry agreed that new impoundments probably could be built in 6 years. Although one industry commenter estimated that it would take more than 10 years to finish new impoundments, in general, the record did not support a 10-year option.

E. Schedule Extension

The Agency recognizes that strict adherence to the schedule may not always be possible or reasonable. The Agency may grant an extension for any schedule milestone for certain reasons.

The first reason for the extension is practicality. The Agency is allowing mill owners 6 years to build new impoundments, because it is the Agency's estimate, supported by the record, that 6 years is normally a sufficient time to design, license and build a new uranium mill tailings impoundment. But the Agency recognizes that, due to circumstances beyond the mill owner's control, situations can arise that delay completion. In these situations, the mill owner can apply for a schedule extension to provide him with sufficient time to complete the new impoundment.

There are other reasons why an extension may be required. For example, as previously noted, each mill is unique and individual mills may present small risks to public health. To take care of any of these situations, the Agency may grant an extension, provided that the mill owner can demonstrate that the extension, under conditions existing at the time of the request, is consistent with protection of public health with an ample margin of safety as specified in § 61.252(e). This extension may be granted for any schedule milestone. For example, the Agency expects that extensions would be granted for mills with moderately sized piles and that have no people living nearby. Such mills present small risks to maximally exposed individuals and small risks to regional and national populations. The Agency may grant an extension, conditionally if required, only upon finding that this extension protects public health with an ample margin of safety.

The Agency may grant these extensions based on an examination of factors relating to the overall remaining health risk, including the size, condition, and location of the pile, the length of extension requested, the expected level of future activity, and any risk reduction practices the mill owner has undertaken or pledges to undertake.

VII. Implementation of the Final Rule

Operators of new tailings impoundments constructed after the promulgation date of this rule must apply to the Administrator of EPA for approval to construct a new impoundment pursuant to section 61.07 of the Clean Air Act.

Operators of existing tailings impoundment should follow the implementation plan detailed in § 61.252 (b) or (c). If the Administrator finds, on the basis of any available information that there is a violation of any

requirement of an applicable implementation plan, the Administrator will enforce with remedies described in section 113 of the Act.

Operators of existing tailings piles who wish an exception listed in § 61.252(d) from the schedules listed in § 61.252 (b) or (c) in order to continue to use a pile should write to the Administrator, providing the reason why the exception is warranted. The Administrator will grant, grant with conditions, or deny the exception. If granted, the owner must reapply to EPA every 5 years that it still meets the criteria for exception. If at anytime neither of the exceptions criteria apply, the owner must notify the Agency and immediately cease use of the pile.

Operators of existing tailings piles who wish extensions from the schedule milestones listed in § 61.252 (b) or (c) in order to continue to use an existing tailings pile should write to the Administrator providing the reasons why an extension should be granted, taking care to provide the information requested in § 61.252(e). This must be done at least 1 year before the milestone date for which the extension is requested. The Administrator will grant, grant with conditions, or deny the extension within 9 months. Although multiple extensions may be granted, each extension will last no more than 5 years.

All requests should be sent to the Assistant Administrator for Air and Radiation (ANR-443), U.S. Environmental Protection Agency, 401 M Street, Washington, DC 20460.

No exception or extension will be effective after December 31, 2001. This deadline allows owners of existing tailings impoundments a chance to use those impoundments in those cases where to do so would not endanger public health, while assuring that the system of exceptions and extensions will not be subject to any potential abuse by mill owners. In this way, the rule will cause even greater reduction in radon emissions as phased or continuous disposal methods are implemented.

Nothing in this rule is intended to affect the existing regulatory authority of the NRC. EPA hopes that it will be able to reach an agreement with NRC to allow NRC to take an important role in the implementation and enforcement of this rule. This would allow EPA to take full advantage of NRC's expertise in this field and help minimize the duplication of effort and conserve administrative resources in accord with § 122 of the Clean Air Act.

VIII. Miscellaneous

A. Docket

The docket is an organized and complete file of all information considered by EPA in the development of this proposed standard. The docket allows interested persons to identify and locate documents so they can participate effectively in the rulemaking process. It also serves as the record for judicial review.

Transcripts of the hearings, all written statements, the Agency's response to comments, and other relevant documents are placed in the docket and are available for inspection and copying during normal working hours.

B. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and, therefore, subject to the requirement of a Regulatory Impact Analysis. The EPA has determined that this rule is not a major rule as defined in section 1(b) of the Executive Order because the annual effect of the rule on the economy will be less than $100 million per year. Also, it will not cause a major increase in costs or prices for any geographic region. Further, it will not result in any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the United States enterprises to compete with foreign enterprises in domestic or foreign markets. Under Executive Order 12291, this rule was submitted to the Office of Management and Budget (OMB) for review. Any comments from OMB to EPA and any response to those comments are included in the docket.

C. Paperwork Reduction Act

The final rule does not impose any reporting or recordkeeping requirements on operators of uranium mills and associated tailings piles.

D. Regulatory Flexibility Analysis

Section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603, requires EPA to prepare and make available for comment an "initial regulatory flexibility analysis" in connection with any rulemaking for which there is a statutory requirement that a general notice of proposed rulemaking be published.

However, section 604(b) of the Regulatory Flexibility Act provides that section 603 "shall not apply to any proposed . . . rule if the head of the Agency certifies that the rule will not, if promulgated have a significant economic impact on a substantial number of small entities."

The EPA believes this final rule will have little or no impact on small business because the total costs associated with the standards will have relatively little impact on the total cost of producing uranium oxide.

For the preceding reasons, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

E. General Provisions

The general provisions of 40 CFR Part 61, Subpart A apply to all sources regulated by this rule, except as otherwise noted.

F. State Implementation and Enforcement of Emission Standards

Under section 112(d)(1) of the CAA, any State may develop and submit to the Administrator a procedure for implementing and enforcing emission standards for hazardous air pollutants for stationary sources located in such State. If the Administrator finds a State's procedure for implementing the standard is adequate, the Federal authority then is delegated to the State. To streamline this procedure, some of EPA's Regional offices have entered into agreements with certain States for "automatic" delegation of new section 112 standards. Under this arrangement, States are delegated authority to implement and enforce all new section 112 standards when they are issued.

The Agency has decided that "automatic" delegation shall not be made for the radionuclide NESHAPs. When EPA entered into these agreements, the State's capabilities and expertise with respect to radionuclides were not considered. Therefore, States must reapply for delegation in the case of radionuclide NESHAPs.

G. Relationship to Other Programs

It is important to note that EPA has authority to regulate mining wastes under the Resource Conservation and Recovery Act (RCRA), as well as the CAA and UMTRCA. Since the considerations under each statute may vary, the regulatory program for uranium mill tailings under the CAA and UMTRCA might well differ from the program EPA intends to develop for mining waste under RCRA. The RCRA program will be tailored to the risks associated with mining wastes and the technical feasibility of various control options (see 51 FR 24496; July 3, 1986).

H. Communications

Communications with the Administrator regarding the reporting and recordkeeping requirements of this

rule, as well as requests for waivers, shall follow the provisions of Part 61.10, except as otherwise noted in this rule.

This rule is effective immediately for new sources and existing facilities. Those facilities that are not in compliance with the final rule based on information currently available to them, may request a compliance waiver from the Administrator under the provisions of section 112(c)(1).

List of Subjects in 40 CFR Part 61

Air pollution control, Hazardous materials, Asbestos, Beryllium, Mercury, Vinyl chloride, Benzene, Arsenic, and Radionuclides.

Dated: August 15, 1986.

Lee M. Thomas,

Administrator.

PART 61—[AMENDED]

Part 61 of Chapter 1 of Title 40 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 61 continues to read as follows:

Authority: Secs. 112 and 301(a) Clean Air Act, as amended [42 U.S.C. 7412 (a)].

2. By adding a new Subpart W to read as follows:

Subpart W—National Emission Standard for Radon-222 Emissions From Licensed Uranium Mill Tailings

Sec.

Subpart W—National Emission Standard for Radon-222 Emissions From Licensed Uranium Mill Tailings

§ 61.250 Applicability.

This subpart applies to licensed sites that manage uranium byproduct materials during and following the processing of uranium ores, commonly referred to as uranium mills and their associated tailings. This subpart applies during the period of operation.

§ 61.251 Definitions.

As used in this subpart, all terms not defined here shall have the meaning given them in the Clean Air Act or Subpart A of Part 61. The following terms shall have the following specific meanings:

(a) "Area" means the area covered by the vertical projection of the pile upon the earth's surface.

(b) "Commission" means the Nuclear Regulatory Commission or its Agreement States (where applicable).

(c) "Continuous disposal" means a method of tailings management and disposal in which tailings are dewatered by mechanical methods immediately after generation. The dried tailings are then placed in trenches or other disposal areas and immediately covered to Federal standards.

