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Presidential Documents

Title 3—

The President

Proclamation 6705 of June 30, 1994

50th Anniversary of the Liberation of Guam

By the President of the United States of America

A Proclamation

Fifty years ago, on July 21, 1944, after two and a half years of occupation, 55,000 United States Marines and soldiers stormed the small Pacific Island of Guam in an effort to bring about the liberation of a people oppressed by tyranny.

The conquest of Guam by Imperial Japanese forces had begun shortly after the attack on Pearl Harbor when Saipan-based Japanese bombers launched the first in a series of raids on the island. The small defending force consisted of a handful of military and civilian construction workers, as well as the local Guam Insular Guard and the Guam Militia. Hopes of defending the island ended in the early morning hours of December 10, 1941, when the island's governor surrendered his post and the island, thus making Guam the only American community to be occupied during World War II.

The Chamorros, the indigenous people of Guam, endured great hardships during the occupation as their captors forced them to work long hours in the fields, repair or build airfields and defense installations, and dig hundreds of Japanese shelter caves. But liberation was close at hand. Guam offered an ideal strategic position for the Allied forces, as it would provide a centralized location between the Japanese homeland and the Philippine Islands to launch long-range bomber attacks. By taking the Marianas Islands back, we would also be able to sever vital enemy supply lines, thus cutting off thousands of enemy soldiers and ending their effectiveness in the war.

The battle for Guam was fierce. Enemy forces continued to launch counter-attacks despite their lack of supplies or hope of winning. But the Americans were just as determined and went to great lengths to complete their mission.

Chief of Staff General Dwight D. Eisenhower stated it best when he said:

> "In a nation at war, teamwork by the whole people is necessary for victory. But the issue is decided on the battlefield, toward which all national effort leads. The country's fate lies in the hands of its soldier citizens; in the clash of battle is found the final test of plans, training, equipment, and—above all—the fighting spirit of units and individuals."

And it was the spirit of the Americans fighting on Guam that brought a quick end to organized resistance on the island as it was secured by the American forces on August 10, 1944.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim July 21, 1994, as the "50th Anniversary of the Liberation of Guam." I call upon all Americans to observe this day with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of June, in the year of our Lord nineteen hundred and ninety-four, and of the Independence of the United States of America the two hundred and eighteenth.

William J. Clinton

[FR Doc. 94-16327
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Rules and Regulations

Federal Register
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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1421

RIN 0560–AD74

General Price Support Regulations for Grain, Rice, and Oilseeds for 1993 and Subsequent Crop Years

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule amends the regulations with respect to the price support loan programs for grains and similarly handled commodities, including oilseeds (canola, mustard seed, rapeseed, safflower seed, soybeans, and sunflower seed), which are conducted by the Commodity Credit Corporation (CCC) in accordance with the Agricultural Act of 1949, as amended (the 1949 Act), and other acts. The amendments made by this interim rule will provide greater clarity, enhance the administration of CCC programs by providing uniformity between CCC price support programs, eliminate obsolete provisions, provide more authority to State and county committees in administering the programs, lessen the administrative actions CCC imposes on producers who violate the loan and loan deficiency payment (LDP) agreements, and correct errors.

DATES: Interim rule effective July 5, 1994. Comments must be received on or before August 4, 1994, in order to be assured of consideration.

ADDRESSES: Submit comments to Director, Cotton, Grain, and Rice Price Support Division, Agricultural Stabilization and Conservation Service, United States Department of Agriculture (USDA), PO Box 2415, Washington, DC 20013–2415; telephone 202–720–7641. Comments received may be inspected between 9 a.m. and 4:30 p.m., Monday through Friday, except holidays, in room 3623, South Agriculture Building, USDA, 14th Street and Independence Avenue, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Margaret Wright, Program Specialist, Cotton, Grain, and Rice Price Support Division, Agricultural Stabilization and Conservation Service, USDA, PO Box 2415, Washington, DC 20013–2415; telephone 202–720–8481.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be not-significant for purposes of Executive Order 12866 and therefore has not been reviewed by OMB.

Federal Assistance Program

The title and number of the Federal Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are Commodity Loans and Purchases—10.051.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable because the CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of these determinations.

Environmental Evaluation

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of human environment.

Executive Order 12372

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

Executive Order 12778

This interim rule has been reviewed pursuant to Executive Order 12778. To the extent State and local laws are in conflict with these regulatory provisions, it is the intent of CCC that the terms of the regulations prevail. The provisions of this interim rule are not retroactive. Prior to any judicial action in a court of competent jurisdiction, administrative review under 7 CFR part 780 must be exhausted.

Paperwork Reduction Act

Public reporting burden for the information collections contained in this regulation with respect to price support programs is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. The information collections have previously been cleared under the current regulations by the Office of Management and Budget (OMB), and assigned OMB Nos. 0560–0087 and 0560–0129. In accordance with the provisions of 44 U.S.C. 35, the information collection requirements that are revised as a result of this rule will be resubmitted to OMB for review.

Comments

Since producers are currently making decisions regarding commodities which may be pledged as collateral for CCC price support loans, the provisions of this interim rule are effective upon publication in the **Federal Register**. Comments are requested, however, and will be taken into consideration when developing the final rule. This interim rule will be scheduled for review so that a final document discussing comments received and any amendments required can be published in the **Federal Register** as soon as possible.

Background

The 1949 Act sets forth the statutory authority for CCC price support programs. CCC price support programs are intended to stabilize market prices and provide interim financing to producers to assist in the orderly marketing of eligible commodities.

This interim rule amends regulations found at 7 CFR part 1421 to provide rules for administering CCC price support programs for the 1993 and subsequent crop years.

Section 1421.1 is amended to remove the reference to soybeans. Soybeans are already included because they are defined as an oilseed in § 1421.3.

Section 1421.3 is amended to: (a) Add the reference to part 1425; (b) clarify that the definitions in this part apply if there are any conflicts with the

referenced parts; and (c) add a definition of high moisture commodities.

This interim rule amends § 1421.4(b) to add references to a receiver, guardian, or trustee which were inadvertently omitted. In addition, § 1421.4(f) is amended to remove an obsolete reference.

Section 1421.5(b)(1) is amended to clarify the application of the provision of the paragraph to loans, purchases, and LDP's and § 1421.5(b)(4)(iv) to correct the unit of measure for peanuts to tons and hundredths of a ton.

Section 110 of the 1949 Act sets forth the statutory authority for the farmer owned reserve (FOR) program for wheat and feed grains.

Producers with regular 9-month nonrecourse price support loans are eligible to enter the FOR upon maturity of the regular loan. Producers may repay regular 9-month loans and repledge the commodity pledged as collateral for such initial loan for a subsequent loan. Under current program regulations, the maturity date for the subsequent loan is the same as the maturity date for the initial 9-month loan. Section 110(b)(1) of the 1949 Act provides, in part, that "an extended loan shall only be made to a producer after the expiration of a 9-month price support loan * * *." Accordingly, under current program regulations, grain pledged as collateral for a subsequent loan is not eligible to be pledged as collateral for a FOR loan because the grain is not placed into the FOR "after the expiration of a 9-month price support loan".

This interim rule amends § 1421.5(d)(2) to provide that CCC may allow producers to extend price support loans which are less than 9 months in length because the collateral securing such loan had been previously pledged as collateral for a price support loan so that the maturity date for such subsequent loan is the last day of the ninth month following the month such subsequent loan was disbursed. This would permit producers having such a loan to enter into the FOR upon maturity if all other eligibility requirements are met.

This interim rule amends § 1421.7 by removing paragraph (b) and redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively. The weed control provisions are removed because CCC has determined that weed control laws do not affect the value of a commodity.

In addition, this interim rule amends § 1421.7(c)(1) to include rice and to remove the reference to the weed control law discounts. Section 1421.7 is also amended to redesignate paragraph (c)(3) as (c)(4) and add a new paragraph (c)(3), which was inadvertently omitted, which includes the method to determine the loan rate for rice based on the milling yield.

This interim rule amends § 1421.8(b)(2) to remove an incorrect reference to the United States Warehouse Act.

This interim rule amends § 1421.9(f)(2)(iv) by removing paragraph (G) to correct an error. Rice has not been stored identity preserved for many years.

This interim rule amends §§ 1421.9(f)(2)(xiv)(B)(5)(*v*) and 1421.18(b)(15)(ii)(G) to correct the terminology that the sunflower seed must pass through a 14/64" round hole screen.

This interim rule amends § 1421.11(a) to correct a typographical error.

Provisions for taking administrative offsets are provided in part 3 of this title and part 1403 of this chapter. Accordingly, this interim rule removes and reserves § 1421.14.

This interim rule amends § 1421.16 (a) and (c) to include applicable references to Forms CCC–666, CCC–666 LDP, CCC–678, and CCC–709 and to remove incorrect references to Forms CCC–700 and CCC–701.

Producers who violate the loan note and security agreement by moving farm-stored loan collateral from the structures designated for the storage of such loan collateral, without prior written consent of the county committee, are subject to liquidated damages. In some cases, the collateral is moved to other structures on the farm which makes it possible for CCC to perfect its security on such collateral. CCC has determined that when such security can be established, producers should not be subject to such liquidated damages. Accordingly, this interim rule amends § 1421.16(b)(2) to clarify that unauthorized removal only includes cases where CCC cannot obtain the first lien on the collateral.

It is difficult to prove the amount of damages to CCC for loan and LDP violations committed by producers; however, 20 and 50 percent of the loan and LDP rates, as applicable, were established for first and second violations, respectively, when the county committee determined that the producer acted in good faith. CCC has determined that the liquidated damages can be reduced without affecting the administration of the loan and LDP programs. Accordingly, this interim rule amends § 1421.16 to: (a) Decrease the liquidated damages amounts; and (b) add paragraph (q) to provide that any or all of the liquidated damages may be waived under certain conditions.

In addition, under certain conditions, producers who violate loan and LDP provisions may be denied loans and LDP's on commodities stored on the farm. CCC has determined that this penalty is severe and should only be assessed when the county committee determines that such action is necessary to protect the interests of CCC. Accordingly, in § 1421.16, paragraphs (d) and (e) have been amended to remove the requirement for denial of farm-stored loans or LDP's and paragraphs (k) and (l) have been amended to clarify that producers must pay the liquidated damages assessed and such amounts cannot be repaid with a commodity certificate under the provisions of part 1470 of this chapter.

Section 1421.17 provides requirements for farm-stored commodities. Section 1421.17 is amended as follows: (a) Paragraph (a) has been amended to clarify that the reduced quantity for loan shall be the mortgaged loan quantity; (b) paragraph (c)(1) has been amended to clarify that, when farm-stored loans are transferred from the farm to warehouse storage, the warehouse-stored quantity cannot exceed 110 percent of the loan quantity transferred from the farm-stored loan; (c) paragraph (c)(3) has been amended to correct a reference; and (d) paragraph (e) has been amended to include a reference to Form CCC–709 which was omitted.

This interim rule amends § 1421.18 to correct the following errors: (a) paragraph (b)(12)(iv)(B) has been amended to correct the spelling of "green"; (b) paragraph (b)(13)(iv)(D) has been amended to correct punctuation; and (c) paragraph (b)(13)(iv)(D)(5) has been amended to correct the spelling of "inconspicuous."

This interim rule amends § 1421.19(b) to correct the spelling of "Form."

This interim rule amends § 1421.20 as follows: (a) paragraph (a)(2) to correct two references; and (b) to add paragraph (e) to provide if a producer moves a commodity from storage without prior approval on a nonworkday, the producer will not be subject to administrative actions providing the producer notifies the county office on the next workday that the commodity has been moved and such movement is approved by CCC.

Section 1421.22 provides the settlement provisions of price support loans. This interim rule amends § 1421.22 as follows: (a) Paragraph (c)(3)(i)(A) to correct the percentage of foreign material for peanuts; (b) paragraph (c)(4) to remove references to location differentials for rice because such reference is obsolete; and (c) to add

paragraphs (e) through (i) to include provisions that: (1) CCC may pay to producers the cost for hauling commodities delivered to CCC beyond the producer's normal delivery point, (2) producers may deliver commodities to CCC directly to rail cars, (3) producers will receive storage credit for commodities delivered or forfeited to CCC in advance of the loan maturity date, and (4) producers will receive credit for prepaid warehouse charges for receiving and loading out for commodities delivered or forfeited to CCC.

Section 1421.29 provides the provisions for LDP's. Section 1421.29 is amended as follows: (a) paragraph (b)(3) removes references to obsolete forms and corrects an incorrect reference; (b) paragraphs (c) and (g) adds references to rice for clarity; and (c) paragraph (h) is removed and paragraph (i) is redesignated as paragraph (h). This provision was included to allow producers delivering commodities to a buyer directly after harvest an opportunity to file for a LDP on the day such commodities were harvested and delivered. This required producers to report deliveries to the county office before the next loan repayment rate announcement. Since this provision was implemented, CCC developed a more workable procedure that allows producers to request LDP's in advance of harvest and delivery with the LDP rate based on the loan repayment rate announced and in effect on the day the commodity is delivered to the processor, buyer, warehouse, or cooperative according to redesignated § 1421.29(h). Accordingly, the provisions in removed paragraph (h) are no longer needed.

This interim rule amends § 1421.202 to add a reference to wheat which was inadvertently omitted and corrects an incorrect reference.

Section 1421.205 is amended as follows: (a) paragraphs (a) and (b) clarify that a reserve loan is approved rather than disbursed; and (b) paragraph (a)(2) clarifies the quantity for which the reserve agreement is approved.

This interim rule amends § 1421.206(b) as follows: (a) removes references to grain which grades "sample grade" because such grain is not eligible for a FOR loan; and (b) removes the provision that corn eligible for the FOR must be shelled corn. Currently, corn pledged as collateral for a FOR loan is restricted to shelled corn. CCC has determined that producers of ear corn should not be denied participation in the FOR and that the quality of the grain in the FOR would not be adversely affected if ear corn is permitted into the FOR. Accordingly, this interim rule removes the stipulation that corn must be shelled.

Quantities of a commodity approved for FOR that are in approved storage earn storage credit and CCC pays producers storage payments at the end of each quarterly period. Producers with commodities stored in approved warehouse storage must pay or provide for the storage charged by the warehouse before CCC will pay the FOR storage payment. This interim rule amends § 1421.207 to clarify these provisions.

Section 1421.208 has been amended to remove a typographical error.

Section 1421.210 provides the commingling and rotation provisions for FOR loans. Accordingly, § 1421.210 is amended as follows: (a) paragraph (a) clarifies the provisions that are applicable to producers who commingle a quantity of an eligible commodity with the quantity approved for FOR; (b) paragraphs (b)(2) and (b)(4) add the provision that producers may rotate FOR loan collateral by replacing such collateral with grain from existing stocks. In the past, producers were only allowed to use grain from their most recent harvest as replacement stocks for rotated FOR loan collateral. CCC has determined that this requirement was unnecessary and that CCC would be at no risk by allowing producers to use grain from their existing stocks of harvested grain from any past harvest; (c) paragraph (b)(5)(i) corrects punctuation, paragraph (b)(5)(ii) removes an incorrect reference, and paragraph (b)(5)(iv) reduces the percent of liquidated damages for failing to replace the rotated quantity; (d) paragraph (c)(1) removes the reference to new grain to conform to the changes made in paragraphs (b)(2) and (b)(4); (e) paragraph (c)(2) corrects a typographical error; (f) paragraph (c)(3) clarifies that storage shall not be earned for FOR collateral released for sale by the producer from the date of the rotation request until the replacement stocks are in place; (g) paragraph (c)(4) requires that the producer certify to the FOR quantity that the producer is requesting CCC to release for rotation that the producer intends to feed and clarifies that storage shall not be earned for such collateral released from the date of the rotation request until the replacement stocks are in place; and (h) paragraph (c)(5) removes the requirement to measure and inspect the grain to be released and the growing crop of the replacement stocks to conform to the changes made in paragraphs (b)(2) and (b)(4), and clarifies that the replacement stocks, when such stocks are already in store on the farm, must be inspected and measured before the release of the FOR collateral.

This interim rule amends § 1421.211 to clarify that producers may repay FOR loans at any time at the marketing loan repayment rate if such rate is in effect.

This interim rule amends § 1421.215 to conform to the existing provisions for loss of or damage to regular loans in § 1421.15.

This interim rule amends § 1421.320 to clarify that rice marketing certificate payments may be paid in a form other than commodity certificates, and such payments apply to that quantity of a commodity redeemed from loan or on which a LDP was made.

This interim rule amends §§ 1421.321 1421.323 and 1421.324 to correct references to the agreement with CCC for a rice marketing certificate payments and amends the heading to § 1421.323.

This interim rule amends § 1421.323(b) to clarify that rice marketing certificate payments apply to that quantity of a commodity redeemed from loan or on which a LDP was made.

List of Subjects in 7 CFR Part 1421

Grains, Loan programs/agriculture, Oilseeds, Peanuts, Price support programs, Reporting and recordkeeping requirements, Soybeans, Surety bonds, Warehouses.

Accordingly, 7 CFR part 1421 is amended as follows:

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

1. The authority citation for 7 CFR part 1421 continues to read as follows:

Authority: 7 U.S.C. 1421, 1423, 1425, 1441z, 1444f–1, 1445b–3a, 1445c–3, 1445e, and 1446f; 15 U.S.C. 714b and 714c. Subpart—Rice Marketing Certificate Program is also issued under authority of 7 U.S.C. 1441–2; 15 U.S.C. 714b and 714c.

2. Section 1421.1 is amended by revising paragraph (a) to read as follows:

§ 1421.1 Applicability.

(a) The regulations of this subpart are applicable to the 1991 and subsequent crops of barley, corn, grain sorghum, oats, peanuts, rice, rye, wheat, and oilseeds as set forth in § 1421.3. These regulations set forth the terms and conditions under which price support loans and purchase agreements shall be entered into and loan deficiency payments made by the Commodity Credit Corporation (CCC). Additional terms and conditions are set forth in the note and security agreement, loan deficiency payment application, and the purchase agreement which must be executed by a producer in order to

receive price support. With respect to warehouse-stored loans for peanuts, such loans shall be made in accordance with part 1446 of this title.

* * * * *

3. Section 1421.3 is revised to read as follows:

§ 1421.3 Definitions.

The definitions set forth in this section shall be applicable for all purposes of program administration. The terms defined in part 719 of this title and parts 1413 and 1425 of this chapter shall also be applicable, except where those definitions conflict with the definitions set forth in this section.

Basic support rate means the price support rate established by CCC for a commodity before any adjustment for premiums and discounts.

Charges means all fees, costs, and expenses incurred in insuring, carrying, handling, storing, conditioning, and marketing the commodity tendered to CCC for price support. Charges also include any other expenses incurred by CCC in protecting CCC's or the producer's interest in such commodity.

High moisture commodities means barley, corn, and grain sorghum normally harvested and intended to be stored or marketed in a high moisture condition.

Loan deficiency quantity means the eligible quantity which was certified by the producer as eligible to be pledged as collateral for a price support loan, for which the producer elected to forgo obtaining price support.

Loan quantity means the quantity on which the price support loan was disbursed shown on the note and security agreement.

Oilseeds means any crop of soybeans, sunflower seed, canola, rapeseed, safflower, flaxseed, mustard seed, and other oilseeds as determined and announced by CCC.

Purchase quantity means the eligible quantity designated on Form CCC–614, Purchase Agreement for purchase by CCC.

4. Section 1421.4 is amended by revising paragraphs (b) and (f) to read as follows:

§ 1421.4 Eligible producers.

* * * * *

(b) A receiver or trustee of an insolvent or bankrupt debtor's estate, an executor or an administrator of a deceased person's estate, a guardian of an estate of a ward or an incompetent person, and trustees of a trust shall be considered to represent the insolvent or bankrupt debtor, the deceased person, the ward or incompetent, and the beneficiaries of a trust, respectively, and the production of the receiver, executor, administrator, guardian, or trustee shall be considered to be the production of the person or estate represented by the receiver, executor, administrator, guardian, or trustee. Loan, loan deficiency payment, or purchase agreement documents executed by any such person will be accepted by CCC only if they are legally valid and such person has the authority to sign the applicable documents.

* * * * *

(f) *Warehouse-stored loans to warehousemen.* Warehouse-stored loans may be made to a warehouseman who, acting on behalf and with the authorization of a producer, tenders to CCC warehouse receipts issued by such warehouseman for a commodity produced by such warehouseman only in those States where the issuance and pledge of such warehouse receipts is valid under State law.

* * * * *

5. Section 1421.5 is amended by revising paragraphs (b)(1), (b)(4)(iv), and (d)(2) to read as follows:

§ 1421.5 General eligibility requirements.

* * * * *

(b) (1) Commodities for loans, purchases, or LDP's must be tendered to CCC by an eligible producer and must be eligible and in existence when approved by CCC. For loans and purchases, commodities must also be stored in approved storage at the time of disbursement of loan or purchase agreement proceeds. The commodity must not have been sold, nor any sales option on such commodity granted, to a buyer under a contract which provides that the buyer may direct the producer to pledge the commodity to CCC as collateral for a price support loan or to obtain a loan deficiency payment. Such commodities must also be merchantable for food, feed, or other uses determined by CCC and must not contain mercurial compounds, toxin producing molds, or other substances poisonous to humans or animals.

* * * * *

(4) * * *

(iv) Quantities of peanuts shall be in tons and hundredths of a ton;

* * * * *

(d) * * *

(2) The commodity reoffered as security for the subsequent loan shall have the same maturity date as the original loan, except that if a farmer owned reserve program is in effect in accordance with §§ 1421.200 through 1421.217, CCC may allow a producer to request that maturity date of such subsequent loan be the last day of the ninth month following the month the subsequent loan is disbursed.

* * * * *

6. Section 1421.7 is amended by:

A. Removing paragraph (b),

B. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c) respectively,

C. Revising redesignated paragraph (c)(1),

D. Redesignating redesignated paragraph (c)(3) as paragraph (c)(4), and

E. Adding a new paragraph (c)(3) to read as follows:

§ 1421.7 Adjustment of basic support rates.