(d) "Covered" means to cover with earth sufficient to meet Federal standards for the management of uranium byproduct materials pursuant to 40 CFR 192.32.

(e) "Dewatered" means to remove the water from recently produced tailings by mechanical or evaporative methods such that the water content of the tailings does not exceed 30 percent by weight.

(f) "Existing tailings pile" means a tailings pile that is in operation on the effective date of this rule.

(g) "Licensed site" means the area contained within the boundary of a location under the control of persons generating or storing uranium byproduct materials under a license issued by the Commission. This includes such areas licensed by Agreement States, i.e., those States which have entered into an effective agreement under Section 274(b) of the Atomic Energy Act of 1954, as amended.

(h) "New tailings" means uranium tailings produced after the effective date of this rule.

(i) "New tailings impoundment" means any location or structure at which uranium mill tailings are temporarily or permanently stored and which is placed in operation after the promulgation of this rule.

(j) "Operation" means that an impoundment is being used for the continued placement of new tailings or is in standby. An impoundment is in operation from the day that tailings are first placed in the impoundment until the day that final closure begins.

(k) "Owner" means any person who owns or operates a uranium mill or an existing tailings pile or a new impoundment.

(l) "Phased disposal" means a method of tailings management and disposal which uses lined impoundments meeting the requirements of 40 CFR Part 192.32, no greater than 40 acres in area, which immediately filled, upon becoming dried, and covered to Federal standards.

(m) "Uranium byproduct material" or "tailings" means the wastes produced by the extraction or concentration of uranium from any ore processed primarily for its source material content. Ore bodies depleted by uranium solution extractions and which remain underground do not constitute byproduct material for the purposes of this subpart.

§ 61.252 Standard.

(a) All new tailings impoundments built after the effective date of this rule shall be designed and constructed to meet one of the two following work practice standards and in the following manner:

(1) Phased disposal in lined tailings impoundments that are no more than 40 acres in area and meet the requirements of 40 CFR 192.32(a). The owner shall have no more than two impoundments in operation at any one site at any one time.

(2) Continuous disposal of tailings such that the tailings are dewatered and immediately disposed with no more than 10 acres of tailings being uncovered at any time and operated in accordance with 40 CFR 192.32(a).

(b) Owners who build new tailings impoundments may continue to place new tailings or waste water associated with milling or mining activities on existing tailings piles only until new tailings impoundments are constructed, and only if the owner is in the process of designing, licensing, and constructing new tailings impoundments in accordance with the following schedule:

(1) As soon as practical, but no later than 2 years after the effective date of this rule, all owners who wish to build new tailings impoundments shall apply to the Administrator for approval to construct under section 61.07. The Administrator shall make a determination to grant or deny any application for approval in accordance with section 61.08, except that the time limitations of subsections (a) and (d) shall not apply.

(2) Within 60 days following the Administrator's approval to construct a new tailings impoundment, the owner shall apply to the Commission for a license to construct a new tailings impoundment.

(3) Following the granting of a license by the Commission, the owner shall begin construction of the new tailings impoundment within 90 days unless seasonal conditions do not permit, in which case construction shall begin at the start of the next construction season. This impoundment shall be completed and shall be ready to receive new tailings within 30 months of the date of licensing by the Commission.

(4) In no event shall new tailings be placed on existing tailings piles after December 31, 1992, unless the owner has received an exception or extension from the Administrator in accordance with paragraphs (d) or (e) of this section.

(c) Owners who do not intend to build a new tailings impoundment must certify to the Administrator as soon as

possible, but no later than 2 years following the effective date of this rule, that they do not intend to build a new impoundment at the mill site. Owners who make this certification will be able to use their existing tailings piles for the deposition of new tailings or waste water associated with milling and mining activities until December 31, 1992, unless they receive an exception or extension from the Administrator in accordance with paragraph (d) or (e) of this section, in which case the owner may continue to use the existing tailings piles as permitted by the terms of the exception or extension.

(d) An exception for continued use of an existing tailings pile shall be granted upon application for approval to the Administrator provided that:

(1) The existing tailings pile is 40 acres or smaller in area and meets the requirements of 40 CFR 192.32(a)(1), or

(2) The combined area of all piles at a licensed site is less than 20 acres.

The Administrator will grant, grant with conditions, or deny the application. If granted, the owner must certify to the Administrator every 5 years that it still meets at least one of the preceding criteria. Following this certification, the Administrator will grant, grant with conditions or deny the exception. At any such time as neither of the two criteria continue to apply, the owner shall so notify the Administrator, and the exception shall terminate.