* * * * *

(c) (1) With respect to all commodities except peanuts and rice, warehouse-stored loans and purchase agreement payments shall be disbursed at levels based on the basic county support rate for the county where the commodity is stored, adjusted for the schedule of premiums and discounts established for the commodity on the basis of quality factors set forth on warehouse receipts or supplemental certificates and for other quality factors, as determined and announced by CCC.

* * * * *

(3) With respect to rice, warehouse-stored loans and purchase agreement payments shall be disbursed at levels based on the milling yields times the whole and broken kernel loan rates, adjusted for the schedule of discounts on the basis of quality factors set forth on warehouse receipts or supplemental certificates and for other quality factors, as determined and announced by CCC.

* * * * *

7. Section 1421.8 is amended by revising paragraph (b)(2) to read as follows:

§ 1421.8 Approved storage.

* * * * *

(b) * * *

(2) A warehouse operated by an approved cooperative as defined in part 1425 of this chapter.

* * * * *

8. Section 1421.9 is amended by:

A. Revising paragraphs (f)(2)(iv)(E) and (f)(2)(iv)(F),

B. Removing paragraph (f)(2)(iv)(G), and

C. Revising paragraph (f)(2)(xiv)(B)(*5*)(*v*) to read as follows:

§ 1421.9 Warehouse receipts.

* * * * *

(f) * * *

(2) * * *

(iv) * * *

(E) Milling yield; and

(F) Moisture.

* * * * *

(xiv) * * *
(B) * * *
(5) * * *
(v) Seed size passing through a 14/64" round hole screen;
* * * * *

9. Section 1421.11(a) is revised to read as follows:

§ 1421.11 Liens.

(a) The county office shall file or record, as required by State law, all security agreements which are issued with respect to commodities pledged as collateral for price support loans. The cost of filing and recording shall be paid for by CCC.
* * * * *

§ 1421.14 [Removed and Reserved]

10. Section 1421.14 is removed and reserved.

11. Section 1421.16 is amended by:

A. Revising paragraph (a)(1) introductory text and revising paragraphs (a)(1)(i), (a)(2), (a)(3), (b)(1), (b)(2), (c), (d) introductory text, and (d)(2),

B. Revising paragraphs (e), (k)(1)(ii)(C), and (k)(1)(ii)(D),

C. Adding paragraph (k)(1)(ii)(E),

D. Revising paragraphs (l)(1)(ii) and (l)(1)(iii), and

E. Adding paragraphs (l)(1)(iv) and (q) to read as follows:

§ 1421.16 Personal liability of the producers.

(a) * * *

(1) When signing Form CCC–666, Farm Stored Loan Quantity Certification, when applicable, Form CCC–677, Farm Storage Note and Security Agreement, and Form CCC–678, Warehouse Storage Note and Security Agreement, that the producer will not:

(i) Provide an incorrect certification of the quantity or make any fraudulent representation for loan, or
* * * * *

(2) When signing Form CCC–666 LDP, Loan Deficiency Payment Application and Certification, or CCC–709, Direct Loan Deficiency Payment Agreement, as applicable, that the producer will not provide an incorrect certification of the quantity or make any fraudulent representation for loan deficiency payment purposes.

(3) That violation of the terms and conditions of the Form CCC–677, Form CCC–678, Form CCC–666 LDP, or Form CCC–709, as applicable, will cause harm or damage to CCC in that funds may be disbursed to the producer for a quantity of a commodity which is not actually in existence or for a quantity on which the producer is not eligible.

(b) * * *

(1) Incorrect certification is the certifying of a quantity of a commodity for the purpose of obtaining a commodity loan or a loan deficiency payment in excess of the quantity eligible for such loan or loan deficiency payment or the making of any fraudulent representation with respect to obtaining loans or loan deficiency payments.

(2) Unauthorized removal is the movement of any farm-stored loan quantity from the storage structure in which the commodity was stored or structures which were designated when the loan was approved to any other storage structure whether or not such structure is located on the producer's farm without prior written authorization from the county committee in accordance with § 1421.20, if the movement of loan collateral prevents CCC from obtaining the first lien on such collateral.
* * * * *

(c) The producer and CCC agree that it will be difficult, if not impossible, to prove the amount of damages to CCC for the violations in accordance with paragraph (b) of this section. Accordingly, if the county committee determines that the producer has violated the terms and conditions of Form CCC–677, Form CCC–678, Form CCC–666 LDP, or Form CCC–709, as applicable, liquidated damages shall be assessed on the quantity of the commodity which is involved in the violation. If CCC determines the producer:

(1) Acted in good faith when the violation occurred, liquidated damages will be assessed by multiplying the quantity involved in the violation by:

(i) 10 percent of the loan rate applicable to the loan note or the loan deficiency payment rate for the first offense; or

(ii) 25 percent of the loan rate applicable to the loan note or the loan deficiency payment rate for the second offense; or

(2) Did not act in good faith with regard to the violation, or for cases other than the first or second offense, liquidated damages will be assessed by multiplying the quantity involved in the violation by 25 percent of the loan rate applicable to the loan note or the loan deficiency payment rate.

(d) For liquidated damages assessed in accordance with paragraph (c)(1) of this section, the county committee shall:
* * * * *

(2) If the producer fails to pay such amount within 30 days from the date of notification, call the applicable loan involved in the violation, or for loan deficiency payments, require repayment of the entire loan deficiency payment and charges plus interest.

(e) For liquidated damages assessed in accordance with paragraph (c)(2) of this section, the county committee shall call the loan involved in the violation, or for loan deficiency payments, require repayment of the entire loan deficiency payment and charges plus interest.
* * * * *

(k) (1) * * *
(ii) * * *

(C) All other costs which CCC would not have incurred but for the fraudulent representation, the unauthorized disposition or movement of the loan collateral;

(D) Interest on such amounts;

(E) Liquidated damages assessed under paragraph (c) of this section; and

(1) With regard to amounts due for a loan, the payment of such amounts may not be satisfied by the forfeiture of loan collateral to CCC of commodities with a settlement value that is less than the total of such amounts; or

(2) By repayment of such loan at the lower loan repayment rate as prescribed in § 1421.25 and may not utilize the provisions of part 1470 of this chapter with respect to such loans.
* * * * *

(l)(1) * * *

(ii) All other costs which CCC would not have incurred but for the producer's fraudulent representation;

(iii) Interest which has accrued with respect to such amounts; and

(iv) Liquidated damages assessed under paragraph (c) of this section.
* * * * *

(q) Any or all of the liquidated damages assessed in accordance with the provisions of paragraph (c) of this section may be waived as determined by CCC.

12. Section 1421.17 is amended by revising paragraphs (a), (c)(1), (c)(3), and (e) to read as follows:

§ 1421.17 Farm-stored commodities.

(a) The quantity of a commodity which shall be used to determine the amount of a farm-stored loan shall not exceed a percentage (the "loan percentage"), as established by the State committee which shall not exceed a percentage established by CCC, of the certified or measured quantity of the eligible commodity stored in approved farm storage and covered by the note and security agreement. The quantity of a commodity pledged as security for a farm-storage loan shall be measured or certified in accordance with paragraph (e) of this section. Farm-stored loans

may be made on less than the maximum quantity eligible for loan at the producer's request. If the loan quantity is reduced by the State committee, the county committee, or by request of the producer, such reduced quantity shall be the mortgaged quantity on the note and security agreement for the commodity in a bin, crib, or lot on which the loan is made.

* * * * *

(c) * * *

(1) Liquidation of the farm-stored loan or part thereof shall be made through the pledge of warehouse receipts for the commodity placed under warehouse-stored loan and the immediate payment by the producer of the amount by which the warehouse-stored loan is less than the farm-stored loan or part thereof and charges plus interest. The loan quantity for the warehouse-stored loan cannot exceed 110 percent of the loan quantity transferred from the farm-stored loan.

* * * * *

(3) For loans extended in accordance with §§ 1421.200 through 1421.217, CCC may limit the quantity for a warehouse-stored loan to the quantity approved on the farmer owned reserve agreement loan.

* * * * *

(e) The quantity of a commodity pledged as security for a farm-stored loan or for which a loan deficiency payment is requested may be determined on the basis of the quantity of the commodity which an eligible producer certifies in writing on Form CCC–666 for a loan and Form CCC–666 LDP or CCC–709, as applicable, for a loan deficiency payment, is eligible to be pledged as collateral and is otherwise available for loan or loan deficiency payment purposes.

* * * * *

13. Section 1421.18 is amended by revising paragraphs (b)(12)(iv)(B), (b)(13)(iv)(D), (b)(13)(iv)(D)(5), and (b)(15)(ii)(G) to read as follows:

§ 1421.18 Warehouse-stored loans.

* * * * *

(b) * * *

(12) * * *

(iv) * * *

(B) For distinctly green seeds, 1.5 percent;

* * * * *

(13) * * *

(iv) * * *

(D) For admixtures:

* * * * *

(5) For inconspicuous admixtures, 5.0 percent;

* * * * *

(15) * * *

(ii) * * *

(G) The sunflower seed gross weight must be adjusted downward to reflect undersized seed, passing through a 14/64" round hole screen, dockage, and for the presence of any admixtures.

14. Section 1421.19 is amended by revising paragraph (b) to read as follows:

§ 1421.19 Liquidation of loans.

* * * * *

(b) If the producer desires to deliver eligible commodities to CCC in satisfaction of the loan, the producer must notify CCC of such intention before the loan maturity date by giving written notice to the county office which disbursed the proceeds for such loan. If the producer fails to deliver such commodities to CCC by the date specified on Form CCC–691, Commodity Delivery Notice, and the producer subsequently redeems the commodity pledged as collateral for the loan before delivery is completed, interest shall continue to be assessed on such amount in accordance with part 1405 of this chapter.

* * * * *

15. Section 1421.20 is amended by:

A. Revising paragraph (a)(2), and

B. Adding paragraph (e) to read as follows:

§ 1421.20 Release of the commodity pledged as collateral for a loan.

(a) * * *

(2) If CCC so announces, an amount less than the principal amount of the loan and charges plus interest under the terms and conditions specified by CCC at the time the producer redeems the commodity pledged as collateral for such loan in accordance with § 1421.25. The producer may request and CCC may approve removal of a quantity of the commodity from storage, without the payment of CCC of the loan amount, if the principal amount outstanding on such loan before such removal does not exceed the maximum loan value of the quantity of the commodity remaining in storage after such removal. When the proceeds of the sale of the commodity are needed to repay all or a part of a farm-stored loan, the producer must request and obtain prior written approval of the county office on a form prescribed by CCC in order to remove a specified quantity of the commodity from storage. Any such approval shall be subject to the terms and conditions set forth in the applicable form, copies of which may be obtained by producers at the county office. Any such approval shall not constitute a release of CCC's security interest in the commodity or release the producer from liability for any amounts due and owing to CCC with respect to the loan indebtedness if full payment of such amounts is not received by the county office. If a producer fails to repay a loan within the time period prescribed by CCC for a farm-storage loan and commodity pledged as loan collateral has been delivered to a buyer in accordance with Form CCC–681–1, Authorization for Delivery of Loan Collateral for Sale, such producer may not repay the loan at the level that is less than the loan level determined in accordance with § 1421.25(a)(1)(ii), (b)(2), or (d)(2).

* * * * *

(e) If the commodity is moved on a nonworkday from storage without obtaining prior approval to move such commodity, such removal shall constitute unauthorized removal or disposition, as applicable, of such commodity unless the producer notifies the county office the next workday that such commodity has been moved and such movement is approved by CCC.

16. Section 1421.22 is amended by:

A. Revising paragraphs (c)(3)(i)(A) and (c)(4), and

B. Adding paragraphs (e), (f), (g), (h), and (i) to read as follows:

§ 1421.22 Settlement.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) $2 per ton, net weight, for each full 1 percent of foreign material in excess of 15 percent; and

* * * * *

(4) With respect to rice acquired by CCC at a location other than an approved warehouse, settlement shall be made on the basis of the class, grade, and quality entries set forth in the Federal-State inspection certificate and on the basis of the quantity set forth in the weight certificates.

* * * * *

(e) When a producer is directed by the county office to haul the commodity for a loan, except aromatic rice, a greater distance than would have been necessary to make delivery to the producer's customary delivery point, as determined by CCC, the producer will be allowed compensation, as determined by the State committee at a rate not to exceed the common carrier truck rate or the rate available from local truckers, for hauling the eligible commodity the additional distance. In determining the rate of payment for excess hauling, the State committee may establish reasonable mileage minimums below which producers will not receive compensation for hauling.

(f) (1) Producers may request trackloading for loan collateral where

approved warehouse space is not available locally or where KCCO determines that it would be to the benefit of CCC. Where local weighing facilities are not available or when requested by producers, destination weights may be used for settlement purposes. All producers loading in the same car must sign an agreement stating the percentage share of the total quantity to be credited to each. When requested by producers prior to delivery of the commodity, settlement may be made on the basis of destination grades. Such destination grade determination for a car shall be applied to the entire quantity of a commodity loaded into the same car, regardless of the grade or quality of a commodity loaded into the car by any producer.

(2) A trackloading payment of 19 cents per bushel (or 31.66 cents per hundredweight in the case of sorghum, oilseeds, and rice, excluding aromatic rice) shall be made to the producer on an eligible commodity delivered to CCC under this subsection.

(g) If a farm-stored commodity is delivered in advance of the applicable loan maturity date as provided in §§ 1421.19 and 1421.21, a deduction for storage charges shall be made. The deduction shall be made for the period from the date of delivery to the applicable maturity date or expiration date for the commodity. Such deduction shall be at the rate charged by the warehouse to which the commodity was delivered. No deduction for storage charges shall be made for early delivery of a farm-stored commodity if the loan maturity date is accelerated by CCC under a general acceleration of the maturity date in a particular area.

(h) A refund of warehouse storage charges will be made by CCC to the producer if the maturity date of a warehouse storage loan is accelerated by CCC for reasons other than any wrongful act or omission on the part of the producer, and the commodity is not redeemed. The amount of the storage charges to be refunded shall be computed at the lesser of the UGSA rate or the rate prepaid by the producer for the period of unearned storage.

(i) If a warehouse charges the producer for either the receiving charges or the receiving and loading out charges on an eligible commodity in an approved warehouse, the producer shall, upon delivery to CCC of warehouse receipts representing the commodity stored in such warehouse, be reimbursed or given credit by the county office for such prepaid charges at the lesser of the UGSA rate or the rate prepaid by the producer. The producer must furnish to the county office, written evidence signed by the warehouse operator that such charges have been paid.

17. Section 1421.29 is amended by:

A. Revising paragraphs (b)(3), (c), and (g) to read as follows,

B. Removing paragraph (h), and

C. Redesignating paragraph (i) as paragraph (h).

§ 1421.29 Loan deficiency payments.

* * * * *

(b) * * *

(3) File and request payment on Form CCC–666 LDP, unless the producer enters into an agreement according to paragraph (h) of this section, for a quantity of an eligible commodity;

* * * * *

(c) The loan deficiency payment rate for a crop shall be the amount by which the price support loan level for the crop exceeds the level at which CCC has announced that producers may repay their price support loans in accordance with § 1421.25. Such rate shall be the amount determined on the day the producer submits a completed request for a loan deficiency payment to the county office. When such request is for rice and the request provides that the loan deficiency payment rate shall be based on the date of delivery, and the documentation of delivery indicates the rice was delivered after 3 p.m. eastern time, the loan deficiency payment rate in effect after 3 p.m. eastern time of the delivery date shall be used. In all other cases for rice where the loan deficiency payment rate is based on the delivery date, the payment rate in effect at 12:00:01 a.m. eastern time of the delivery date shall be used.

* * * * *

(g) Notwithstanding any other provision of this section, on the day of the announcement of the adjusted world price, applications for loan deficiency payments for rice that specify the payment rate will not be accepted between 2 p.m. eastern time and the time of the world price announcement.

* * * * *

18. Section 1421.202 is revised to read as follows:

§ 1421.202 Length of reserve agreements.

The length of a FOR loan shall be 27 months from the maturity date of the regular price support loan. The day following the maturity date of the regular price support loan shall be the effective date of the FOR loan agreement. In order to assure that producers throughout the United States are treated in a fair and equitable manner, CCC may allow extensions of regular price support loans for wheat, corn, grain sorghum, oats, and barley which expire in or before the month following the month of the date for such commodity as specified in § 1421.201(b). The terms and conditions of such extension shall be provided through actual notice to affected producers. FOR agreements may be extended by CCC, at CCC's sole discretion, at maturity for an additional six months.

19. Section 1421.205 is amended by revising paragraph (a) introductory text and revising paragraphs (a)(2) and (b) to read as follows:

§ 1421.205 Quantity eligible for grain reserve loans.

(a) Farm-stored FOR loans shall be approved on a quantity not to exceed the lesser of:

* * * * *

(2) The quantity upon which the disbursement of the regular price support loan was based.

(b) Warehouse-stored FOR loans shall be approved on a quantity not to exceed the quantity shown on the warehouse receipt or the supplemental certificate, if applicable, which secured the regular price support loan.

20. Section 1421.206 is amended by revising paragraph (b) to read as follows:

§ 1421.206 Quality eligibility requirements of FOR loans.

* * * * *

(b) Grain which is pledged as collateral for a FOR loan must meet the quality eligibility requirements for securing a regular price support loan.

* * * * *

21. Section 1421.207 is amended by revising paragraphs (b)(1), (b)(2)(i), and (b)(2)(iii) to read as follows:

§ 1421.207 Storage rates.

* * * * *

(b) (1) Storage payments shall be paid quarterly, starting from the effective date of the FOR loan. Such payments shall be paid within 30 days after the end of each quarter in which such payments are earned. Storage payments shall not be earned when the grain which was pledged as collateral for the FOR loan is not in storage, as determined by CCC. Storage payments shall not be earned when the 5-day adjusted market price determined in accordance with § 1421.209(e) equals or exceeds 95 percent of the current year's established price for the commodity. In such instance, no storage payments shall be earned from the day the 5-day adjusted market price was equal to or exceeded 95 percent of such established price through the ninetieth day following the last day on which the 5-

day adjusted market price equalled or exceeded 95 percent of such established price.

(2) * * *

(i) A FOR agreement shall not be approved until the producer provides written evidence to CCC that at least the next year's storage, including any storage deduction applicable to the regular loan, has been paid to the warehouse or arrangements for the payment of such storage have been made with the warehouse on the FOR loan quantity.

* * * * *

(iii) The eighth quarterly storage payment shall not be made until the producer provides written evidence to CCC that storage has been paid to the warehouse or arrangements for the payment of such storage have been made with the warehouse on the FOR quantity through the FOR loan maturity date.

* * * * *

22. Section 1421.208 is revised to read as follows:

§ 1421.208 Charging interest.

FOR loans shall not accrue interest unless CCC determines that the 5-day adjusted market price determined in accordance with § 1421.209(e) for the commodity is equal to or exceeds 105 percent of the current year's established price for such commodity. In such instance, interest shall accrue from the day the 5-day adjusted market price was equal to or exceeded 105 percent of such established price and continue to accrue for the balance of the month following the last day on which the 5-day adjusted market price equaled or exceeded 105 percent of such established price through the two succeeding months. The rate of interest which shall be applicable to a FOR loan during an interest-accruing period shall be the rate applicable to the regular price support loan as determined in accordance with part 1405 of this chapter.

23. Section 1421.210 is amended by revising paragraphs (a), (b)(2), (b)(4) introductory text, (b)(4)(ii), (b)(5)(i), (b)(5)(ii), (b)(5)(iv), (c)(1) introductory text, (c)(2), (c)(3), (c)(4), and (c)(5) to read as follows:

§ 1421.210 Commingling and replacement of wheat and feed grains.

(a) In the case of farm-stored FOR loans, if an eligible quantity of a commodity has been commingled with an ineligible quantity of the commodity, the commingled commodity is not eligible to be pledged as collateral for a FOR loan unless the provisions in § 1421.17 (b)(1) or (b)(2) are met.

(b) * * *

(2) Grain which is used to replace existing FOR loan collateral must have been produced by the producer and be eligible to be pledged as collateral for a regular price support loan, except that compliance with the terms and conditions of any commodity program conducted in accordance with part 1413 of this chapter on the farm on which such replacement grain was produced is not required. Replacement loan collateral may be grain from the crop which is harvested after the date established by the State committee in accordance with paragraph (b)(1) of this section or be grain from a producer's existing stocks in CCC-approved farm storage. This grain must not have been purchased and must be free of any liens or encumbrances unless waivers that fully protect the interest of CCC are obtained. With respect to wheat, such replacement grain must be of the same class as the regular price support loan collateral.

* * * * *

(4) To protect the interest of CCC in the quantity of collateral to be released for replacement in accordance with paragraph (c)(1)(i) or (c)(1)(iii) of this section, the county committee may require producers to remit payments to the CCC before a request to replace FOR loan collateral is approved. In such cases, the amount to be remitted shall be the smaller of:

* * * * *

(ii) The product of the market price available in the county office on the date that the replacement request was made, times the quantity to be replaced, as determined by CCC.

(5) * * *

(i) The principal amount of the FOR loan and other charges plus interest from the disbursement date of such amount;

(ii) Storage payments made in accordance with the loan from the date the request for replacement was approved for CCC to the disbursement date of such payments;

* * * * *

(iv) Liquidated damages computed by multiplying the quantity not replaced by 25 percent of the loan rate applicable to the loan note.

(c) (1) A producer who files a Form CCC–687–1 or CCC–681 requesting the approval to replace existing FOR loan collateral may after approval of the request:

* * * * *

(2) A producer who delivers grain to a CCC-approved warehouse in accordance with paragraph (c)(1) of this section shall cause to be delivered to CCC a warehouse receipt issued in the name of CCC with respect to such grain. The warehouse receipt shall show that storage charges have been paid or otherwise provided for through the final date specified to complete the replacement, and CCC shall retain control of the receipt until the producer has replaced the original FOR loan collateral with eligible replacement grain. Except as provided in paragraph (b)(3) of this section, if the producer fails to replace the grain within the approved replacement period, CCC shall take title to the warehouse receipt without any further action by the producer and shall determine the value of the grain represented by the receipt. This value shall be determined in accordance with § 1421.22 and shall be credited to the amount owed by the producer as determined in accordance with paragraph (b)(5) of this section.

(3) A producer who, in accordance with paragraph (c)(1) of this section, sells the grain which is the collateral for the FOR loan shall only sell such grain to the person specified on Form CCC–681. Storage payments shall not be earned on the quantity rotated, as determined by CCC, from the date the rotation request is approved until the replacement stocks are in place. To protect the interest of CCC in the quantity of collateral to be released for replacement, the county committee may require the purchaser to make and remit to CCC a check for the full amount of the purchase. In such instances, CCC shall make these funds available to the producer upon the replacement of the original FOR loan collateral with eligible replacement grain if such replacement occurs prior to the final date of the approved replacement period. Except as provided in paragraph (b)(3) of this section, if the producer fails to replace the grain by this date, the producer shall forfeit the sales proceeds to CCC without any further action by the producer. Such sales proceeds shall be credited to the amount owed by the producer as determined in accordance with paragraph (b)(5) of this section.

(4) A producer who, in accordance with paragraph (c)(1) of this section, intends to feed such grain to the producer's own livestock, may only feed the quantity of grain which was approved by the county committee for such purposes. The producer must certify to the quantity the producer intends to use for feed during the approved rotation period. Storage payments shall not be earned on the quantity rotated, as determined by CCC, from the date the rotation request is approved until the replacement stocks

are in place in CCC-approved farm storage.

(5) Any producer who files a Form CCC–687–1 or CCC–681 with the county committee shall not remove the existing FOR loan collateral until written approval has been made by the county committee. The producer shall allow a representative of the county committee to inspect and measure, at the producer's expense, the quantity of replacement grain when such replacement stocks are in place in CCC-approved farm storage. Producers who request approval to replace existing FOR loan collateral with existing stocks in CCC-approved farm storage shall not receive approval to remove the existing FOR loan collateral until the replacement stocks have been inspected and measured.

24. Section 1421.211 is revised to read as follows:

§ 1421.211 Redemption requirements and emergency call.

(a) A producer may redeem the commodity pledged as collateral for a FOR loan at any time by repaying the principal amount of the FOR loan and other charges plus interest as provided in this part or, if CCC so announces, an amount less than the principal amount of the FOR loan and other charges plus interest in accordance with § 1421.25(d)(2).

(b) Notwithstanding any other provision of this part, the Secretary may require producers to repay FOR loans prior to the maturity date of such loans if the Secretary determines that emergency conditions exist which require that the commodity which is serving as collateral for the FOR loan be made available in the market to meet urgent domestic or international needs and such determination and the reasons therefore are reported to the President, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committee on Agriculture of the House of Representatives at least fourteen days before taking such action. Repayment shall consist of the amount in accordance with paragraph (a) of this section. If the called loan is not redeemed within the time prescribed by the Secretary, CCC may take title to the commodity without any further action by the producer.

25. Section 1421.215 is revised to read as follows:

§ 1421.215 Loss or damage to the commodity.

The producer is responsible for any and all loss in quantity or quality of the commodity pledged for a FOR loan. CCC shall not assume any loss in quantity or quality of the FOR farm-stored loan collateral.

26. Section 1421.320 is amended by revising paragraphs (a) and (c)(2) to read as follows:

§ 1421.320 General provisions.

(a) This subpart sets out the terms and conditions under which the CCC shall make payments to eligible persons who have entered into an agreement with CCC to participate in the rice marketing certificate program.

* * * * *

(c) * * *

(2) With respect to eligible rice which has not been and will not be pledged as collateral for a price support loan received a loan deficiency payment in accordance with § 1421.29.

27. Section 1421.321 is amended by revising introductory text to read as follows:

§ 1421.321 Eligible persons.

For the purposes of this subpart, the following persons shall be considered to be eligible to enter into an agreement with CCC and to receive payment in accordance with this subpart:

* * * * *

28. Section 1421.323 is revised to read as follows:

§ 1421.323 Rice marketing certificate payments.

(a) Payments in accordance with this subpart shall be made available to eligible persons who have complied with the terms and conditions set forth in this subpart and who have entered into an agreement with CCC.

(b) Payments in accordance with this subpart shall be made when the producer receives a loan deficiency payment in accordance with § 1421.29 or when the producer repays a loan in accordance with § 1421.25.

29. Section 1421.324 is revised to read as follows:

§ 1421.324 Payment rate.

The payment rate for the purposes of calculating payments made available in accordance with this subpart shall be based upon the difference between the adjusted world price for the class of rice and the loan repayment level in effect for the loan deficiency payment or loan repayment.

Signed in Washington, DC, on June 27, 1994.

Bruce R. Weber,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 94–16111 Filed 7–1–94; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Rural Electrification Administration

7 CFR Part 1755

RIN 0572–AA57

Specification for Filled Fiber Optic Cables

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

SUMMARY: The Rural Electrification Administration (REA) amends its regulations on Telecommunications Standards and Specifications for Materials, Equipment and Construction by rescinding REA Bulletin 345–90, REA Specification for Totally Filled Fiber Optic Cable, PE–90, and codifying the revised specification. The revised specification: Allows the use of dispersion-shifted single mode fibers; allows use of 62.5/125 micrometer multimode fibers; includes a section on self-supporting aerial fiber optic cable; and establishes end product requirements associated with the options stated above. This revised specification updates the end product performance requirements of filled fiber optic cables brought about through technological advancements made during the last seven years.

DATES: *Effective date:* August 4, 1994.

Incorporation by reference: Incorporation by reference of certain publications listed in this final rule is approved by the Director of the Federal Register as of August 4, 1994.

FOR FURTHER INFORMATION CONTACT: Garnett G. Adams, Chief, Outside Plant Branch, Telecommunications Standards Division, Rural Electrification Administration, room 2844, South Building, U.S. Department of Agriculture, Washington, DC 20250–1500, telephone number (202) 720–0667.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule is issued in conformance with Executive Order 12866.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. If adopted, this final rule will not:

(1) Preempt any State or local laws, regulations, or policies;

(2) Have any retroactive effect; and

(3) Require administrative proceedings before parties may file suit challenging the provisions of this rule

Regulatory Flexibility Act Certification

The Administrator of REA has determined that this final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. *et seq.*). This final rule involves standards and specifications, which may increase the direct short-term costs to the REA borrower. However, the long-term direct economic costs are reduced through greater durability and lower maintenance cost over time.

Information Collection and Recordkeeping Requirements

In compliance with the Office of Management and Budget (OMB) regulations (5 CFR Part 1320) which implements the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and section 3504 of that Act, information collection and recordkeeping requirements contained in this final rule have been submitted to OMB for approval. Comments concerning these requirements should be directed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USDA, room 3201, New Executive Office Building (NEOB), Washington, DC 20503. When OMB has approved the information and recordkeeping requirement contained in this final rule, REA will publish an amendment to this final rule to add the OMB control number and statement to the regulatory text.

National Environmental Policy Act Certification

The Administrator of REA has determined that this final rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

Catalog of Federal Domestic Assistance

The program described by this final rule is listed in the Catalog of Federal Domestic Assistance programs under No. 10.851, Rural Telephone Loans and Loan Guarantees; and No. 10.852, Rural Telephone Bank Loans. This catalog is available on a subscription basis from the Superintendent of Documents, United States Government Printing Office, Washington, DC 20402.

Executive Order 12372

This final rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. A Notice of Final rule titled Department Programs and Activities Excluded from Executive Order 12372 (50 FR 47034) exempts REA and RTB loans and loan guarantees, and RTB bank loans, to governmental and nongovernmental entities from coverage under this Order.

Background

REA issues publications titled "Bulletin" which serve to guide borrowers regarding already codified policy, procedures, and requirements needed to manage loans, loan guarantee programs, and the security instruments which provide for and secure REA financing. REA issues standards and specifications for the construction of telephone facilities financed with REA Loan Funds. REA is rescinding Bulletin 345–90, "REA Specification for Totally Filled Fiber Optic Cable, PE–90," and codifying this specification at 7 CFR 1755.900, REA Specification for Filled Fiber Optic Cables.

Filled fiber optic cable is used in outside plant by REA telephone borrowers as a physical transport medium for voice and data. The current REA Specification PE–90 limits the type of single mode fiber to dispersion-unshifted. The limitation was established because REA borrowers' lightwave systems operate at the 1310 nanometer wavelength for which the dispersion-unshifted fiber is optimally designed. The dispersion-unshifted single mode fiber can also be used in lightwave systems operating at the 1550 nanometer wavelength window but with a degradation in signal transmission. To provide REA borrowers with a quality fiber optic cable to be used in lightwave systems operating at 1550 nanometers without signal degradation, the revised specification will include single mode dispersion-shifted fiber as an option to single mode dispersion-unshifted fiber.

The current REA Specification PE–90 limits multimode fiber to 50/125 micrometers because at the time the specification was written, it was the only diameter multimode fiber in existence. Since that time the fiber optic industry has developed several multimode fiber designs of which the 62.5/125 micrometer design has become the de facto standard. Now that 62.5/125 micrometer multimode fiber is an accepted industry standard, the revised specification will include the 62.5/125 multimode fiber as an option to the 50/125 multimode fiber.

The current REA Specification PE–90 does not include a self-supporting aerial fiber optic cable because when the specification was written, no such cable design existed. Since issuance of the current specification, fiber optic cable manufacturers have developed such cable designs. These designs have been installed in operating telephone systems and are providing satisfactory field performance. The installation cost of self-supporting aerial fiber optic cable is less than the installation cost of lashed aerial fiber optic cable. To provide REA borrowers with a less costly aerial fiber optic cable installation, the revised specification will include a section on self-supporting aerial fiber optic cable.

The current specification includes only end product requirements associated with filled fiber optic cable utilizing only dispersion-unshifted single mode fibers and 50/125 micrometers multimode fibers and lashed aerial fiber optic cables. Since the revised specification will allow dispersion-shifted single mode fibers, 62.5/125 micrometers multimode fibers, and self-supporting aerial fiber optic cables, end product requirements have been included to assure quality products for these applications.

This action establishes REA requirements for a wider range of filled fiber optic cables without affecting current designs or manufacturing techniques. This widened selection of cables will afford REA telephone borrowers the opportunity to increase subscriber services in an economical and efficient manner through enhanced cable designs brought about by technological advancements made during the past seven years.

Comments

On September 1, 1993, REA published a proposed rule (58 FR 46097) to rescind REA Bulletin 345–90, REA Specification for Totally Filled Fiber Optic Cable, PE–90, and to codify the revised specification at 7 CFR 1755.900, REA Specification for Filled Fiber Optic Cables. Comments on this proposed rule were due by October 1, 1993. Comments and recommendations were received from several companies by this due date. The comments, recommendations, and responses are summarized as follows:

One respondent commented that the language in paragraphs (a)(1)(i) through (a)(1)(iv) of 7 CFR 1755.900 should be changed to reflect fiber optic cable designs currently being used by REA borrowers.

Response: REA reviewed the proposed language submitted by the commenter and as a result of our review will change the present language in paragraphs (a)(1)(i) through (a)(1)(iv) of 7 CFR 1755.900 to the language proposed by the commenter.

One respondent commented that the language "twenty-four colors" in paragraph (a)(2) of the specification should be changed to "twelve colors" because the Electronic Industries Association/Telecommunications Industries Association (EIA/TIA) 598 Standard, Color Coding of Fiber Optic Cables, defines twelve standard colors with black and yellow striping used to expand identification up to twenty-four colors.

Response: Since the EIA/TIA 598 Standard allows for identification of twenty-four fibers using a twenty-four color coding scheme that is identical to the twenty-four color coding scheme specified in 7 CFR 1755.900, REA will not change the language "twenty-four colors" to the commenter proposed language of "twelve colors."

Three respondents commented that the issue dates of the Electronic Industries Association (EIA) and the Electronic Industries Association/ Telecommunications Industries Association (EIA/TIA) Standards referenced in paragraphs (a)(8) and (a)(9) of the specification should be changed to reflect their current issue dates.

Response: REA agrees with the commenters recommendations and will change paragraphs (a)(8) and (a)(9) of the specification to reflect the current issue dates of the EIA and EIA/TIA Standards.

One respondent commented that the mode-field diameter requirement of 7.5±1.3 micrometers for dispersion-shifted single mode fibers specified in paragraph (b)(4) of the specification will eliminate the use of their currently manufactured dispersion-shifted single mode fiber by REA borrowers.

Response: Since it is not REA's intent to eliminate the use of dispersion-shifted single mode fibers which are currently manufactured and used on non-REA telecommunication systems with satisfactory results, REA will change the mode-field diameter requirement for dispersion-shifted single mode fibers from 7.5±1.3 micrometers to 7.5+1.5 micrometers/ −1.3 micrometers to allow use of the manufacturer's dispersion-shifted single mode fiber by REA borrowers.

Two commenters recommended that paragraph (b)(14) of the specification which requires that all optical fibers in any single length of cable of the same type be eliminated from the specification because it would deny REA borrowers the opportunity of purchasing hybrid cables which contain both single mode and multimode fibers.

Response: In reviewing past REA 515 Contracts containing fiber optic cables, REA borrowers never purchased hybrid cables containing both single mode and multimode optical fibers. Review of current REA 515 Contracts reveal that REA borrowers are still not purchasing these hybrid fiber optic cables. In fact REA borrowers only purchase single mode fiber optic cables. Since there is no current interest by REA borrowers in purchasing hybrid cables containing both single mode and multimode optical fibers, REA at this time will not eliminate paragraph (b)(14) from the specification as recommended by the commenters.

Two respondents commented on the shrinkback test to be performed on both loose tube and tight tube buffers. The first respondent indicated that tight tube buffers containing the optical fibers cannot meet criterion specified in the specification. The second respondent recommended that the shrinkback test be eliminated from the specification because they consider this test to be a cable component test and not a completed cable performance test.

Response: In regard to the first commenter's comment, REA has no data from other manufacturers indicating that tight tube buffers containing the optical fibers cannot comply with the shrinkback requirement of the specification. In addition the respondent did not provide test data as to what the requirement should be for tight tube buffers containing the optical fibers. Finally paragraph (c)(6) of the specification allows the manufacturer the option of removing the optical fibers from the tight tube buffers prior to performance of the shrinkback test. Since the respondent did not provide an alternative requirement and the fact that the specification allows for removal of the fibers from the buffer tubes prior to shrinkback testing, REA will not change the shrinkback requirement specified in the specification.

Regarding the second respondent's comment, REA considers the shrinkback test for loose and tight tube buffers to be a completed cable performance test because the shrinkback test provides REA with one means of assuring that the buffer tubes can withstand the rigors of the field cable splicing operation. Since REA considers the performance of the buffer tubes to be a critical requirement of the field cable splicing operation, REA will not eliminate the shrinkback test from the specification as recommended by the respondent.

One respondent recommended that the cold bend test for loose and tight tube buffers be eliminated from the specification because they consider this test to be a cable component test and not a completed cable performance test. The same respondent also recommended that if REA maintained the cold bend test that the mandrel diameter be changed from 5 times the tube diameter to 10 times the tube diameter.

Response: REA considers the cold bend test for loose and tight tube buffers to be a completed cable performance test because the cold bend test provides REA with one means of assuring that the buffer tubes can withstand the rigors of the field cable splicing operation. Since REA considers the performance of the buffer tubes to be a critical requirement of the field cable splicing operation, REA will not eliminate the cold bend test from the specification as recommended by the respondent.

In response to the commenter's recommendation for changing the size of the test mandrel diameter, REA would like to point out that mandrel diameter of 5 times the buffer tube diameter is the same mandrel diameter as specified in REA Bulletin 345–90. Since manufacturers have been performing the cold bend test using the mandrel diameter of 5 times the buffer tube diameter as specified in REA Bulletin 345–90 for more than seven years without any reported problems, REA will not change the mandrel diameter for the cold bend test specified in 7 CFR 1755.900 to the mandrel diameter recommended by the commenter.

Three respondents recommended that reference in paragraph (d)(2) of the specification for defining the color limits of the colored optical fibers be changed from EIA–359–A–1984 to EIA/TIA–598.

Response: The reason that REA referenced the EIA–359–A–1984 copper cable standard for defining the color limits of the colored optical fibers except for rose and aqua colors in 7 CFR 1755.900 is because at the time of its writing no EIA standard existed for defining the color limits for fiber optic cables. Since EIA has now published a color coding standard solely for fiber optic cables which includes the rose color, REA will change the reference in paragraph (d)(2) of 7 CFR 1755.900 from EIA–359–A–1984 to EIA/TIA–598.

Five respondents recommended that the color limits specified in paragraph (d)(2)(i) of the specification for rose be eliminated and the aqua limits be changed to the proposed EIA limits.

Response: The reason for specifying the rose and aqua color limits in 7 CFR 1755.900 was because the EIA–359–A–1984 standard did not contain limits for these colors. Since the EIA/TIA–598 Standard specifies the rose color limits, REA will eliminate the rose color limits

from paragraph (d)(2)(i) of 7 CFR 1755.900.

Regarding the aqua color limit, EIA/TIA–598 contains a color limit for aqua but the fiber optic cable industry is dissatisfied with the limits of the EIA/TIA standard. In fact EIA/TIA is revising the current standard to reflect the new aqua limits being proposed by the industry. Therefore to assure that the aqua color limits of 7 CFR 1755.900 will coincide with the proposed aqua limits of the revised EIA/TIA–598 Standard, REA will change the aqua limits currently specified in 7 CFR 1755.900 to the aqua color limits proposed for incorporation into the revised EIA/TIA–598 Color Standard.

One respondent commented that paragraph (d)(2)(ii) of the specification which states that REA will not accept alternative coloring schemes which deviate from the color coding scheme specified in paragraph (d)(1) of 7 CFR 1755.900 be eliminated from the specification.

Response: The reason for this requirement is to provide REA borrowers with one color coding standard for identification of buffer tubes and optical fibers to facilitate the splicing of fiber optic cables in the field. If REA allowed alternative coloring schemes for identification of buffer tubes and optical fibers as recommended by the commenter, REA would be doing a disservice to our borrowers by negating the requirement's intended purpose of facilitating field splicing of fiber optic cables by REA borrowers. Since this requirement will facilitate the splicing of fiber optic cables in the field by REA borrowers, REA will not eliminate paragraph (d)(2)(ii) from the specification as recommended by the commenter.

Two respondents commented on the splicing of strength members as specified in paragraph (e)(4) of the specification. The first respondent recommended that the 1 kilometer splicing limitation for strength members be changed to 500 meters. The second respondent questioned the rationale for limiting the number of strength member splices.

Response: REA limits the number of strength member splices to 1 per kilometer in the completed cable to avoid strength member splices being in close proximity to one another which in the opinion of REA could lead to failure of the cable during installation as a result of splice breakage. Since REA borrowers have been installing fiber optic cables with the above strength member splice requirement for the past seven years without any reported installation failures, REA will not change the requirement specified in paragraph (e)(4) of 7 CFR 1755.900.

Two respondents commented that the language of paragraph (f)(3) should be modified to allow the cable manufacturer the option of using natural colored threads and tapes as core binders.

Response: REA has reviewed the suggested change in language and the reasons for the change in language presented by the commentators. Because REA agrees with the reasons for their suggested change in language, REA will modify the language in paragraph (f)(3) of the specification to allow manufacturers the option of providing natural colored threads and tapes as core binders.

One respondent commented that the language in paragraph (f)(4) of 7 CFR 1755.900 should be changed to better reflect the functional needs of fiber optic cables currently being used by REA borrowers.

Response: REA reviewed the reason for the proposed change in language submitted by the commenter and as a result of our review will change the present language in paragraph (f)(4) of 7 CFR 1755.900 to the language proposed by the commenter.

Two respondents commented on the core wrap section of 7 CFR 1755.900. The first commenter recommended that the core wrap section (paragraph (h) of the specification) be revised to more clearly indicate that the use of core wraps in the manufacture of fiber optic cable is an option. The second commenter recommended that the core wrap section be further modified to allow one or more core wraps in the manufacture of fiber optic cable.

Response: In regards to the first respondent's comment, REA has reviewed the present language of paragraph (h) and agrees with the respondent's comment that the core wrap section does not clearly indicate that the use of a core wrap in the manufacture of the cable is at the option of the manufacturer. Since REA agrees with the commenter's comment, REA will revise paragraph (h) of 7 CFR 1755.900 to clearly indicate that the use of a core wrap is at the option of the manufacturer.

Regarding the second respondent's comment, the latest issues of REA's copper cable specifications covered under 7 CFR 1755.390 and 7 CFR 1755.890 allow the use of multiple core wraps in manufacture of these type cables provided at the filling compound is applied between each core wrap layer. Since REA allows the use of multiple core wraps in the manufacture of copper cables, REA will also allow the use of multiple core wraps in the manufacture of fiber optic cables. Therefore paragraph (h) of 7 CFR 1755.900 will be modified to allow the use of multiple core wraps by fiber optic cable manufacturers. REA will also modify paragraph (h) to indicate that when multiple core wraps are used that the filling compound must be applied between each core wrap layer to prevent the ingress of water between each core wrap layer.

Two respondents commented that the testing of the inner jacket for fungus resistance as specified in paragraph (i)(3) of the specification should be eliminated because the polyethylene compounds used for the inner jackets are inherently resistant to fungus attack.

Response: The current REA Bulletin 345–90 allows fiber optic cable manufacturers the option of using any available material for producing inner jackets. To assure that these inner jacket materials would provide satisfactory field service, the bulletin required that they pass a fungus resistance test. Since 7 CFR 1755.900 now specifies that only polyethylene compounds can be used to produce inner jackets and REA knows that these compounds are inherently resistant to fungus attack, REA will eliminate the fungus resistance test, paragraph (i)(3), for inner jacket materials from 7 CFR 1755.900.

One respondent commented that paragraph (j)(2) of 7 CFR 1755.900 should be modified to indicate that a flooding compound is only required for armored cable and that jacket slip test reference in the paragraph be clarified to indicate that it only applies to flooded cable designs.