(e) An owner may apply to the Administrator on an impoundment-by-impoundment basis, for an extension to continue using an existing tailings pile.

(1)(i) An extension may be granted upon a showing that, despite a good faith effort by the owner, it cannot, due to circumstances beyond its control, meet any paragraph (b) schedule deadline.

(ii) An extension may be granted, for any paragraph (b) or (c) schedule deadline at the Administrator's discretion, upon a showing by the owner that the extension is consistent with protection of the public health with an ample margin of safety. To make this showing, the owner must first certify that it is in compliance with applicable existing NRC regulations and license conditions. In addition, the Administrator will also take into account: the size and condition of the pile, the size and location of the nearby population, the length of extension requested, the existence and effectiveness of any risk reduction practices that are or will be taken, and the expected level of future mill activity.

(2) The owner may apply for an extension at any time up to 1 year before the cease-use date. The Administrator will have 9 months from the date of application to grant, grant with conditions or deny the extension. Subject to paragraph (g) of this section, no extension will be granted for longer than 5 years, and no extension pursuant to paragraph (e)(1)(i) shall be granted for any period longer than necessary for the owner to meet applicable paragraph (b) requirements.

(3) The owner may apply for as many extensions as needed. Each extension must be applied for and proven separately.

(4) The Administrator will provide for public notice and comment on all applications for approval of extensions.

(f) All applications for approval of exceptions or extensions shall be sent to the Assistant Administrator for Air and Radiation (ANR–443), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

(g) New tailings shall not be placed on any existing tailings pile after December 31, 2001, and no exception or extension shall be effective after that date.

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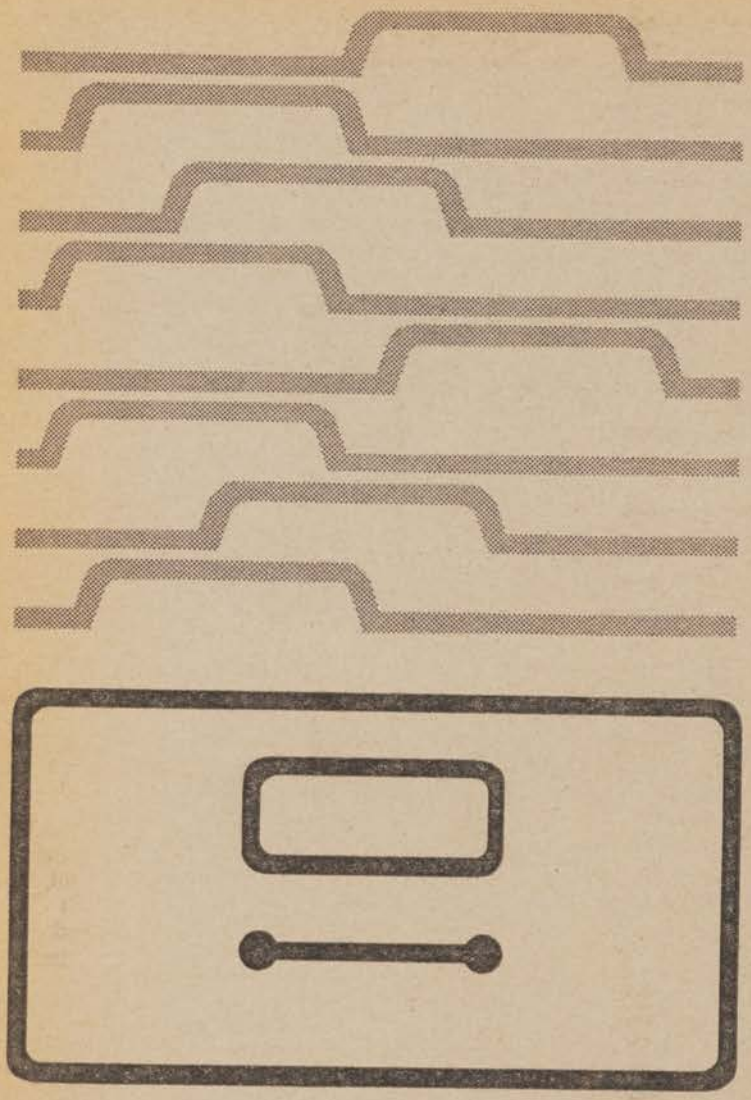

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