Response: In reviewing the present language of the flooding compound section, paragraphs (j)(1) through (j)(4), of 7 CFR 1755.900, paragraph (j)(1) clearly indicates that flooding compound applies only to armored fiber optic cable designs. Also the present language of the jacket slip test, paragraph (III)(3), Appendix A, clearly indicates that this test is only performed on flooded cable designs. Because the present language in both paragraphs clearly indicate the intent of the commenter's recommendation, REA will not revise paragraph (j)(2) of 7 CFR 1755.900 as recommended by the commenter.

One respondent commented that "water blocking tape" language of paragraph (j)(4) be changed to "water blocking material" to allow for the use of water blocking tapes or powders in lieu of a flooding compound.

Response: REA has allowed the use of water blocking tapes in place of flooding compounds in filled fiber optic cables

for several years with satisfactory field performance, but the use of water blocking powders in place of the flooding compound is a new application for fiber optic cables with limited field experience. Until fiber optic cables using water blocking powders as replacements for flooding compounds gain more field experience to assure reliable service, REA will not change the language in paragraph (j)(4) of 7 CFR 1755.900 to the language recommended by the commenter.

One respondent recommended that armor overlap be changed from 3.0 millimeters to either 1.8 millimeters or sufficient to meet the requirements of paragraph (q) of 7 CFR 1755.900.

Response: The reason 7 CFR 1755.900 specifies a minimum armor overlap of 3.0 millimeters is to assure proper forming of the armor overlap is achieved to avoid longitudinal splitting of the jacket during installation. Since REA is concerned that armor overlaps less than 3.0 millimeters can result in longitudinal splitting of the jacket during installation because of improper forming, REA will not change the present requirement of 3.0 millimeters to the recommended comments of the respondent.

One commenter recommended that reduction in thickness of the armoring material due either to corrugating or the application process be changed from 10 percent to 5 percent.

Response: REA would like to point out that the 10 percent requirement for the reduction in armor thickness is the same requirement as specified in REA Bulletin 345–90. Since manufacturers have been meeting the 10 percent armor reduction thickness requirement as specified in REA Bulletin 345–90 for more than seven years without any reported problems, REA will not change the 10 percent armor reduction thickness requirement in 7 CFR 1755.900 to the 5 percent armor reduction thickness requirement as recommended by the commenter.

Two respondents recommended changing the present language of paragraph (k)(6) to more clearly define the intent of the requirement.

Response: REA has reviewed the proposed language submitted by both commentators and agrees that their proposed language will more clearly define the intent of the requirement. Therefore, REA will change the present language of paragraph (k)(6) specified in 7 CFR 1755.900 to the proposed language recommended by the commenters.

One respondent recommended that paragraphs (k)(8), (k)(9), and (k)(10) of the specification be eliminated from the specification because they consider these tests to be cable component tests and not completed cable performance tests.

Response: REA considers the tests specified in paragraphs (k)(8), (k)(9), and (k)(10) of the specification to be completed cable performance tests because these tests provide REA with the means of assuring that the plastic coated steel armor of the cable will withstand the rigors of the installation as well as a means of assuring that the plastic coated steel armor of the cable will provide satisfactory service over the life of the completed cable. Since REA considers the performance of the plastic coated steel armor to be a critical requirement in the installation and service life of completed cables, REA will not eliminate paragraphs (k)(8), (k)(9), and (k)(10) from 7 CFR 1755.900 as recommended by the respondent.

One respondent recommended that paragraph (k)(10) of 7 CFR 1755.900 be modified to exclude from the 90 percent calculation the area of the armor under the strength members for cables containing embedded strength members in the outer jacket because these type cables can still pass the armor to jacket bond strength requirement specified in paragraph (k)(10) of the specification.

Response: A review of recent armor to jacket bond strength data for cables containing embedded strength members in the outer jacket when the area of the armor under the strength members is excluded from the 90 percent calculation revealed that these type cables can pass the requirement specified in paragraph (k)(10) of the specification without difficulty. Since test data indicate that these type cables can pass the armor to jacket bond strength requirement, REA will modify paragraph (k)(10) of 7 CFR 1755.900 to allow the exclusion of the area of the armor under the strength members for cables containing embedded strength members in the outer jacket from the 90 percent calculation.

One respondent recommended that low density polyethylene, low density ethylene copolymer, and linear low density polyethylene compounds not be allowed as outer jacket materials. The reason for their comment is that installation damage to the cable can occur as a result of the above materials becoming soft at the high temperatures experienced during hot summer weather.

Response: Low density polyethylene, low density ethylene copolymer, and linear low density polyethylene compounds have been used by REA as outer jacket materials for copper cables for over twenty years and for fiber optic cables for over seven years without any reported high temperature installation problems associated with hot summer weather. Since REA has never received complaints from borrowers installing cables using any one of the above compounds during hot summer weather, REA will not eliminate the use of low density polyethylene, low density ethylene copolymer, and linear low density polyethylene compounds as outer jacket materials from the specification as recommended by the commenter.

One respondent recommended that melt flow rate, environmental stress crack, and impact tests for jacketing materials be eliminated from the specification because they consider these tests to be cable component tests and not completed cable performance tests.

Response: REA considers the melt flow rate, environmental stress crack, and impact tests for jacketing materials to be completed cable performance tests because these tests provide REA with the means of assuring that the jacketing material of the cable will withstand the rigors of installation as well as a means of assuring that the jacketing material of the cable will provide satisfactory service over the life of the completed cable. Since REA considers the performance of jacket material to be a critical requirement in the installation and service life of completed cables, REA will not eliminate the melt flow rate, environmental stress crack, and impact tests for jacketing materials from 7 CFR 1755.900 as recommended by the respondent.

One commenter recommended replacing the ASTM D 4565–90a test method referenced for both jacket tensile strength/elongation and jacket shrinkback in 7 CFR 1755.900 with the EIA–455–89A test method for jacket tensile strength/elongation and the EIA–455–86 test method for jacket shrinkback because these test methods are the current fiber optic industry standards for these jacket properties.

Response: A review of the ASTM and EIA test methods for jacket tensile strength/elongation and jacket shrinkback properties indicates that the EIA test methods are more applicable for the testing of fiber optic cables than the ASTM test method. Since the EIA test methods are more applicable to the testing of fiber optic cables, REA will replace the reference to ASTM D 4565–90a in paragraphs (m)(5)(ii) and (m)(5)(iv) of 7 CFR 1755.900 with EIA–455–89A and EIA–455–86, respectively.

One respondent recommended that the minimum jacket thickness over the strength members for cables containing

embedded strength members in the outer jacket be changed from 0.5 millimeter to 0.9 millimeter.

Response: REA has accepted one manufacturer of fiber optic cable containing embedded strength members in the outer jacket using the 0.5 millimeter minimum jacket thickness over the embedded strength members. That manufacturer's cable has been used by REA borrowers for over four years without any reported field failures. Since REA has satisfactory field performance history on fiber optic cables with embedded strength members using the minimum 0.5 millimeter jacket thickness over the embedded strength members, REA will not change the 0.5 millimeter minimum jacket thickness specified in 7 CFR 1755.900 to the minimum jacket thickness recommended by the commenter.

One respondent recommended that the maximum tolerance limit for the web width of self-supporting cable be changed from +0.51 millimeters to +1.58 millimeters.

Response: The reason that the maximum tolerance limit for the web width of self-supporting cables is specified at +0.51 millimeters is to assure that the web of self-supporting cables can be slit by craftpersons during installation using existing slitting tools. Increasing the maximum web width tolerance to +1.58 millimeters as recommended by the commenter would require the development of special slitting tools to assure satisfactory installation of these thicker webbed self-supporting cables by craftpersons. Since it is not the intent of REA to burden craftpersons with special tools needed to install theses thicker webbed self-supporting cables, REA will not change the maximum tolerance limit for the web width of self-supporting cables specified in 7 CFR 1755.900 to the maximum tolerance limit recommended by the respondent.

One respondent recommended that the sheath slitting cord be made a mandatory component of the cable instead of an optional cable component.

Response: The reasons 7 CFR 1755.900 specifies that the sheath slitting cord is an optional component of the cable are because not all cable installers use the sheath slitting cord to open the cable jacket during installation and during extremely cold weather installation. The sheath slitting cord does not aid the installer in opening the cable jacket because of the stiffness of the jacket. Because of the above reasons, REA will not make the sheath slitting cord a mandatory cable component in 7 CFR 1755.900.

Two respondents commented that the language in paragraph (n)(2) of 7 CFR 1755.900 should be changed to better reflect the functional needs of fiber optic cables currently being used by REA borrowers and to quantify the sheath slitting cord requirement.

Response: REA reviewed the reasons for the proposed change in language submitted by the commentators and as a result of our review will change the present language in paragraph (n)(2) of 7 CFR 1755.900 to better reflect the functional needs of fiber optic cables currently being used by REA borrowers and to quantify the sheath slitting cord requirement.

One respondent recommended that the numbering sequence for re-marked cables be changed from 3,000 to 1,000.

Response: REA would like to point out that the 3,000 numbering sequence for re-marked cables specified in 7 CFR 1755.900 is the same numbering sequence for re-marked cables as specified in REA Bulletin 345–90. Since manufacturers have been using the 3,000 numbering sequence for re-marked cables as specified in REA Bulletin 345–90 for more than seven years without any reported problems, REA will not change the numbering sequence for re-marked cables specified in 7 CFR 1755.900 to the numbering sequence for re-marked cables recommended by the commenter.

One respondent recommended adding a new identification marking requirement to 7 CFR 1755.900 that requires a telephone handset symbol to be marked on the outer jacket of fiber optic cables intended for direct burial installation in accordance with Rule 350G of the 1993 National Electric Safety Code (NESC).

Response: Since the REA Form 515 Construction Contract requires that all types of construction comply with the safety requirements specified in the NESC, REA will change paragraph (o)(2) in 7 CFR 1755.900 to require that all direct buried fiber optic cables be marked with the telephone handset symbol in accordance with Rule 350G of the 1993 NESC. This change will cause existing paragraphs (o)(2) through (o)(11) to be renumbered as paragraphs (o)(3) through (o)(12) in 7 CFR 1755.900.

Two respondents commented on the attenuation requirements specified in paragraph (p)(1)(i) of 7 CFR 1755.900. The first respondent recommended deleting the reference to EIA/TIA–455–59 because this standard is used to determine point discontinuities and not attenuation. The second respondent recommended changing the attenuation values specified in 7 CFR 1755.900 for dispersion-unshifted and dispersion-shifted single mode optical fibers to 0.4 dB/km and 0.25 dB/km, respectively.

Response: With regard to the EIA/TIA–455–59 reference, REA agrees with the commenter and will eliminate the reference to EIA/TIA–455–59 in paragraph (p)(1)(i) of 7 CFR 1755.900.

In regard to the change in attenuation requirements, REA is satisfied that the 0.5 dB/km maximum attenuation requirement for both dispersion-unshifted and dispersion-shifted single mode optical fibers, although considered very loose when compared to other industry standards, will provide REA borrowers with satisfactory optical signal transmission. REA would also like to point out that the REA Form 515 Construction Contract allows REA borrowers the opportunity to specify lower attenuation values than the 0.5 dB/km maximum specification value for these type optical fibers and when such values are specified in the contract they must be met by the cable supplier to execute the contract.

Since REA is satisfied that 0.5 dB/km maximum attenuation for both dispersion-unshifted and dispersion-shifted single mode optical fibers will provide satisfactory optical transmission and the knowledge that REA borrowers can specify lower attenuation values than the specification value to successfully execute the REA Form 515 Construction Contract, REA will not change the attenuation values specified in 7 CFR 1755.900 to values recommended by the commenter.

One respondent recommended deleting the requirement to conduct attenuation measurements at the wavelength specified for the application as stated in paragraphs (p)(1)(iv) and (p)(2)(iii) of 7 CFR 1755.900. The reason for the respondent's recommendation is the possibility of REA borrowers specifying attenuation requirements at nonstandard wavelengths which would require the development of new test equipment. The development of this new equipment would in turn result in added cable costs.

Response: A review of past REA Form 515 Construction Contracts indicated that REA borrowers were specifying attenuation requirements at the accepted industry wavelengths of 850 and 1300 nanometers for multimode fibers, and 1310 and 1550 for single mode fibers. A review of present construction contracts also reveals that REA borrowers are still specifying attenuation requirements at the accepted industry wavelengths of 850 and 1300 nanometers for multimode fibers, and 1310 and 1550 for single mode fibers.

Since REA borrowers are specifying attenuation requirements at the industry accepted wavelengths and not at nonstandard wavelengths, the requirement to conduct attenuation measurements at the wavelength specified in paragraphs (p)(1)(iv) and (p)(2)(iii) of 7 CFR 1755.900 will not be deleted from the specification as recommended by the commenter.

One respondent commented that the dispersion and dispersion slope requirements of 2.7 ps/nm•km and 0.085 ps(nm²•km), respectively for dispersion-shifted single mode fibers specified in paragraph (p)(1)(vii) of the specification will eliminate the use of their currently manufactured dispersion shifted single mode fiber by REA borrowers.

Response: Since it is not REA's intent to eliminate the use of dispersion-shifted single mode fibers which are currently manufactured and used on non-REA telecommunication systems with satisfactory results, REA will change the dispersion and dispersion slope requirements for dispersion-shifted single mode fibers from 2.7 ps/nm•km and 0.085 ps(nm²•km), respectively to 3.5 ps/nm•km and 0.095 ps(nm²•km), respectively to allow use of the manufacturer's dispersion shifted single mode fiber by REA borrowers.

Three respondents recommended changing the 1250 nanometer cut-off wavelength for single mode fibers specified in paragraph (p)(1)(viii) of 7 CFR 1755.900 to the industry accepted wavelength of 1260 nanometers.

Response: If 7 CFR 1755.900 maintained the 1250 nanometer cut-off wavelength for single mode fibers, REA would force manufacturers to maintain two separate fiber optic cable inventories based solely on the different cut-off wavelength requirements. This in turn would result in higher fiber optic cable prices to REA borrowers. By changing the cut-off wavelength requirement for single mode fibers from 1250 nanometers to 1260 nanometers, REA would eliminate the need for manufacturers to maintain separate fiber optic cable inventories. This change would reduce fiber optic cable costs to REA borrowers. Therefore, REA will change the single mode fiber cut-off wavelength requirement in paragraph (p)(1)(viii) of 7 CFR 1755.900 from 1250 nanometers to 1260 nanometers.

One respondent commented on the mechanical requirements for multimode fiber optic cables specified in 7 CFR 1755.900. The first comment recommended deleting the mechanical requirements for multimode fiber optic cables specified in paragraphs (q)(1) through (q)(5) of the specification because they feel that the qualification of single mode fiber optic cable designs to the mechanical requirements are adequate to qualify multimode fiber optic cable designs. The second comment recommended that if REA retained the mechanical requirements for multimode fiber optic cables that the allowable change in attenuation be changed from a maximum of 0.030 dB to a maximum of 0.040 dB since this is the present de facto industry requirement for multimode optical fibers.

Response: In regards to the first comment, 7 CFR 1755.900 requires both multimode and single mode fiber optic cables to be tested for the mechanical properties specified in paragraphs (q)(1) through (q)(5) of the specification to assure that both cable types will withstand the rigors of field installation and provide satisfactory service over their useful lives. REA is of the opinion that both multimode and single mode fiber optic cable designs must be tested for the mechanical requirements specified in paragraphs (q)(1) through (q)(5) of the specification to assure REA borrowers that these designs will withstand the rigors of field installation and provide satisfactory performance over their useful service lives. Therefore, REA will not eliminate the mechanical requirements for multimode fiber optic cables specified in paragraphs (q)(1) through (q)(5) of 7 CFR 1755.900.

Regarding the second comment, since it is REA's intent to use de facto industry requirements; where applicable, REA will change the maximum allowable change in attenuation for multimode fiber optic cables from 0.30 dB to 0.40 dB in paragraphs (q)(1) through (q)(5) of 7 CFR 1755.900.

Two respondents recommended that mechanical testing specified in paragraphs (q)(1) through (q)(5) of 7 CFR 1755.900 for dispersion-unshifted single mode fiber optic cables be performed at only the 1550 nanometer wavelength in place of the required testing at both 1310 and 1550 nanometer wavelengths. The reasons for their comments are based on the data indicating that testing of optical fibers at the 1550 nanometer wavelength is considered the worst case condition because the fibers are more sensitive to bends at this wavelength.

Response: 7 CFR 1755.900 requires mechanical testing of dispersion-unshifted single mode fiber optic cables at both the 1310 nanometer and 1550 nanometer wavelengths. The reason for the mechanical testing of dispersion-unshifted single mode fiber optic cables at both the 1310 and 1550 nanometer wavelengths is to assure satisfactory transmission of the optical signals at these wavelengths when specified by REA borrowers. Although REA agrees with the commentators comments, data from the REA Form 515 Construction Contracts indicate that the majority of lightwave systems installed by REA borrowers operate at the 1310 nanometer wavelength and not at the 1550 nanometer wavelength.

Since the majority of REA borrower lightwave systems operate at the 1310 nanometer wavelength, REA must require mechanical testing of dispersion-unshifted single mode fiber optic cables at the 1310 nanometer wavelength to assure that cables installed by REA borrowers with lightwave systems operating at the 1310 nanometer wavelength will provide satisfactory optical signal transmission. Therefore, REA will not eliminate the mechanical testing of dispersion-unshifted single mode fiber optic cables at the 1310 nanometer wavelength as recommended by the commenters.

One respondent recommended changing the cable bend test temperature of −46°C, Test Condition C of EIA/TIA–455–37A, specified in paragraph (q)(1)(iii) of 7 CFR 1755.900 to −30°C, Test Condition E of EIA/TIA–455–37A, because this is the de facto industry test temperature for fiber optic cables.

Response: Since it is REA's intent to use de facto industry requirements where applicable, REA will change the cable bend test temperature of −46°C, Test Condition C of EIA/TIA–455–37A, to −30°C, Test Condition E of EIA/TIA–455–37A, in paragraph (q)(1)(iii) of 7 CFR 1755.900.

Three respondents recommended replacing the cable bend test mandrel diameter of 15 times the cable diameter specified in paragraph (q)(1)(iii)(A) of 7 CFR 1755.900 with a test mandrel diameter of 20 times the cable diameter because this is the de facto industry requirement for fiber optic cables.

Response: Since it is REA's intent to use de facto industry requirements where applicable, REA will change the cable bend test mandrel diameter of 15 times the cable diameter to a test mandrel diameter of 20 times the cable diameter in paragraph (q)(1)(iii)(A) of 7 CFR 1755.900.

Two respondents recommending deleting the cable bend test requirement that the armor overlap be on the outside of the bend when bend testing armored cables in accordance with paragraph (q)(1)(iii)(C) of 7 CFR 1755.900.

Response: REA would like to point out that the cable bend test requirement stipulating that the armor overlap be on

the outside of the bend when bend testing armored cables specified in 7 CFR 1755.900 is the same requirement for armored cables as specified in REA Bulletin 345–90. Since manufacturers have been bend testing armored cables using this requirement in REA Bulletin 345–90 for more than seven years without any reported problems, REA will not delete the requirement that the armor overlap be on the outside of the bend when bend testing armored cables in 7 CFR 1755.900.

One respondent recommended that the requirement that there be no delamination of jacket bond after cable bend testing specified in paragraph (q)(1)(iv) of 7 CFR 1755.900 be deleted from the specification.

Response: REA would like to point out that the cable bend test requirement stipulating that there be no delamination of jacket bond after cable bend testing specified in 7 CFR 1755.900 is the same requirement as specified in REA Bulletin 345–90. Since manufacturers have been bend testing cables using this requirement in REA Bulletin 345–90 for more than seven years without any reported problems, REA will not delete the requirement that there be no delamination of jacket bond after cable bend testing in paragraph (q)(1)(iv) of 7 CFR 1755.900.

Two respondents commented on the cable compression test, paragraph (q)(3)(iii), of 7 CFR 1755.900. The first respondent recommended changing the rate for applying the compressive force from a nominal of 5 millimeters per minute to a range of 3 millimeters to 20 millimeters per minute to make the cable compression test of 7 CFR 1755.900 compatible with the de facto industry standard. The second respondent recommended changing holding time of the compressive force from 15 minutes to 10 minutes because the 10 minute requirement is the de facto industry requirement for fiber optic cables.

Response: Since it is REA's intent to use de facto industry requirements where applicable, REA will change the rate for applying the compressive force from a nominal of 5 millimeters per minute to a range of 3 millimeters to 20 millimeters per minute and will also change the holding time of the compressive force from 15 minutes to 10 minutes in paragraph (q)(3)(iii) of 7 CFR 1755.900.

Three respondents commented on the cable flex test requirements specified in paragraph (q)(5)(iv) of 7 CFR 1755.900. Two of the respondents recommended that a fracture length of no more than 5 millimeters be allowed on the armor after flexing since this is the de facto industry requirement for fiber optic cables. The third respondent recommended deleting the requirement that there be no delamination of jacket to armor bond in nonflooded cables after flex testing.

Response: 7 CFR 1755.900 requires that there be no visible evidence of fracture of the armor after flexing. Reason for the requirement is one means of assuring that continuity of the armor will be maintained after the rigors of installation. Maintaining the armor continuity after installation is important requirement in assuring protection of the telephone equipment and telephone company personnel against hazardous electrical currents. If REA allowed a minimum fracture length of the armor after flexing but before installation, the possibility exists that these small fracture lengths in the armor could develop into complete breaks of the armor at these fractured locations as a result of difficulties encountered during installation. These breaks in the armor would result in loss of armor continuity. The loss of armor continuity in turn would subject the telephone equipment and telephone company personnel to possible hazardous electrical currents which could result in damaged equipment or personal injury to telephone company personnel. Since REA has a responsibility to its borrowers to assure that their telephone equipment and personnel are protected against hazardous electrical currents, REA will not change the present requirement of no visible evidence of fracture of the armor after flexing specified in 7 CFR 1755.900 to the recommendation requested by the first two commenters.

In regard to the requirement that there be no delamination of jacket to armor bond in nonflooded cables after flex testing, REA specified this requirement on nonflooded cables to assure that the bond strength between the outer jacket and the plastic coated armor would be maintained after installation to assure that water could not enter nonflooded cables at the outer jacket/armor interface. If REA eliminated this requirement as recommended by the third commenter, voids at the outer jacket/armor interface could develop in nonflooded cables after installation. These voids could allow the entry of water into nonflooded cables resulting in possible degradation of the optical signal over time. Since REA has a responsibility to our borrowers to assure that optical signal of nonflooded cables will not degrade as a result of water entry, REA will not eliminate the requirement that there be no delamination of jacket to armor bond in nonflooded cables after flex testing as recommended by the third commenter.

Seven respondents recommended replacing Appendix A of 7 CFR 1755.900 with de facto industry tests to determine the long term stability of their fiber optic cables.

Response: The tests specified in Appendix A of 7 CFR 1755.900 have been used by REA for over sixteen years for determining the long term performance of copper cables with satisfactory results. Since these test have proven invaluable for determining the long term stability of copper cables, REA decided to apply these same proven tests to determine the long term stability of fiber optic cables. Therefore REA will not replace Appendix A with de facto industry tests as recommended by the commenters.

List of Subjects in 7 CFR Part 1755

Incorporation by reference, Loan programs—communications, Reporting and recordkeeping requirements, Rural areas, Telephone.

For the reasons set out in the preamble, REA amends chapter XVII of title 7 of the Code of Federal Regulations as follows:

PART 1755—TELECOMMUNICATIONS STANDARDS AND SPECIFICATIONS FOR MATERIALS, EQUIPMENT AND CONSTRUCTION.

1. The authority citation for part 1755 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.*, 1921 *et seq.*

§ 1755.97 [Amended]

2. Section 1755.97 is amended by removing the entry REA Bulletin 345–90 from the table.

3. Section 1755.900 is added to read as follows:

§ 1755.900 REA specification for filled fiber optic cables.

(a) *Scope.* (1) This section covers the requirement for filled fiber optic cables intended for aerial installation either by attachment to a support strand or by an integrated self-supporting arrangement, for underground application by placement in a duct, or for buried installations either by trenching or by direct plowing.

(i) The optical waveguides are glass fibers having directly-applied protective coatings, and are called "fibers", herein. These fibers may be assembled in either loose fiber bundles with a protective core tube, encased in several protective buffer tubes, or in tight buffer tubes.

(ii) Fillers, strength members, core wraps, and bedding tapes may complete the cable core.

(iii) The core or buffer tubes containing the fibers and the interstices between the buffer tubes, fillers, and strength members in the core structure are filled with a suitable material to exclude water.

(iv) The cable structure is completed by an extruded overall plastic jacket. This jacket may have strength members embedded in it, in some designs.

(v) Buried installation requires an armor under the outer jacket.

(vi) For self-supporting cable the outer jacket may be extruded over the support messenger and cable core.

(2) The cable is fully color coded so that each fiber is distinguishable from every other fiber. A basic color scheme of twenty-four colors allows individual fiber identification. Colored tubes, binders, threads, stripings, or markings provide fiber group identification.

(3) Cable manufactured to this section must demonstrate compliance with the qualification testing requirements to ensure satisfactory end-use performance characteristics for the intended applications.

(4) Optical cable designs not specifically addressed by this section may be allowed if accepted by REA. Justification for acceptance of a modified design must be provided to substantiate product utility and long term stability and endurance.

(5) All cables sold to REA borrowers for projects involving REA loan funds under this section must be accepted by REA Technical Standards Committee "A" (Telephone). For cables manufactured to the specification of this section, all design changes to an accepted design must be submitted for acceptance. REA will be the sole authority on what constitutes a design change.

(6) The American National Standard Institute/Institute of Electrical and Electronics Engineers, Inc (ANSI/IEEE), 1993 National Electrical Safety Code (NESC) referenced in this section is incorporated by reference by REA. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ANSI/IEEE 1993 NESC are available for inspection during normal business hours at REA, room 2845, U.S. Department of Agriculture, Washington, DC 20250–1500 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies are available from IEEE Service Center, 445 Hoes Lane, Piscataway, NJ 08854, telephone number 1 (800) 678–4333.

(7) American Society for Testing and Materials Specifications (ASTM) A 640–91, Standard Specification for Zinc-Coated Steel Strand for Messenger Support of Figure 8 Cable; ASTM B 736–92a, Standard Specification for Aluminum, Aluminum Alloy, and Aluminum-Clad Steel Cable Shielding Stock; ASTM D 1238–90b, Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer; ASTM D 1248–84 (1989), Standard Specification for Polyethylene Plastic Molding and Extrusion Materials, ASTM D 1535–89, Standard Test Method for Specifying Color by the Munsell System; ASTM D 3349–86, Standard Test Method for Absorption Coefficient of Carbon Black Pigmented Ethylene Plastic; ASTM D 4565–90a, Standard Test Methods for Physical and Environmental Performance Properties of Insulations and Jackets for Telecommunications Wire and Cable; ASTM D 4566–90, Standard Test Methods for Electrical Performance Properties of Insulations and Jackets for Telecommunications Wire and Cable; ASTM D 4568–86, Standard Test Methods for Evaluating Compatibility Between Cable Filling and Flooding Compounds and Polyolefin Cable Materials; and ASTM E 29–90, Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications, referenced in this section are incorporated by reference by REA. These incorporations by references were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ASTM standards are available for inspection during normal business hours at REA, room 2845, U.S. Department of Agriculture, Washington, DC 20250–1500 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies are available from ASTM, 1916 Race Street, Philadelphia, Pennsylvania 19103–1187, telephone number (215) 299–5585.

(8) Electronic Industries Association Standards (EIA)–455–20, Measurement of Change in Optical Transmittance; EIA–455–41, Compressive Loading Resistance of Fiber Optic Cables; EIA–455–86, Fiber Optic Cable Jacket Shrinkage; EIA–455–89A, Fiber Optic Cable Jacket Elongation And Tensile Strength; and EIA–455–174, Mode Field Diameter of Single-Mode Optical Fiber by Knife-Edge Scanning in the Far Field, referenced in this section are incorporated by reference by REA. These incorporations by references were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of EIA standards are available for inspection during normal business hours at REA, room 2845, U.S. Department of Agriculture, Washington, DC 20250–1500 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies are available from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, telephone number (303) 792–2181.

(9) Electronic Industries Association/Telecommunications Industries Association Standards (EIA/TIA)–455–25A, Repeated Impact Testing of Fiber Optic Cables and Cable Assemblies; EIA/TIA–455–30B, Frequency Domain Measurement of Multimode Optical Fiber Information Transmission Capacity; EIA/TIA–455–31B, Fiber Tensile Proof Test Method; EIA/TIA–455–37A, Low or High Temperature Bend Test for Fiber Optic Cable; EIA/TIA–455–45B, Method for Measuring Optical Fiber Geometry Using a Laboratory Microscope; EIA/TIA–455–46A, Spectral Attenuation Measurement for Long-Length, Graded-Index Optical Fibers; EIA/TIA–455–48B, Measurement of Optical Fiber Cladding Diameter Using Laser-Based Instruments; EIA/TIA–455–51A, Pulse Distortion Measurement of Multimode Glass Optical Fiber Information Transmission Capacity; EIA/TIA–455–53A, Attenuation by Substitution Measurement for Multimode Graded-Index Optical Fibers or Fiber Assemblies Used in Long Length Communications Systems; EIA/TIA–455–55B, End-View Methods for Measuring Coating and Buffer Geometry of Optical Fibers; EIA/TIA–455–58A, Core Diameter Measurement of Graded-Index Optical Fibers; EIA/TIA–455–59, Measurement of Fiber Point Defects Using an OTDR; EIA/TIA–455–61, Measurement of Fiber or Cable Attenuation Using an OTDR; EIA/TIA–455–78A, Spectral-Attenuation Cutback Measurement for Single-Mode Optical Fibers; EIA/TIA–455–81A, Compound Flow (Drip) Test for Filled Fiber Optic Cable; EIA/TIA–455–82B, Fluid Penetration Test for Fluid-Blocked Fiber Optic Cable; EIA/TIA–455–85A, Fiber Optic Cable Twist Test; EIA/TIA–455–104A, Fiber Optic Cable Cyclic Flexing Test; EIA/TIA–455–164A, Single-Mode Fiber, Measurement of Mode Field Diameter by Far-Field Scanning; EIA/TIA–455–165A, Mode Field Diameter Measurement Near Field Scanning Technique; EIA/TIA–455–167A, Mode Field Diameter, Variable Aperture in the Far Field; EIA/TIA–455–168A, Chromatic Dispersion Measurement of Multimode Graded-Index and Single-Mode Optical Fibers by Spectral Group

Delay Measurement in the Time Domain; EIA/TIA–455–169A, Chromatic Dispersion Measurement of Single-Mode Optical Fibers by the Phase-Shift Method; EIA/TIA–455–170, Cable Cutoff Wavelength of Single-Mode Fiber by Transmitted Power; EIA/TIA–455–173, Coating Geometry Measurement for Optical Fiber Side-View Method; EIA/TIA–455–175A, Chromatic Dispersion Measurement of Single-Mode Optical Fibers by the Differential Phase Shift Method; EIA/TIA–455–176, Method for Measuring Optical Fiber Cross-Sectional Geometry by Automated Grey-Scale Analysis; EIA/TIA–455–177A, Numerical Aperture Measurement of Graded-Index Optical Fibers; EIA/TIA–455–178, Measurements of Strip Force Required for Mechanically Removing Coatings from Optical Fibers; and EIA/TIA–598, Color Coding of Fiber Optic Cables, referenced in this section are incorporated by reference by REA. These incorporations by references were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of EIA/TIA standards are available for inspection during normal business hours at REA, room 2845, U.S. Department of Agriculture, Washington, DC 20250–1500 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies are available from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, telephone number (303) 792–2181.

(10) REA intends that the optical fibers contained in the cables manufactured in accordance with this section have characteristics that will allow signals, having a range of wavelengths, to be carried simultaneously.

(b) *Optical fibers.* (1) The solid glass optical fibers must consist of a cylindrical core and cladding covered by either an ultraviolet-cured acrylate or other suitable coating.

(2) The optical fiber types must be one of the following:

(i) Dispersion-unshifted single mode fiber EIA Class IVa;

(ii) Dispersion-shifted single mode fiber EIA Class IVb;

(iii) 50/125 micrometer multimode fiber EIA Class Ia; or

(iv) 62.5/125 micrometer multimode fiber EIA Class Ia.

(3) The dispersion-unshifted single mode fiber core must have either a matched or depressed clad step refractive index profile with a mode-field diameter of 9.0±1.0 micrometers when measured at 1300 nanometers and 10.5+1.0 micrometers/−1.5 micrometers when measured at 1550 nanometers in accordance with any one of the following test methods:

(i) EIA/TIA–455–164A;

(ii) EIA/TIA–455–165A;

(iii) EIA/TIA–455–167A; or

(iv) EIA–455–174.

(4) The dispersion-shifted single mode fiber core must have either a segmented core design or depressed clad step refractive index profile with a mode-field diameter of 7.5+1.5 micrometers/−1.3 micrometers when measured at 1550 nanometers in accordance with any one of the test procedures specified in paragraph (b)(3) of this section.

(5) The core clad off-set of the dispersion-unshifted and dispersion-shifted single mode fibers must not be greater than 1.0 micrometer when measured in accordance with either EIA/TIA–455–45B or EIA/TIA–455–176.

(6) The multimode fiber cores must have graded (parabolic) refractive index profiles with core diameters of 50.0±3.0 micrometers or 62.5±3.0 micrometers when measured in accordance with either EIA/TIA–455–58A, or EIA/TIA–455–176.

(7) The core noncircularity of multimode fibers must not exceed 6 percent when measured in accordance with either EIA/TIA–455–45B or EIA/TIA–455–176.

(8) The outside diameter of the glass fiber for both single mode and multimode fibers must be 125±2.0 micrometers when measured in accordance with any one of the following test methods:

(i) EIA/TIA–455–45B;

(ii) EIA/TIA–455–176; or

(iii) EIA/TIA–455–48B, Methods A or B.

(9) The outside diameter of the glass fiber must be nominally concentric with the fiber core as is consistent with the best commercial practice.

(10) The individual fibers must be proof tested at a minimum tensile stress of 0.35 gigapascal for approximately one second when measured in accordance with EIA/TIA–455–31B.

(11) Factory splices of fibers are allowed provided that prior acceptance from REA is obtained for the splice technique, that all splices are documented and reported to the customer and that the spliced fiber meets all requirements of this section.

(12) The optical fiber must be coated with a suitable material to preserve the intrinsic strength of the glass having an outside diameter of 250±15 micrometers when measured in accordance with either EIA/TIA–455–55B or EIA/TIA–455–173.

(13) The maximum force required to remove 25 millimeters of protective fiber coating must not exceed 13 newtons when measured in accordance with EIA/TIA–455–178.

(14) All optical fibers in any single length of cable must be of the same type.

(c) *Buffer/coating.* (1) The optical fibers contained in a tube buffer (loose tube), an inner jacket (unit core), a channel or otherwise loosely packaged must have a clearance between the fibers and the inside of the container sufficient to allow for thermal expansions without constraining the fibers. The protective container must be manufactured from a material having a coefficient of friction sufficiently low to allow the fibers free movement.

(2) Optical fibers covered in near contact with an extrusion (tight tube) must have an intermediate soft buffer to allow for thermal expansions and minor pressures.

(3) All protective coverings in any single length of cable must be continuous and be of the same material except at splice locations.

(4) The protective coverings must be free from holes, splits, blisters, and other imperfections and must be as smooth and concentric as is consistent with the best commercial practice.

(5) Repairs to the fiber coatings are not allowed except at splice locations.

(6) Both loose tube and tight tube coverings of each color and other fiber package types removed from the finished cable must meet the following shrinkback and cold bend performance requirements. The fibers may be left in the tubes.

(i) *Shrinkback.* Testing must be conducted in accordance with ASTM D 4565–90a, paragraph 14.1, using a talc bed at a temperature of 95 °C. Shrinkback must not exceed 5 percent of the original 150 millimeter length of the specimen. The total shrinkage of the specimen must be measured.

(ii) *Cold bend.* Testing must be conducted on at least one tube from each color in the cable. Stabilize the specimen to −20±1 °C for a minimum of four hours. While holding the specimen and mandrel at the test temperature, wrap the tube in a tight helix ten times around a mandrel with a diameter not greater than five times the tube diameter. The tube must show no evidence of cracking when observed with normal or corrected-to-normal vision.

Note: Channel cores and similar slotted single component core designs need not be tested for cold bend.

(d) *Fiber and buffer tube identification.* (1) The colors designated for identification of loose buffer tubes, tight tube buffer fibers and individual

fibers in multifiber tubes, slots or bundles are shown in the following table:

Buffer tube and fiber No.	Color
1	Blue.
2	Orange.
3	Green.
4	Brown.
5	Slate.
6	White.
7	Red.
8	Black.
9	Yellow.
10	Violet.
11	Rose.
12	Aqua.
13	Blue/Black Tracer.
14	Orange/Black Tracer.
15	Green/Black Tracer.
16	Brown/Black Tracer.
17	Slate/Black Tracer.
18	White/Black Tracer.
19	Red/Black Tracer.
20	Black/Yellow Tracer.
21	Yellow/Black Tracer.
22	Violet/Black Tracer.
23	Rose/Black Tracer.
24	Aqua/Black Tracer.

(2) *Standards of color.* Except for the aqua color, the colors of fibers and tubes supplied in accordance with this section are specified in terms of the Munsell Color System (ASTM D 1535–89) and must comply with the color limits as defined in EIA/TIA–598. (A visual color standard meeting these requirements and entitled "Munsell Color Charts for Color Coding," may be obtained from the Munsell Color Company, Inc., 2441 North Calvert Street, Baltimore, Maryland 21218. The latest edition of the color standard should be used.)

(i) The aqua color limits using the Munsell Color System must be as follows:

MUNSELL NOTATION

Symbol	Aqua color
Centroid	10BG 7/6
H++	5B 7/6
H– –	5BG 7/6
V++	10BG 8/4
V– –	10BG 6/6
C++	None
C– –	10BG 7/4

(ii) Other coloring schemes used for providing identification of buffer tubes and optical fibers which deviate from the requirements of paragraph (d)(1) of this section will not be accepted by REA.

(e) *Strength members.* (1) Strength members must be an integral part of the cable construction, but are not considered part of the support messenger for self-supporting optical cable.

(2) The combined strength of all the strength members must be sufficient to support the stress of installation and to protect the cable in service.

(3) Strength members may be incorporated into the core as a central support member or filler, as fillers between the fiber packages, as an annular serving over the core, as an annular serving over the intermediate jacket, embedded in the outer jacket or as a combination of any of these methods.

(4) The central support member or filler must contain no more than one splice per kilometer of cable. Individual fillers placed between the fiber packages and placed as annular servings over the core must contain no more than one splice per kilometer of cable. Cable sections having central member or filler splices must meet the same physical requirements as unspliced cable sections.

(5) Strength member materials and splicing techniques must be accepted by REA prior to their use.

(6) In each length of completed cable having a metallic central member, the dielectric strength between the armor and the metallic center member must withstand at least 15 kilovolts direct current for 3 seconds.

(f) *Forming the cable core.* (1) Protected fibers must be assembled with the optional central support member, fillers and strength members in such a way as to form a cylindrical group.

(2) The standard cylindrical group or core designs shall consist of 4, 6, 8, 10, 12, 16, 18, 20, or 24 fibers. Cylindrical groups or core designs larger than the sizes shown above must meet all the requirements of this section.

(3) When threads or tapes are used as core binders, they must be colored either white or natural and must be a nonhygroscopic and nonwicking dielectric material.

(4) When threads or tapes are used as unit binders to define optical fiber units in loose tube, tight tube, slotted, or bundled cored designs, they must be colored in accordance with the table listed below and must be a nonhygroscopic and nonwicking dielectric material or be rendered such by the filling compound. The colors of the binders must be in accordance with paragraphs (d)(2) introductory text and (d)(2)(i) of this section.

Unit No.	Binder color
1	Blue.
2	Orange.
3	Green.
4	Brown.
5	Slate.
6	White.
7	Red.
8	Black.
9	Yellow.
10	Violet.
11	Rose.
12	Aqua.
13	Blue-Black.
14	Orange-Black.
15	Green-Black.
16	Brown-Black.
17	Slate-Black.
18	White-Black.
19	Red-Black.
20	Black-Black-Yellow.
21	Yellow-Yellow-Black.
22	Violet-Black.
23	Rose-Black.
24	Aqua-Black.

(g) *Filling compound.* (1) To prevent the ingress of water into the core, a filling compound must be applied into the interior of the loose fiber tubes and into the interstices of the core. When a core wrap is used, the filling compound must also be applied to the core wrap, over the core wrap and between the core wrap and inner jacket when required.

(2) The materials must be homogeneous and uniformly mixed; free from dirt, metallic particles and other foreign matter; easily removed; nontoxic and present no dermal hazards.

(3) The individual cable manufacturer must satisfy REA that the filling compound selected for use is suitable for its intended application. The filling compound must be compatible with the cable components when tested in accordance with ASTM D 4568–86 at a temperature of 80° C.

(h) *Core wrap (optional).* (1) At the option of the manufacturer, one or more layers of nonhygroscopic and nonwicking dielectric material may be applied over the core.

(2) The core wrap(s) can be used to provide a heat barrier to prevent deformation or adhesion between the fiber tubes or can be used to contain the core.

(3) When core wraps are used, sufficient filling compound must be applied to the core wraps so that voids or air spaces existing between the core wraps and between the core the inner side of the core wrap are minimized.

(i) *Inner jacket.* (1) Inner jackets may be applied directly over the core or over the strength members.

(i) For armored cable an inner jacket is optional but recommended. The inner jacket may absorb stresses in the cable core that may be introduced by armor application or by armored cable installation.

(ii) For unarmored cable an inner jacket is optional.

(2) The inner jacket material and test requirements must be as for the outer jacket material per paragraphs (m)(3) introductory text through (m)(3)(v) of this section, except that either black or natural polyethylene may be used. In the case of natural polyethylene, the requirements for absorption coefficient and the inclusion of furnace black are waived.

(j) *Flooding compound.* (1) Sufficient flooding compound must be applied between the inner jacket and armor and between the armor and outer jacket so that voids and air spaces in these areas are minimized. The use of floodant between the armor and outer jacket is not required when uniform bonding, per paragraph (k)(10) of this section, is achieved between the plastic-clad armor and the outer jacket.

(2) The flooding compound must be compatible with the jacket when tested in accordance with ASTM D 4568–86 at a temperature of 80° C. The floodant must exhibit adhesive properties sufficient to prevent jacket slip when tested in accordance with the requirements of Appendix A, paragraph (III)(3), of this section.

(3) The individual cable manufacturer must satisfy REA that the flooding compound selected for use is acceptable for the application.

(4) In lieu of a flooding compound, water blocking tapes may be applied between the inner jacket and armor and between the armor and outer jacket to prevent water migration. The use of the water blocking tape between the armor and outer jacket is not required when uniform bonding, per paragraph (k)(10) of this section, is achieved between the plastic-clad armor and the outer jacket.

(k) *Armor.* (1) A steel armor, plastic coated on both sides, is required for direct buried cable manufactured under the provisions of this section. An armor is optional for duct and aerial cable as required by the purchaser. The plastic coated steel armor must be applied longitudinally directly over the core wrap or the intermediate jacket and have a minimum overlap of 3.0 millimeters.

(2) The uncoated steel tape must be electrolytic chrome coated steel (ECCS) with a thickness of 0.155 ± 0.015 millimeters.

(3) The reduction in thickness of the armoring material due to the corrugating or to the application process must be kept to a minimum and must not exceed 10 percent at any spot.

(4) The armor of each length of cable must be electrically continuous with no more than one joint or splice allowed per kilometer of cable. This requirement does not apply to a joint or splice made in the raw material by the raw material manufacturer.

(5) The breaking strength of any section of an armor tape, containing a factory splice joint, must not be less than 80 percent of the breaking strength of an adjacent section of the armor of equal length without a joint.

(6) For cables containing no floodant over the armor, the overlap portions of the armor tape must be bonded in cables having a flat, noncorrugated armor to meet the requirements of paragraphs (q)(1) through (q)(7)(ii) of this section. If the tape is corrugated, the overlap portions of the armor tape must be sufficiently bonded and the corrugations must be sufficiently in register to meet the requirements of paragraphs (q)(1) through (q)(7)(ii) of this section.

(7) The armor tape must be so applied as to enable the cable to pass the bend test as specified in paragraph (q)(1) of this section.

(8) The protective coating on the steel armor must meet the Bonding-to-Metal, Heat Sealability, Lap-Shear and Moisture Resistance requirements of Type I, Class 2 coated metals in accordance with ASTM B 736–92a.

(9) The ability of the plastic-clad metal to resist the flooding compound must be determined as required by ASTM D 4568–86 using a one meter length of coated steel which must be aged for 7 days at 68±1 °C. There must be no delamination of the coating from the steel at the conclusion of the test.

(10) When the jacket is bonded to the plastic coated armor, the bond between the plastic coated armor and the outer jacket must not be less than 525 newtons per meter over at least 90 percent of the cable circumference when tested in accordance with ASTM D 4565–90a. For cables with strength members embedded in the jacket, and residing directly over the armor, the area of the armor directly under the strength member is excluded from the 90 percent calculation.

(l) *Optional support messenger (aerial cable).* (1) When a self-supporting aerial cable containing an integrated support messenger is supplied, the support messenger must comply with the requirements specified in paragraphs (l)(2) introductory text through (l)(6) of this section.

(2) The fully flooded, stranded support messenger must be 6.35 millimeters diameter, 7 wire, extra high strength grade, Class A galvanized steel strand conforming to ASTM A 640–91 with exceptions and additional provisions as follows:

(i) The maximum lay of the individual wires of the strand must be 140 millimeters.

(ii) Any section of a completed strand containing a joint must have minimum tensile strength and elongation of 29,500 newtons and 3.5 percent, respectively, when tested in accordance with the procedures specified ASTM A 640–91.

(iii) The individual wires from a completed strand which contain joints must not fracture when tested according to the "Ductility of Steel" procedures specified in ASTM A 640–91 except that the mandrel diameter must be equal to 5 times the nominal diameter of the individual wires.

(3) The support strand must be completely covered with a corrosion protective floodant. The floodant must be homogeneous and uniformly mixed.

(4) The floodant must be nontoxic and present no dermal hazard.

(5) The floodant must be free from dirt, metallic particles, and other foreign matter that may interfere with the performance of the cable.

(6) The floodant must be compatible with the polyethylene outer jacket and must be acceptable to REA.

(7) Other methods of providing self-supporting cable specifically not addressed in this section may be allowed if accepted by REA. Justification for acceptance of a modified design must be provided to substantiate product utility and long term stability and endurance.

(m) *Outer jacket.* (1) The outer jacket must provide the cable with a tough, flexible, protective covering which can withstand exposure to sunlight, to atmosphere temperatures and to stresses reasonably expected in normal installation and service.

(2) The jacket must be free from holes, splits, blisters, or other imperfections and shall be as smooth and concentric as is consistent with the best commercial practice.

(3) The raw material used for the outer jacket must be one of the five types listed in paragraphs (m)(3)(i) through (m)(3)(v) of this section. The raw material must contain an antioxidant to provide long term stabilization and the materials must contain a 2.60±0.25 percent concentration of furnace black to provide ultraviolet shielding. Both the antioxidant and furnace black must be compounded into the material by the raw material supplier.

(i) Low density, high molecular weight polyethylene (LDHMW) must conform to the requirements of ASTM D 1248–84(1989), Type I, Class C, Category 4 or 5, Grade J3.

(ii) Low density, high molecular weight ethylene copolymer (LDHMW) must conform to the requirements of ASTM D 1248–84(1989), Type I, Class C, Category 4 or 5, Grade J3.

(iii) Linear low density, high molecular weight polyethylene (LLDHMW) must conform to the requirements of ASTM D 1248–84(1989), Type I, Class C, Category 4 or 5, Grade J3.

(iv) High density polyethylene (HD) must conform to the requirements of ASTM D 1248–84(1989), Type III, Class C, Category 4 or 5, Grade J4.

(v) Medium density polyethylene (MD) must conform to the requirements of ASTM D 1248–84(1989), Type II, Class C, Category 4 or 5, Grade J4.

(vi) Particle size of the carbon selected for use must not average greater than 20 nanometers.

(vii) Absorption coefficient must be a minimum of 400 in accordance with the procedures of ASTM D 3349–86.

(4) The outer jacketing material removed from or tested on the cable must be capable of meeting the following performance requirements:

Property	LLDHMW ethylene copolymer	LDHMW poly-ethylene	HD or MD poly-ethylene
Melt Flow Rate:			
Percent increase from raw material, Maximum	.....	50	50
<0.41 (Initial Melt Index)	100		
0.41–2.00 (Initial Melt Index)	.....	50	
Tensile Strength:			
Minimum, Megapascals	12	12	16.5
Ultimate Elongation:			
Minimum, Percent	400	400	300
Environmental Stress Cracking:			
Maximum, Failures	0/10	2/10	2/10
Shrinkback:			
Maximum, Percent	5	5	5
Impact:			
Maximum, Failures	2/10	2/10	2/10

(5) *Testing procedures.* The procedures for testing jacket specimens for compliance with paragraph (m)(4) of this section must be as follows:

(i) *Melt flow rate.* The melt flow rate must be determined by ASTM D 1238–90b, Condition E. Jacketing material must be free from flooding and filling compound.

(ii) *Tensile strength and ultimate elongation.* Test in accordance with EIA–455–89A, using a jaw separation speed of 500 millimeters per minute for low density material and 50 millimeters per minute for high and medium density materials.

(iii) *Environmental stress cracking.* Test in accordance with ASTM D 4565–90a.

(iv) *Shrinkback.* Test in accordance with the procedures specified in EIA–455–86 using a temperature of 100 ± 1° C for a 4 hour period for low density material and a test temperature of 115 ± 1° C for a 4 hour period for high and medium density materials.

(v) *Impact.* The test must be performed in accordance with ASTM D 4565–90a using an impact force of 4 newton-meters at a temperature of −20 ± 2° C. A cracked or split jacket constitutes failure.

(6) *Jacket thickness.* The nominal outer jacket thickness must not be less than 1.3 millimeters. The test method used must either be the End Sample Method (paragraph (m)(6)(i) of this section) or the Continuous Uniformity Thickness Gauge Method (paragraph (m)(6)(ii) of this section).

(i) *End sample method.* The jacket must be capable of meeting the following requirements:

Minimum Average Thickness: 90 percent (%) of nominal thickness

Minimum Spot Thickness: 70 % of nominal thickness

(ii) *Continuous uniformity thickness gauge.* (A) The jacket must be capable of meeting the following requirements:

Minimum Average Thickness: 75 % of nominal thickness

Minimum Thickness: 70 % of nominal thickness

Maximum Eccentricity: 40 % of nominal thickness

$$\text{Eccentricity} = \frac{\text{Max. Thickness} - \text{Min. Thickness}}{\text{Average Thickness}} \times 100$$

(B) The maximum and minimum thickness values shall be based on the average of each axial section.

(7) For jackets having embedded strength members, the jacket thickness must meet the requirements of paragraph (m)(6) of this section except that the jacket thickness over the strength members must not be less than 0.50 millimeters.

(8) The minimum jacket thickness at any point over the support messenger for self-supporting aerial cable utilizing such an element must be 1.1 millimeters.

(9) The web dimension for self-supporting aerial cable utilizing such a feature must be as follows:

Height: 2.29 ± 0.750 millimeters

Width: $1.52^{+0.51}_{-0.25}$ millimeters

(n) *Sheath slitting cord (optional).* (1) A sheath slitting cord is optional.

(2) When a sheath slitting cord is used it must be nonhygroscopic and nonwicking or be rendered such by the filling or flooding compound, continuous throughout a length of cable and of sufficient strength to open the sheath over at least a one meter length without breaking the cord at a temperature of 23±5 °C.

(o) *Identification marker and length marker.* (1) Each length of cable must be permanently labeled either Optical Cable, OC, Optical Fiber Cable, or OF on the outer jacket and identified as to manufacturer and year of manufacture.

(2) Each length of cable intended for direct burial installation shall be marked with a telephone handset in compliance with Rule 350G of the 1993 National Electrical Safety Code (NESC).

(3) Mark the number of fibers on the jacket.

(4) The markings must be printed on the jacket at regular intervals of not more than 2 meters.

(5) An alternative method of marking may be used if acceptable to REA.

(6) The completed cable must have sequentially numbered length markers in Meters or Feet at regular intervals of not more than 2 meters along the outside of the jacket.

(7) Continuous sequential numbering must be employed in a single length of cable.

(8) The numbers must be dimensioned and spaced to produce good legibility and must be approximately 3 millimeters in height.. An occasional illegible marking is permissible if there is a legible marking located not more than 2 meters from it.

(9) The method of marking must be by means of suitable surface markings producing a clear distinguishable contrasting marking acceptable to REA. Where direct or transverse printing is employed, the characters should be indented to produce greater durability of marking. Any other method of length marking must be acceptable to REA as producing a marker suitable for the field. Size, shape and spacing of numbers, durability and overall legibility of the marker will be considered in acceptance of the method.

(10) Agreement between the actual length of the cable and the length marking on the cable jacket must be within the limits of +1 percent, −0 percent.

(11) The color of the initial marking must be white or silver. If the initial marking fails to meet the requirements of the preceding paragraphs, it will be permissible to either remove the defective marking and re-mark with the white or silver color or leave the defective marking on the cable and re-mark with yellow. No further re-marking is permitted. Any re-marking must be on a different portion of the cable circumference than any existing marking when possible and have a numbering sequence differing from any other existing marking by at least 3,000.

(12) Any reel of cable that contains more than one set of sequential markings must be labeled to indicate the color and sequence of marking to be used. The labeling must be applied to the reel and also to the cable.

(p) *Optical performance.* (1) The optical performance of the single mode fibers must be in accordance with the requirements specified in paragraphs (p)(1)(i) through (p)(1)(viii) of this section.

(i) The attenuation values of the single mode fibers within the cable must not exceed 0.5 decibel per kilometer (dB/km) for dispersion-unshifted single mode fiber at 1310 and 1550 nanometers and must not exceed 0.5 dB/km for dispersion-shifted single mode fiber at 1550 nanometers. The test method used for measuring the attenuation must be in accordance with either:

(A) EIA/TIA–455–78A; or

(B) EIA/TIA–455–61.

(ii) The attenuation values for wavelengths between 1285 and 1330 nanometers and between 1525 and 1575 nanometers for dispersion-unshifted fibers must not exceed the attenuation at 1310 and 1550 nanometers by more than 0.1 dB/km. The attenuation values for wavelengths between 1525 and 1575 nanometers for dispersion-shifted fibers must not exceed the attenuation at 1550 nanometers by more than 0.1 dB/km. The test method used for measuring the attenuation must be in accordance with any one of the methods specified in paragraph (p)(1)(i) of this section.

(iii) Attenuation discontinuities in the fiber's length must not exceed 0.1 decibel (dB) for dispersion-unshifted fiber at 1310±20 and 1550±20 nanometers and must not exceed 0.1 dB for dispersion-shifted fiber at 1550±20 nanometers when measured in accordance with EIA/TIA–455–59.

(iv) Measurement of the attenuation must be conducted at the wavelength specified for application and must be expressed in decibels per kilometer.

(v) Because the accuracy of attenuation measurements for single mode fibers becomes questionable when measured on short cable lengths, attenuation measurements are to be made utilizing characterization cable lengths. If the ship length of cable is less than one kilometer, the attenuation values measured on longer lengths of cable (characterization length of cable) before cutting to the ship lengths of cable may be applied to the ship lengths.

(vi) For dispersion-unshifted fiber the zero dispersion wavelength must be between 1300 and 1322 nanometers, and the value of the dispersion slope at the zero-dispersion wavelength must not be greater than 0.092 picosecond per nanometer squared times kilometer (ps/(nm^2•km) when measured in accordance with either:

(A) EIA/TIA–455–168A;

(B) EIA/TIA–455–169A; or

(C) EIA/TIA–455–175A.

(vii) For dispersion-shifted fiber, the dispersion over the wavelength range between 1525 and 1575 nanometers must not exceed 3.5 picosecond per nanometer times kilometer (ps/(nm^2•km)) and must have a maximum dispersion slope of 0.095 ps/(nm^2•km) at the zero dispersion wavelength when measured in accordance with any one of the test procedures specified in paragraph (p)(1)(vi) of this section.

(viii) The cut off wavelength of the dispersion-unshifted and the dispersion-shifted fibers in a cable must be less than 1260 nanometers when measured in accordance with EIA/TIA–455–170.

(2) The optical performance of the multimode fibers must be in accordance with the requirements specified in paragraphs (p)(2)(i) through (p)(2)(vi) of this section.

(i) The attenuation values of the 50/125 and 62.5/125 micrometer multimode fibers within the cable must not exceed 1.5 dB/km at 1300 nanometers when measured in accordance with either:

(A) EIA/TIA–455–46A;

(B) EIA/TIA–455–53A; or

(C) EIA/TIA–455–61.

(ii) Attenuation discontinuities in the fiber's length must not exceed 0.2 dB for both multimode fiber types at 1300±20 nanometers when measured in accordance with EIA/TIA–455–59.

(iii) Measurement of the attenuation must be conducted at the wavelength specified for application and must be expressed in decibels per kilometer.

(iv) Because the accuracy of attenuation measurements for multimode fibers becomes questionable when measured on short cable lengths, attenuation measurements are to be made utilizing characterization cable lengths. If the ship length of cable is less than one kilometer, the attenuation values measured on longer lengths of cable (characterization length of cable) before cutting to the ship lengths of cable may be applied to the ship lengths.

(v) The bandwidth of the multimode fibers at the −3 dB optical power of the optical fibers within the cable must be within the limits prescribed in the purchase order.

(vi) The test methods used to measure bandwidth must be in accordance with either EIA/TIA–455–30B or EIA/TIA–455–51A.

(3) Numerical aperture (NA) for each multimode optical fiber in the cable must be 0.20±0.015 for the 50/125 micrometer design and 0.275±0.015 for the 62.5/125 micrometer design when measured in accordance with EIA/TIA–455–177A.

(q) *Mechanical requirements*—(1) *Cable bend test.* (i) All cables manufactured in accordance with the requirements of this section must be capable of meeting the following bend test without exhibiting an increase in fiber attenuation greater than 0.10 dB for single mode fibers and 0.40 dB for multimode fibers.

(ii) Measure the attenuation of dispersion-unshifted single mode fibers at 1310±20 and 1550±20 nanometers, dispersion-shifted single mode fibers at 1550±20 nanometers and multimode fibers at 1300 20 nanometers.

(iii) After measuring the attenuation of the optical fibers, test the cable sample in accordance with EIA/TIA–455–37A, Test Condition E, Turns Test Level 3. The following detailed test conditions shall apply:

(A) Section 4.2—Mandrel diameter must be 20 times the cable diameter.

(B) Section 4.5—Measure the attenuation increase of the wound sample at the test temperature and specified wavelengths in accordance with EIA–455–20.

(C) For armored cable, the armor overlap must be on the outside of the bend.

(D) For self-supporting cable, the jacketed support messenger and connection web must be removed prior to testing.

(iv) The cable may be allowed to warm to room temperature before visual inspection. The bent area of the cable must show neither visible evidence of fracture of the jacket nor delamination of the bond at the overlap and to the outer jacket in nonflooded cable. After removal of the jacket, there must be no visible evidence of fracture of the armor, when present, and of the components in the core.

(2) *Cable impact test.* (i) All cables manufactured in accordance with the requirements of this section must be capable of meeting the following impact test without exhibiting an increase in fiber attenuation greater than 0.10 dB for single mode fibers and 0.40 dB for multimode fibers, and without cracking or splitting of the cable jacket.

(ii) Measure the attenuation of the optical fibers in accordance with paragraph (q)(1)(ii) of this section.

(iii) After measuring the attenuation of the optical fibers, test the cable in accordance with EIA/TIA–455–25A.

(3) *Cable compression test.* (i) All cables manufactured in accordance with the requirements of this section must be capable of meeting the following compressive strength test without exhibiting an increase in fiber attenuation greater than 0.10 dB for single mode fibers and 0.4 dB for multimode and without cracking or splitting of the cable jacket when subjected to a minimum compressive load of 440 newtons per centimeter for armored cable and 220 newtons per centimeter for nonarmored cable.

(ii) Measure the attenuation of the optical fibers in accordance with paragraph (q)(1)(ii) of this section.

(iii) After measuring the attenuation of the optical fibers, test the cable in accordance with EIA–455–41 using a rate of 3 millimeters to 20 millimeters per minute and maintaining the load for 10 minutes.

(4) *Cable twist test.* (i) All cables manufactured in accordance with the requirements of this section must be capable of meeting the following twist test without exhibiting an increase in fiber attenuation greater than 0.10 dB for single mode fibers and 0.40 dB for multimode fibers, and without cracking or splitting of the cable jacket.

(ii) Measure the attenuation of the optical fibers in accordance with paragraph (q)(1)(ii) of this section.

(iii) After measuring the attenuation of the optical fibers, test the cable in accordance with EIA/TIA–455–85A, using a maximum cable twisting length of 4 meters.

(5) *Cable flex test.* (i) All cables manufactured in accordance with the requirements of this section must be capable of meeting the following flex test without exhibiting an increase in fiber attenuation greater than 0.10 dB for single mode fibers and 0.40 dB for multimode fibers.

(ii) Measure the attenuation of the optical fibers in accordance with paragraph (q)(1)(ii) of this section.

(iii) After measuring the attenuation of the optical fibers, test the cable in accordance with EIA/TIA–455–104A, Test Conditions I and II, flexed for 25 cycles using a sheave diameter not less than 20 times the cable diameter (Test condition letter B).

(iv) After completion of the test, the bent area of the cable must show neither visible evidence of fracture of the jacket nor delamination of the bond at the overlap and to the outer jacket in nonflooded cable. After removal of the jacket, there must be no visible evidence of fracture of the armor, when present, and of the components in the core.

(6) *Water penetration test.* (i) A one meter length of completed fiber optic cable must be preconditioned for 24 hours at 23±5 °C and then tested in accordance with EIA/TIA–455–82B using a one meter water head over the sample or placed under the equivalent continuous pressure for one hour.

(ii) After the one hour period, there must be no water leakage through the sheath interfaces, under the core wrap, between the cable core interstices or through the fiber buffers.

(iii) If water leakage is detected in the first sample, one additional 3 meter sample from EACH END of the same reel must be tested in accordance with paragraph (q)(6)(i) of this section. If either sample exhibits water leakage, the entire reel of cable is to be rejected. If the samples exhibit no leakage, the entire reel of cable is considered acceptable.

(7) *Compound flow test.* (i) Three 300 millimeter long test samples must be preconditioned for 24 hours at 23±5 °C and then tested in accordance with EIA/TIA–455–81A using a test temperature of 80 ± 1 °C.

(ii) The amount of filling or flooding compounds that flowed or dripped from any of the suspended cable specimens must be less than or equal to 0.5 grams of material. The measurement of an amount greater than 0.5 grams for any of the suspended cable specimens constitutes failure.

(r) *Preconnectorized cable (optional).* (1) At the option of the manufacturer and upon request by the purchaser, the cable may be factory terminated with connectors acceptable to REA.

(2) All connectors must be accepted by REA prior to their use.

(s) *Acceptance testing and extent of testing.* (1) The tests described in Appendix A of this section are intended for acceptance of cable designs and major modifications of accepted designs. What constitutes a major modification is at the discretion of REA. These tests are intended to show the inherent capability of the manufacturer to produce cable products that have satisfactory performance characteristics, long life and long-term optical stability but are not intended as field tests.

(2) For initial acceptance, the manufacturer must submit:

(i) An original signature certification that the product fully complies with each section of the specification:

(ii) Qualification Test Data, per Appendix A of this section;

(iii) A set of instructions for handling the cable;

(iv) OSHA Material Safety Data Sheets for all components;

(v) Agree to periodic plant inspections;

(vi) A certification that the product does or does not comply with the domestic origin manufacturing provisions, of the "Buy American requirements of the Rural Electrification Act of 1938 (52 Stat. 818);

(vii) Written user testimonials concerning field performance of the product; and

(viii) Other nonproprietary data deemed necessary by the Chief, Outside Plant Branch (Telephone).

(3) For requalification acceptance, the manufacturer must submit an original signature certification that the product fully complies with each section of the specification, excluding the Qualification Section, and a certification that the product does or does not comply with the domestic origin manufacturing provisions of the "Buy American" requirements of the Rural Electrification Act of 1938 (52 Stat. 818), for acceptance by September 30 every three years. The required data and certification must have been gathered within 90 days of the submission.

(4) Initial and requalification acceptance requests should be addressed to: Chairman, Technical Standards Committee "A" (Telephone), Telecommunications Standards Division, Rural Electrification Administration, Washington, DC 20250–1500.

(5) *Tests on 100 percent of completed cable.* (i) The armor for each length of cable must be tested for continuity using the procedures of ASTM D 4566–90.

(ii) Attenuation for each optical fiber in the cable must be measured

(iii) Optical discontinuities must be isolated and their location and amplitude recorded.

(6) *Capability tests.* Tests on a quality assurance basis must be made as frequently as is required for each manufacturer to determine and maintain compliance with:

(i) Numerical aperture and bandwidth of multimode fibers;

(ii) Cut off wavelength of single mode fibers;

(iii) Dispersion of single mode fibers;

(iv) Shrinkback and cold testing of loose tube and tight tube buffers;

(v) Adhesion properties of the protective fiber coating;

(vi) Dielectric strength between the armor and the metallic central member;

(vii) Performance requirements for the inner and outer jacketing materials;

(viii) Performance requirements for the filling and flooding compounds;

(ix) Bonding properties of the coated armoring material;

(x) Sequential marking and lettering;

(xi) Cable bend and cable impact tests;

(xii) Water penetration and compound flow tests;

(xiii) Cable twist, cable flex, and cable compression tests; and

(xiv) Performance requirements of support messenger.

(t) *Records of optical and physical tests.* (1) Each manufacturer must maintain suitable summary records for a period of at least 3 years of all optical and physical tests required on completed cable by this section as set forth in paragraphs (s)(5) and (s)(6) of this section. The test data for a particular reel must be in a form that it may be readily available to REA upon request. The optical data must be furnished to the purchaser on a suitable and easily readable form.

(2) Measurements and computed values must be rounded off to the number of places or figures specified for the requirement according to ASTM E 29–90.

(u) *Manufacturing irregularities.* (1) Repairs to the armor, when present, are not permitted in cable supplied to end users under this section.

(2) Minor defects in the inner and outer jacket (defects having a dimension of 3 millimeter or less in any direction) may be repaired by means of heat fusing in accordance with good commercial practices utilizing sheath grade compounds.

(3) Buffer tube repair is permitted only in conjunction with fiber splicing.

(v) *Packaging and preparation for shipment.* (1) The cable must be shipped on reels. The diameter of the drum must be large enough to prevent damage to the cable from reeling and unreeling. The reels must be substantial and so constructed as to prevent damage during shipment and handling.

(2) A circumferential thermal wrap or other means of protection complying with the requirements of Appendix B of this section must be secured between the outer edges of the reel flange to protect the cable against damage during storage and shipment.

(3) Cable manufactured to the requirements of this section must be sealed at the ends to prevent entrance of moisture. The method of sealing must be accepted by REA prior to its use.

(4) The end-of-pull (outer end) of the cable must be securely fastened to prevent the cable from coming loose during transit. The start-of-pull (inner end) of the cable must project through a slot in the flange of the reel, around an inner riser, or into a recess on the reel flange near the drum and fastened in such a way to prevent the cable from becoming loose during installation.

(5) Spikes, staples or other fastening devices must be used in a manner which will not result in penetration of the cable.

(6) The arbor hole must admit a spindle 63.5 millimeters in diameter without binding. Steel arbor hole liners may be used but must be accepted by REA prior to their use.

(7) Each reel must be plainly marked to indicate the direction in which it should be rolled to prevent loosening of the cable on the reel.

(8) Each reel must be stenciled or lettered with the name of the manufacturer.

(9) The following information must be either stenciled on the reel or on a tag firmly attached to the reel:

Optical Cable
Number of Fibers
Armored or Nonarmored
Year of Manufacture
Name of Cable Manufacturer
Length of Cable
Reel Number
REA 7 CFR 1755.900

Example:

Optical Cable
4 fiber
Armored
1988
XYZ Company
1050 meters
Reel Number 3
REA 7 CFR 1755.900

(10) When preconnectorized cable is shipped, the splicing modules must be protected to prevent damage during shipment and handling. The protection method must be accepted by REA prior to its use.

Appendix A to 7 CFR 1755.900 —Qualification Tests Methods

(I) The test procedures described in this appendix are for qualification of initial cable designs and major modifications of accepted designs. Included in (V) of this appendix are suggested formats that may be used in submitting test results to REA.

(II) Sample selection and preparation. (1) All testing must be performed on lengths removed sequentially from any of the same cables listed below. The cables must not have been exposed to temperatures in excess of 38°C since their initial cool downs after sheathing. The lengths specified are minimum lengths and if desirable from a laboratory testing standpoint longer lengths may be used:

(a) 12 single mode fiber jacketed cable consisting of 6 single mode dispersion-unshifted fibers and 6 single mode dispersion-shifted fibers.

(b) 12 multimode fiber jacketed cable consisting of 6 50/125 micrometer multimode fibers and 6 62.5/125 micrometer multimode fibers.

(c) 24 fiber jacketed combination cable consisting of 6 single mode dispersion-unshifted fibers; 6 single mode dispersion-shifted fibers; 6 50/125 micrometer multimode fibers; and 6 62.5/125 micrometer multimode fibers.

(2) Length A shall be a minimum of 500 meters long. Coil the sample with a diameter of 50 to 75 times its sheath diameter. Three lengths are required if only requesting acceptance for either single mode fiber cable (a), multimode fiber cable (b), or using the combination fiber cable (c). Six lengths, 3 lengths of single mode fiber cable (a), and 3 lengths of multimode fiber cable (b), are

required if requesting acceptance for both single mode and multimode fiber cables.

(3) Length B shall be one meter long. Four lengths of either single mode fiber cable (a), multimode fiber cable (b) or the combination fiber cable (c) are required.

(4) Length C shall be 600 millimeters long. Four lengths of either single mode fiber cable (a), multimode fiber cable (b) or the combination fiber cable (c) are required.

(5) Data reference temperature. Unless otherwise specified, all measurement shall be made at 23±5°C.

(III) *Environmental tests*—(1) *Heat aging test.* (a) *Test samples.* Place one or two samples of length A and one sample each of lengths B and C in an oven or environmental chamber. The ends of sample A must exit from the chamber or oven for optical tests. Securely seal the oven exit holes.

(b) *Sequence of tests.* The samples are to be subjected to the following tests after conditioning:

(i) Water Penetration Test outlined in paragraph (III) (2) of this appendix; and

(ii) Jacket Slip Strength Test outlined in paragraph (III) (3) of this appendix. (For Flooded Designs Only)

(c) *Initial measurements.* (i) For sample(s) A measure the attenuation for the single mode dispersion-unshifted fibers at 1310 and 1550 nanometers, for single mode dispersion-shifted fibers at 1550 nanometers and/or for multimode fibers at 1300 nanometers at a temperature of 23±5°C. Also measure the bandwidth of the multimode fibers. Calculate the attenuation data on a per kilometer basis. Calculate the bandwidth data on a megahertz-kilometer (MHz-km) basis.

(ii) Record on suggested formats in (V) of this appendix or on other easily readable formats.

(d) *Heat conditioning.* (i) Immediately after completing the initial measurements, condition the sample(s) for 14 days at a temperature of 65±2°C.

(ii) At the end of this period note any exudation of cable filler. Measure the parameters given in paragraph (III)(1)(c) of this appendix. Record on suggested formats in (V) of this appendix or on other easily readable formats.

(e) *Overall optical deviation.* (i) Calculate the change in all parameters between the final parameters after conditioning with initial parameters in paragraph (III)(1)(c) of this appendix.

(ii) The stability of the optical parameters after completion of this test must be within the following prescribed limits:

(A) *Attenuation.* The attenuation of each multimode fiber must not change by more than 0.3 db/km and the attenuation of each single mode fiber must not change by more than 0.1 dB/km.

(B) *Bandwidth.* The bandwidth of each multimode fiber must not change by more than 15 percent from their original values.

(2) *Water penetration testing.* (a) A watertight closure must be placed over the jacket of length B from paragraph (III)(1)(a) of this appendix. The closure must not be placed over the jacket so tightly that the flow of water through pre-existing voids or air spaces is restricted. The other end of the sample must remain open.

(b) Test per Option A or Option B. (i) *Option A.* Weigh the sample and closure prior to testing. Fill the closure with water and place under a continuous pressure of 10 ± 0.7 kilopascals for one hour. Collect the water leakage from the end of the test sample during the test and weigh to the nearest 0.1 gram. Immediately after the one hour test, seal the ends of the cable with a thin layer of grease and remove all visible water from the closure, being careful not to remove water that penetrated into the core during the test. Reweigh the sample and determine the weight of water that penetrated into the core.

(ii) *Option B.* Fill the closure with a 0.2 gram sodium fluorscein per liter water solution and apply a continuous pressure of 10 ± 0.7 kilopascals for one hour. Catch and weigh any water that leaks from the end of the cable during the one hour period. If no water leaks from the sample, carefully remove the water from the closure. Then carefully remove the outer jacket, armor, if present, inner jacket, if present, and core wrap one at a time, examining with an ultraviolet light source for water penetration. After removal of the core wrap, carefully dissect the core and examine for water penetration within the core. Where water penetration is observed, measure the penetration distance.

(3) *Jacket slip strength test.* (For Flooded Design Only) (a) *Sample selection.* Test sample C from paragraph (III)(1)(a) of this appendix.

(b) *Sample preparation.* Prepare test sample in accordance with the procedures specified in ASTM D 4565–90a.

(c) *Sample conditioning and testing.* Remove the sample from the tensile tester prior to testing and condition for one hour at 50 ± 2°C. Test immediately in accordance with the procedures specified in ASTM D 4565–90a. A minimum jacket slip strength of 67 newtons is required. Record the load attained on the suggested formats in (V) of this appendix or on other easily readable formats.

(4) *Temperature and humidity exposure.* (a) Repeat paragraphs (III)(1)(a) through (III)(1)(c)(ii) of this appendix for separate set of samples A, B and C which have not been subjected to prior environmental conditioning.

(b) Immediately after completing the measurements, expose the test sample to 100 temperature cyclings. Relative humidity within the chamber shall be maintained at 90 ± 2 percent. One cycle consists of beginning at a stabilized chamber and test sample temperature of 52 ± 2°C, increasing the temperature to 57 ± 2°C, allowing the chamber and test samples to stabilize at this level, then dropping the temperature back to 52 ± 2°C.

(c) Repeat paragraphs (III)(1)(d)(ii) through (III)(3)(c) of this appendix.

(5) *Temperature cycling.* (a) Repeat paragraphs (III)(1)(a) through (III)(1)(c)(ii) of this appendix for separate set of samples A, B, and C which have not been subjected to prior environmental conditioning.

(b) Immediately after completing the measurements, subject the test sample to 10 cycles of temperature between −40°C and +60°C. The test sample must be held at each temperature extreme for a minimum of 1½ hours during each cycle of temperature. The air within the temperature cycling chamber must be circulated throughout the duration of the cycling.

(c) Repeat paragraphs (III)(1)(d)(ii) through (III)(3)(c) of this appendix.

(IV) *Control sample*—(a) *Test samples.* A separate set of lengths B and C must have been maintained at 23 ± 5°C for at least 48 hours before the testing.

(b) Repeat paragraphs (III)(2) through (III)(3)(c) of this appendix for these samples.

(V) The following suggested formats may be used in submitting the test results to REA:

HEAT AGING TEST—SINGLE MODE CABLE

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km		
	Initial	Final	Change	Initial	Final	Change
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

HEAT AGING TEST—MULTIMODE CABLE

Fiber No.	Attenuation—1300 nm dB/km			Bandwidth dB/km		
	Initial	Final	Change	Initial	Final	Change (%)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

HEAT AGING TEST—COMBINATION CABLE

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km			Bandwidth MHz-km		
	Initial	Final	Change	Initial	Final	Change	Initial	Final	Change (%)
1									
2									
3									
4									
5									
6									

HEAT AGING TEST—COMBINATION CABLE—Continued

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km			Bandwidth MHz-km		
	Initial	Final	Change	Initial	Final	Change	Initial	Final	Change (%)
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									
23									
24									

TEMPERATURE/HUMIDITY TEST—SINGLE MODE CABLE

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km		
	Initial	Final	Change	Initial	Final	Change
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

TEMPERATURE/HUMIDITY TEST—MULTIMODE CABLE

Fiber No.	Attenuation—1300 nm dB/km			Bandwidth MHz-km		
	Initial	Final	Change	Initial	Final	Change
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

TEMPERATURE/HUMIDITY TEST—COMBINATION CABLE

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km			Bandwidth MHz-km		
	Initial	Final	Change	Initial	Final	Change	Initial	Final	Change (%)
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									

TEMPERATURE/HUMIDITY TEST—COMBINATION CABLE—Continued

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km			Bandwidth MHz-km		
	Initial	Final	Change	Initial	Final	Change	Initial	Final	Change (%)
23									
24									

TEMPERATURE CYCLING TEST—SINGLE MODE CABLE

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km		
	Initial	Final	Change	Initial	Final	Change
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

TEMPERATURE CYCLING—MULTIMODE CABLE

Fiber No.	Attenuation—1300 nm dB/km			Bandwidth MHz–km		
	Initial	Final	Change	Initial	Final	Change (%)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

TEMPERATURE CYCLING TEST COMBINATION CABLE

Fiber No.	Attenuation—1310 nm dB/km			Attenuation—1550 nm dB/km			Bandwidth MHz-km		
	Initial	Final	Change	Initial	Final	Change	Initial	Final	Change (%)
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
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18									
19									
20									
21									
22									
23									
24									

WATER PENETRATION TEST

	Option A		Option B	
	End leakage grams	Weight gain grams	End leakage grams	Penetration millimeters
Control				
Heat Age				
Humidity Exposure				
Temperature Cycling				

JACKET SLIP STRENGTH @ 50°C

	Load in Newtons
Control	
Heat Age	
Humidity Exposure	
Temperature Cycling	
	Filler Exudation (grams)
Heat Age	
Humidity Exposure	
Temperature Cycle	

Appendix B to 7 CFR 1755.900—Thermal Reel Wrap Qualification

(I) The test procedures described in this appendix are only for qualification of initial and subsequent changes in thermal reel wraps.

(II) *Sample selection.* All testing must be performed on two 450 millimeter lengths of cable removed sequentially from the same fiber jacketed cable. This cable must not have been exposed to temperatures in excess of 38 °C since its initial cool down after sheathing.

(III) *Test procedure.* (1) Place the two samples on an insulating material such as wood.

(2) Tape thermocouples to the jackets of each sample to measure the jacket temperature.

(3) Cover one sample with the thermal reel wrap.

(4) Expose the samples to a radiant heat source capable of heating the uncovered jacket sample to a minimum of 71 °C. A GE 600 watt photoflood lamp or an equivalent lamp having the light spectrum approximately that of the sun shall be used.

(5) The height of the lamp above the jacket shall be 380 millimeters or an equivalent height that produces the 71 °C jacket temperature on the unwrapped sample shall be used.

(6) After the samples have stabilized at the temperature, the jacket temperatures of the samples shall be recorded after one hour of exposure to the heat source.

(7) Compute the temperature difference between jackets.

(8) For the thermal reel wrap to be acceptable to REA, the temperature difference between the jacket with the thermal reel wrap and the jacket without the reel wrap shall be greater than or equal to 17 °C.

Dated: June 2, 1994.

Bob J. Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 94–14104 Filed 7–1–94; 8:45 am]

BILLING CODE 3410–15–P

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. 93–137–2]

Importation of Ratites and Hatching Eggs of Ratites

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of reopening and extension of comment period.

SUMMARY: We are reopening and extending the comment period for our interim rule that required specified identification and recordkeeping for ratites and ratite hatching eggs that are intended for importation into the United States. This extension will provide interested persons with additional time in which to prepare comments on the interim rule.

DATES: Consideration will be given only to written comments on Docket No. 93–137–1 that are received on or before July 20, 1994.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 93–137–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Keith Hand, Senior Staff Veterinarian, Import-Export Animals Staff, National Center for Import-Export, Veterinary Services, APHIS, USDA, room 768, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–5907.

SUPPLEMENTARY INFORMATION: On March 8, 1994, we published in the **Federal Register** (59 FR 10729–10734, Docket No. 93–137–1) an interim rule that amended the animal import regulations in 9 CFR part 92 by requiring that specified identification and recordkeeping requirements be met in the country of export for ratites and ratite hatching eggs intended for importation into the United States. Comments on the interim rule were required to be received on or before May 9, 1994.

So that we may consider comments received after that date, we are extending and reopening the public comment period until 15 days after publication of this notice. During this period, other interested persons may also submit their comments for our consideration. Therefore, in this document, we are reopening and extending the comment period on Docket No. 93–137–1, so that we may consider all written comments received on or before July 20, 1994.

Authority: 7 U.S.C. 1622, 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC, this 29th day of June 1994.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 94–16201 Filed 7–1–94; 8:45 am]

BILLING CODE 3410–34–P

Food Safety and Inspection Service

9 CFR Chapter III

[Docket No. 94–019N]

Use of Direct Final Rulemaking

AGENCY: Food Safety and Inspection Service.

ACTION: Policy statement.

SUMMARY: The Food Safety and Inspection Service is implementing a new rulemaking procedure to expedite noncontroversial changes to its regulations. Rules that the agency judges to be noncontroversial and unlikely to result in adverse comments will be published as "direct final" rules. "Adverse comments" are comments that suggest that a rule should not be adopted or suggest that a change should be made to the rule. Each direct final rule will advise the public that no adverse comments are anticipated and that unless written adverse comments or written notice of intent to submit adverse comments are received within 30 days, the revision made by the rule will be effective 60 days from the date the direct final rule is published in the **Federal Register**. This new policy should expedite the promulgation of routine or otherwise noncontroversial rules by reducing the time that would be required to develop, review, clear, and publish separate proposed and final rules.

FOR FURTHER INFORMATION CONTACT: Paula M. Cohen, Director, Regulations Development, Policy, Evaluation and Planning Staff, Room 3812 South Agriculture Building, 14th and Independence Avenue SW., Washington, DC 20250–3700; (202) 720–7164.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) is committed to improving the efficiency of our regulatory process. As such, we plan to adopt the rulemaking technique known as "direct final rulemaking," which will be used to promulgate some of FSIS' rules.

The Direct Final Rule Process

Rules that FSIS judges to be noncontroversial and unlikely to generate adverse comments will be published as direct final rules. Such direct final rules will advise the public that no adverse comments are anticipated and that unless written adverse comments or written notice of intent to submit adverse comments are received within 30 days, the revision made by the rule will be effective 60 days from the date the direct final rule is published in the **Federal Register**.

"Adverse comments" are comments that suggest that the rule should not be adopted or that a change should be made to the rule. A comment expressing support for the rule as published would not be considered adverse. Also, a comment suggesting that requirements in the rule should, or should not, be employed by FSIS in programs or situations outside the scope of the direct final rule would not be considered adverse.

In accordance with the rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553), this procedure gives the public general notice of FSIS' intent to revise or adopt a new rule and gives interested persons an opportunity to participate in the rulemaking through submission of comments. The major feature of direct final rulemaking is that if FSIS receives no written adverse comments within 30 days of the publication of a direct final rule or any written notice of intent to submit adverse comments, the rule will become effective without the need to publish a separate final rule. However,

FSIS will publish notice in the **Federal Register** stating that no written adverse comments and no written notice of intent to submit adverse comments were received regarding the direct final rule, and confirming that the direct final rule is effective on the date stated in the direct final rule.

If FSIS receives written adverse comments or written notice of intent to submit adverse comments within 30 days of the publication of a direct final rule, FSIS will publish in the **Federal Register** a notice of withdrawal of the direct final rule. If FSIS intends to proceed with the rulemaking, the direct final rule will be republished as a proposed rule, and we will proceed through the normal notice-and-comment rulemaking procedures.

Determining When To Use Direct Final Rulemaking

Not all FSIS rules are good candidates for direct final rulemaking. We intend to use the direct final procedure only for rules that we consider noncontroversial and unlikely to generate adverse comments. The decision to use direct final rulemaking for particular situations will be based on FSIS' experience with similar rules.

Done in Washington, DC., on June 27, 1994.

William J. Hudnall,

Acting Administrator.

[FR Doc. 94–16109 Filed 7–1–94; 8:45 am]

BILLING CODE 3410–DM–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 33, and 190

Risk Disclosure by Futures Commission Merchants, Introducing Brokers, Commodity Pool Operators and Commodity Trading Advisors to Customers; Bankruptcy Disclosure

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rules.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is amending its rules to permit registrants to deliver to customers a generic risk disclosure statement which will satisfy risk disclosure requirements applicable to domestic and foreign commodity futures and commodity option transactions subject to regulation by the Commission. The Commission also is permitting such statement to substitute for the special disclosure requirement related to futures-style margining of the options premium permitted on certain foreign exchanges. The generic statement may be used by firms subject to CFTC jurisdiction in lieu of the separate disclosure statements that will continue to be authorized by Commission rules. The statement, which was developed in cooperation with various international regulators, also is intended to satisfy the risk disclosure requirements of certain foreign jurisdictions who have implemented the language of this proposed risk disclosure statement in their jurisdictions in accordance with their domestic law.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: Jane C. Kang, Esq., or Robert H. Rosenfeld, Esq., Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581; telephone (202) 254–8955.

SUPPLEMENTARY INFORMATION:

Background

On March 30, 1993, the Commodity Futures Trading Commission (Commission) approved for publication in the **Federal Register** amendments to its rules 1.55, 30.6, 33.7, 180.3, 190.06 and 190.10.[1] Among other things, the rule amendments consolidated the foreign futures and foreign commodity options risk disclosure statement required by rule 30.6 with the domestic futures risk disclosure statement required by rule 1.55.

In addition, rule 1.55 was amended to provide in paragraph (c) that the Commission may approve for use in lieu of the prescribed rule 1.55 disclosure statement a risk disclosure statement approved by one or more foreign regulatory agencies or self-regulatory organizations if the Commission determines that such statement is reasonably calculated to provide the disclosures specified by rule 1.55. Rule 1.55(c) was adopted by the Commission to permit firms doing multinational business to use the same risk disclosure statement for foreign and U.S.-based business, thereby reducing duplicative disclosure requirements without sacrificing important customer protections or obscuring any special risks of trading outside the U.S.[2]

Although initially addressed to the approval of the individual disclosure statements of a particular jurisdiction, the Commission in proposing the amendments to, among others, rule 1.55, stated that the rule contemplates a mechanism for eventually substituting a uniform disclosure format, accepted internationally, that could be used on a general basis and supplemented as warranted for particular kinds of transactions or special markets.[3]

The Commission also noted that it was considering development of a "plain language" option disclosure statement and requested comment concerning the desirability of developing a simpler options disclosure statement and other possible improvements.[4] Generally, the commenters who addressed this issue supported the development of a plain language generic options risk disclosure statement and also encouraged the Commission to consider incorporating the required options disclosure into the revised rule 1.55 statement. However, the Commission deferred taking such action pending the outcome of international efforts to develop a consolidated futures and options statement.[5]

In this connection, the Commission stated that certain international regulators were endeavoring to develop a single risk disclosure statement that would be acceptable in multiple jurisdictions for domestic and cross-border transactions in futures and options and stated that:[6]

> The Commission is monitoring developments in this area and anticipates that if a universal statement of this nature is developed, it will consider permitting the use of such a statement in lieu of the new consolidated rule 1.55 risk disclosure statement as well as the options disclosure statement required by rule 33.7.

On January 5, 1994, the Commission approved for publication in the Federal **Register** an advance notice of proposed rulemaking which requested comment on the text of a two-page generic risk disclosure statement then the subject of multilateral discussions among international regulators.[7] The proposed text was intended to meet the risk disclosure requirements for both domestic and foreign commodity futures and commodity option products subject

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[1] 58 FR 17495 (April 5, 1993). On May 5, 1994, the Commission also proposed substantial revisions to the disclosure framework applicable to commodity pool operators (CPOs) and commodity trading advisors (CTAs) designed to achieve greater simplicity, focus and clarity in performance history presentation, streamlining other required disclosures and a more concise and readable format for disclosure documents. 59 FR 25351 (May 16, 1994). If adopted, these changes would substitute Part 4 disclosure for rule 1.55 disclosure in certain cases.

[2] *See* 57 FR 46101, 46103 (October 7, 1992).

[3] 57 FR 46101, 46103–46104 (October 7, 1992).

[4] 57 FR 46101, 46108 (October 7, 1992).

[5] 58 FR 17495, 17502 (April 5, 1993).

[6] 58 FR 17495, 17497 (April 5, 1993).

[7] 59 FR 1506, 1508 (January 11, 1994).

to regulation by the CFTC and thereby substitute for the statements required by rules 1.55, 33.7 and 190.10 as well as the special disclosures related to futures-style margining of options permitted on certain foreign exchanges.[8]

Comments on Advance Notice and Related Text Modifications

The Commission received comments from the National Futures Association (NFA), the Futures Industry Association (FIA), the Chicago Mercantile Exchange (CME), the Business Law Section of the American Bar Association (ABA), and Schulte Roth & Zabel (SRZ), a law firm. All commenters generally supported the Commission's proposal for a broader consolidated risk disclosure statement. The commenters particularly supported substituting the generic risk disclosure statement for the current rule 33.7 statement for domestic exchange-traded commodity options. The commenters generally believed that consolidation of risk disclosure statements into one concise document could increase the clarity of generic disclosure to customers and make the disclosure statement a more effective customer protection mechanism by focusing customers' attention on particular risks and upon obtaining adequate information on risks.

In response to the Commission's query whether use of the generic statement should be made mandatory or discretionary, and whether any distinctions should be made with respect to the type of firm that should be permitted to use the generic statement, commenters urged the Commission not to eliminate the current risk disclosure statement(s) but rather to permit firms to choose which disclosure statement(s) to provide to customers. For example, firms may not wish to redesign and reprint disclosure statements.

The Commission, therefore, agrees that all firms (without regard to whether the firms engage in cross-border business) should have the flexibility to determine whether they distribute to customers the new generic disclosure statement or the existing separate risk disclosure statements referred to above.

Several commenters stated that the section on electronic execution systems needed clarification. Specifically, as published in the advance notice, paragraph 11 of the generic statement on electronic trading referred to the possibility that losses resulting from systems failure may be subject to limitations on liability. Commenters noted that liability limitations are not unique to electronic trade execution systems and may have the unintended implication that such systems are less safe than floor-based systems. They recommended that this language appear in the section on trading facilities (paragraph 10), which applies to all trading systems (floor and electronic). The Commission agrees that both floor and electronic trading venues are supported by systems for which certain types of features are beyond the control of the exchange and that liability limitations may apply to such features. As a consequence it believes that the foregoing alteration of the text is appropriate and is more satisfactory to the international regulators who are considering adoption of the generic risk disclosure statement, some of which only have electronic systems.[9] The Commission therefore has amended the language accordingly.

The advance notice of proposed rulemaking on the generic risk disclosure statement noted that an additional topic addressed in the generic statement was the risks of off-exchange trading. In particular, the informational working group drafting the generic statement concluded that such a provision, if worded appropriately, would not mislead or confuse customers in those jurisdictions which, for example, do not permit retail customers to participate in off-exchange markets. Although the Commission received no comments on this provision, in view of current public discussions related to over-the-counter derivatives, the Commission has decided to add the words "and attendant risks" at the end of paragraph 12 to enhance relevant disclosure in this regard. The Commission notes in this regard that the generic risk statement is intended to cause a customer to ask additional questions of its broker.

Some commenters raised concerns as to the reference in paragraph 1 of the proposed disclosure statement regarding the time frame for meeting margin calls. They believed the reference could be construed as overriding the terms set forth in a customer account agreement between the firm and its customer. The Commission wishes to clarify that the language of the generic risk disclosure statement is not intended to modify the terms and conditions of a firm's customer account agreement concerning the timing of margin payments (provided that these are consistent with the Commodity Exchange Act (CEA)) but to call to the customer's attention generally that failure to post margin can have significant consequences.

One commenter suggested that in order to alleviate the paperwork burden on registrants, the Commission should not require inclusion in the risk disclosure statement that is delivered to customers the Addendum that sets forth the participating jurisdictions which have adopted the generic statement and the products for which the statement may be used. Although the Commission believes that the Addendum is necessary to enable firms to ensure that use of the generic statement for a particular product is in compliance with the applicable risk disclosure requirements of various jurisdictions, the Addendum ordinarily should not be necessary for customers who should receive additional or different disclosure if the generic statement is not accepted by a particular jurisdiction or for a particular product.[10] Otherwise, although the Commission intends to publish, amend and update, as appropriate, the Addendum to the generic risk disclosure statement, the Commission agrees that apart from the limitations on its use in the U.S. to futures, options on futures and options on commodities, the Addendum listing participating jurisdictions need not be made part of the disclosure document itself. Firms may, however, elect to include the Addendum as long as it appears on a separate page after the actual risk disclosure text.

In its advance notice, the Commission noted that the elimination of a Commission mandated description of options trading and other educational material from the mandated risk

[8] *See, e.g.*, CFTC Advisory No. 90–1 [1987–1990 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶24,597 (disclosure statement relating to the deferred payment of option premiums, superseding separate disclosure addenda required by orders concerning the London International Financial Futures Exchange (54 FR 37636 (September 12, 1989)), the International Petroleum Exchange (54 FR 50356 (December 6, 1989)), and the London Futures and Options Exchange (renamed as the London Commodity Exchange) (54 FR 50348 (December 6, 1989)); and 55 FR 14238 (April 17, 1990) (Sydney Futures Exchange). The text of the generic risk disclosure statement regarding futures-style margining of the options premium is substantially similar to the language of the addenda referred to above.

[9] The international regulators currently prepared to permit the use of the generic risk disclosure statement in their jurisdictions and the products for which the statement may be used are specified in the Addendum to the statement. The Commission intends to update and amend the list periodically, as appropriate, in the **Federal Register**. In addition, the Commission notes that notwithstanding the adoption of the generic risk disclosure statement by a foreign jurisdiction, other disclosure requirements may continue in effect in such jurisdictions.

[10] It is, however, important in the U.S. that there be no possible confusion as to what disclosure is required for options on equities, which are governed by U.S. securities laws. In order to be used in the U.S., therefore, the Addendum must reflect the products for which use of the generic risk disclosure statement is permitted.

disclosure statement does not mean that firms do not have the obligation to provide all material disclosures consistent with the product traded and level of experience, sophistication and financial capacity of customers in compliance with Commission and NFA rules.[11] One commenter believed that the streamlined disclosure statement was sufficient and that if the Commission believes that additional disclosures are necessary that it provide specific guidance on this issue.

As discussed by the Commission when it adopted rule 1.55(d) (currently rule 1.55(f)), the obligations of a futures commission merchant (FCM) and introducing broker (IB) to disclose material information to customers arise under the CEA and other applicable law. The Commission further noted that the essential purpose of the rule was to confirm the existing obligations of an FCM or IB under the law and to make clear that distribution of a standard disclosure statement was not intended to alter those obligations.[12]

Because the nature and extent of the disclosure which an FCM or IB may be required to make to a customer necessarily must depend on the facts and circumstances of the particular transaction and also on the precise nature of the FCM's or IB's relationship to the customer, any attempt by the Commission to enumerate the precise scope and form of disclosure for all conceivable customer relationships, products and trading strategies would be difficult to accomplish and would diminish the impact of the generic statement which is intended to highlight the significant risks of futures and options trading and the areas where customers should seek additional particularized information.[13] These considerations continue to apply to the current rulemaking, which is intended to consolidate and improve the mandated disclosure process. Accordingly, nothing in the current rulemaking should be construed as reducing the existing obligation to make all disclosures required under applicable law.

Finally, one commenter suggested that the acknowledgement requirement should be eliminated with respect to sophisticated investors. The CFTC has determined not to address this matter at this time.

Procedure—Final Rule Amendments

When the Commission issued its advance notice concerning the proposed text of a generic disclosure statement that could be adopted by several jurisdictions regulating futures and options transactions, the Commission contemplated that a further comment process could be necessary. However, for the reasons noted below, the Commission believes that a complete rulemaking record has been compiled and that further proposal of the text of the generic risk disclosure statement is unnecessary.

Public comments received on the advance notice were unanimous in recommending the adoption of the generic risk disclosure statement (subject to minor revision), including substituting the proposed generic statement for the rule 33.7 statement for domestic exchange-traded commodity options and the statement required by rule 190.10 for non-cash deposits as margin.[14] Second, the Commission received comment on the generic risk disclosure proposal in connection with the recent amendments consolidating rules 1.55 and 30.6, which contemplated Commission approval of the substitution of a document which can be used in multiple jurisdictions.[15] Third, as provided herein, the use of the generic risk disclosure is not mandatory, *i.e.*, the language *may* be used but is not required to be substituted for the statements now required by rules 1.55, 33.7 and 190.10(c) and other disclosure requirements set forth in the advance notice.

Accordingly, the final rules amend §§ 1.55(c), 33.7 and 190.10(c) to incorporate text which permits registrants to satisfy the requirements of rules 1.55, 33.7 and 190.10(c) by substituting the generic risk disclosure statement as set forth below, which will be published in a new appendix to part 1 of the Commission's regulations. The Commission also clarifies herein that the generic risk disclosure statement may be used in lieu of the special disclosure addendum to rule 33.7 in connection with transactions on certain foreign exchanges which do not collect the full option premium.

Effect of Alternate Disclosure Statement

The Commission is hereby permitting the generic risk disclosure statement set forth herein in appendix A to rule 1.55(c) to be used in lieu of the statements required by rules 1.55 (which incorporates the risk-disclosure contained in Commission rule 30.6 for foreign futures and foreign commodity options), rule 33.7 (domestic exchange-traded commodity options) and the special bankruptcy disclosures of Commission rule 190.10(c) related to the acceptance of non-cash margin.

The approval of the generic risk disclosure statement is not intended to alter disclosure requirements other than those specifically addressed. For example, the disclosure statement would be required to be delivered prior to the opening of the account and the acknowledgement and manner of delivery of the disclosure statement (*i.e.*, as a separate written statement or in a booklet) would not be altered. The Commission also would not change the requirement that compliance with requirements related to providing customers with risk disclosure statements does not relieve an FCM or IB from any other disclosure obligation it may have under applicable law.[16] Similarly, the single signature acknowledgment procedure contained in rule 1.55(d) would continue to apply[17] as will the amendment to CFTC rule 190.10(c) eliminating the requirement that the prescribed

[11] 59 FR 1506, 1507 (January 11, 1994), *citing* Commission rule 1.55(f), which provides that: "This section [requiring distribution of a risk disclosure statement] does not relieve a futures commission merchant or introducing broker from any other disclosure obligation it may have under applicable law." *See also* NFA Compliance Rule 2–30 ("know your customer" rule).

[12] See 50 FR 5380 (February 8, 1985).

[13] The extent of these obligations is constantly being defined on a case-by-case basis in administrative and reparations proceedings and civil actions. Further, the language of the generic risk disclosure statement specifically directs the customer to elicit further information from the broker on certain issues.

[14] 59 FR 1506, 1508 (January 11, 1994). In addition to expressly inviting public comment on the draft text of the generic risk disclosure statement to substitute for current disclosures contained in rules 1.55, 33.7, 190.10 and Commission orders and Advisories regarding disclosures related to futures-style margining of options premium allowed by certain foreign exchanges, the Commission also requested comment on whether the statement would be most useful if made mandatory and whether its use should be limited to firms doing cross-border business or more broadly.

[15] 58 FR 17495, 17497 (April 5, 1993); 57 FR 46101, 46103 (October 7, 1992).

[16] In addition to clarifying that firms have an obligation to disclose all material facts, the Commission also wishes to clarify that firms must comply with the disclosure obligations imposed by other regulatory authorities, U.S. or foreign.

[17] The Commission wishes to reiterate that the single signature acknowledgment format may *not* generally be used for the endorsements required by rule 180.3 with respect to arbitration and other dispute resolution agreements *except* with respect to Qualified Eligible Participants (QEPs) as defined in rule 4.7(a)(1)(ii) and for certain persons or entities specifically within the scope of rule 4.5(a). *See* rule 180.3(b)(2) (as amended by 58 FR 17495 (April 5, 1993)). Nor would the single acknowledgment affect the obligation of an FCM or IB to obtain, by instrument separate and apart from the customer agreement, a customer's consent that the FCM may knowingly take the other side of a customer's order, or to transfer funds from a customer's segregated account to an account that is not segregated. *See* discussion in 58 FR 17495, 17499 (April 5, 1993).

disclosure concerning the treatment of non-cash margin in FCM bankruptcies be acknowledged.[18]

The distribution of the generic risk disclosure statement also could substitute for the special disclosure requirements related to futures-style margining of option premiums permitted on certain foreign exchanges.

The generic risk disclosure statement would not, however, alter the separate disclosure requirements concerning electronic trading systems or trading linkages between domestic and foreign futures exchanges that may be mandated by U.S. self-regulatory organizations.[19]

Finally, the Commission notes that if a firm elects to use the generic risk disclosure statement rather than the statement required by rule 190.10(c), and uses a separate subordination agreement required by Financial and Segregation Interpretation No. 12—"Deposit of Customer Funds in Foreign Depositories" for customers depositing margin in foreign depositories,[20] that statement must be separately acknowledged.[21] A separate signature also would continue to be necessary where subordination or similar consent to contractual modification of certain rights is required for other purposes, such as for participation in cross-margining programs.[22]

Separate Statement

In its previous revision of rule 1.55, the Commission included an amendment intended to clarify that the prescribed risk disclosure statement may be provided as a physically separate document or in a booklet containing other commodity interest account materials, as long as the rule 1.55 risk disclosure statement appears as the cover page or the first page, and is the only material on such page, by which it means the page immediately following the cover page.

As the generic statement requires approximately two pages of printed text, the statement may appear on more than one page, provided that it is the only text that appears on those pages.

Application to Rule 30.3 and 30.10 Orders

After the effective date of these rule amendments, all firms operating pursuant to confirmed rule 30.10 relief,[23] and firms complying with the terms of an outstanding order under rule 30.3 may elect to use the generic risk disclosure statement or the risk disclosure statements mandated by rules 1.55 and 33.7 and applicable Commission orders, as appropriate.[24]

Timetable for Implementation

Under the most recent disclosure revisions, the Commission stated that firms would be permitted to use existing disclosure statements (*i.e.*, either separate rule 1.55, 30.6, 33.7 and 190.10(c) documents) up to and including July 1, 1994.[25]

Although the Commission intends for the current rulemaking to take effect upon the publication of this **Federal Register** release, the Commission is permitting firms for a period not to exceed sixty days after the date herein to continue to use the separate statements contained in rules 1.55 and 30.6.

Accordingly, after the date herein, firms may use either the new generic risk disclosure statement or the revised rule 1.55 risk disclosure statement (which incorporates the rule 30.6 disclosure statement) or, for a period not to exceed sixty days after the effective date of this **Federal Register** release, the separate rule 1.55 and rule 30.6 risk disclosure statements to comply with relevant risk disclosure obligations.[26]

Amendment of CFR

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (PRA), 44 U.S.C. 3501 *et seq.*, imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the Paperwork Reduction Act. The amendments to rules 1.55, 33.7 and 190.10 do not change the burdens associated with those rules. The groups of rules of which they are a part have the following burdens:

Rule 33.7—(3038–0007)
- Average Burden Hours Per Response—50.32
- Number of Respondents—190,197
- Frequency of Response—Occasionally

Rule 190.10—(3038–0021)
- Average Burden Hours—0.35
- Number of Respondents—802
- Frequency of Response—Occasionally
- No additional burden is associated with the amendments to rules 33.7 and 190.10.

The burden associated with the group which encompasses rules 1.55, 180.3 and rule 1.65 is:

Rules 1.55, 180.3 and 1.65—(3038–0022)
- Average Burden Hours Per Response—613.26
- Number of Respondents—4295
- Frequency of Response—Occasionally

No additional burden is associated with the amendments to rule 1.55.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. § 601 *et seq.*, requires that agencies, in proposing rules, consider the impact of these rules on small business. In this connection, the Commission previously has determined that FCMs and Commodity Pool Operators should not be considered small entities for purposes of the RFA.[27] With respect to IBs and Commodity Trading Advisors (CTAs), the Commission has stated that it would evaluate within the context of each proposal whether all or some IBs and CTAs should be considered small entities, and if so, that it would analyze the economic impact on them of any rule.[28] Because the proposed amendments to the Commission rules discussed herein will not result in any significant additional burdens to the above mentioned registrants and may in practice result in a reduction of certain

[18] The Commission notes that the generic statement discloses more clearly than the statement in CFTC rule 190.10(c) that cash and non-cash margin may be subject to the same treatment in the event of a firm bankruptcy.

[19] *See* 58 FR 17495, 17496, n.7 (April 5, 1993) *citing*, for example, NFA Compliance Rule 2–28, CME rule 874 and Commodity Exchange Inc. rule 5.14 (addressing risk disclosure requirements applicable to foreign futures and options as a result of trading linkages between domestic and foreign exchanges). *See also* CME rule 577 and Chicago Board of Trade rule 9A.20 which address the risk disclosure requirements applicable to users of GLOBEX, and New York Mercantile Exchange rule 6.22 which addresses the risk disclosure requirements applicable to the users of the ACCESS electronic trading system.

[20] *See* 53 FR 46911 (November 21, 1988). The Commission stated that the subordination agreement discussed in Financial and Segregation Interpretation No. 12 may be incorporated into the rule 190.10(c) bankruptcy disclosure document or separately executed. *Id.* at 46913–46914.

[21] Separate acknowledgement of the rule 190.10(c)(2) disclosure statement in this context is a substitute for execution of a separate subordination agreement.

[22] *Id.*, *citing* "Financial and Segregation Interpretation No. 12."

[23] Firms operating pursuant to Commission rule 30.10 relief had been permitted to comply with the risk disclosure requirements set forth in the relevant Commission orders, *i.e.*, they could continue to use the text of rule 30.6 as published prior to the 1993 revisions to Commission rules 1.55 and 30.6 (which incorporated the rule 30.6 disclosures for foreign futures into the rule 1.55 disclosures for domestic futures) (*see* 58 FR 17496 (April 5, 1993)).

[24] *See, e.g.*, CFTC Advisory No. 90–1 [1987–1990 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶24,597 (disclosure statement relating to the deferred payment of option premiums for options).

[25] *See* 58 FR 17495, 17497 (April 5, 1993).

[26] *See* no action letter of the CFTC's Division of Trading and Markets dated June 8, 1994 regarding the July 1, 1994 effective date of the revised rule 1.55 risk disclosure statement.

[27] 47 FR 18618 (April 30, 1982).

[28] *Id.* (CTAs) and 48 FR 35248, 35276 (August 3, 1983) (IBs).

existing burdens, the Commission believes that the proposed rule amendments will not have a significant economic impact on such entities. Therefore, pursuant to section 3(a) of the RFA, 5 U.S.C. § 605(b), the Acting Chairman of the Commission certifies that these proposed rule amendments will not have a significant economic impact on a substantial number of small entities.

List of Subjects

17 CFR Part 1

Commodity futures, Domestic exchange-traded commodity option transactions.

17 CFR Part 33

Commodity futures, Domestic exchange-traded commodity option transactions.

17 CFR Part 190

Bankruptcy.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act, and in particular, sections 2(a)(1), 4b, 4d, 4f and 8a of the Act, as amended, 7 U.S.C. 2, 6b, 6d, 6f and 12a, the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 6p, 7, 7a, 7b, 8, 9, 12, 12a, 12c, 13a, 13a-1, 16, 16a, 19, 21, 23 and 24.

2. Section 1.55 is amended by revising paragraph (c) and by adding a new Appendix A to read as follows:

§ 1.55 Distribution of "Risk Disclosure Statement" by futures commission merchants and introducing brokers.

* * * * *

(c) The Commission may approve for use in lieu of the risk disclosure document required by paragraph (b) of this section a risk disclosure statement approved by one or more foreign regulatory agencies or self-regulatory organizations if the Commission determines that such risk disclosure statement is reasonably calculated to provide the disclosure required by paragraph (b) of this section. Notice of risk disclosure statements that may be used to satisfy Commission disclosure requirements, what requirements such statements meet and the jurisdictions which accept each format will be set forth in appendix A to this section.

* * * * *

Appendix A to CFTC Rule 1.55(c)—Generic Risk Disclosure Statement

Risk Disclosure Statement for Futures and Options

This brief statement does not disclose all of the risks and other significant aspects of trading in futures and options. In light of the risks, you should undertake such transactions only if you understand the nature of the contracts (and contractual relationships) into which you are entering and the extent of your exposure to risk. Trading in futures and options is not suitable for many members of the public. You should carefully consider whether trading is appropriate for you in light of your experience, objectives, financial resources and other relevant circumstances.

Futures

1. Effect of 'Leverage' or 'Gearing'

Transactions in futures carry a high degree of risk. The amount of initial margin is small relative to the value of the futures contract so that transactions are 'leveraged' or 'geared'. A relatively small market movement will have a proportionately larger impact on the funds you have deposited or will have to deposit: this may work against you as well as for you. You may sustain a total loss of initial margin funds and any additional funds deposited with the firm to maintain your position. If the market moves against your position or margin levels are increased, you may be called upon to pay substantial additional funds on short notice to maintain your position. If you fail to comply with a request for additional funds within the time prescribed, your position may be liquidated at a loss and you will be liable for any resulting deficit.

2. Risk-reducing orders or strategies

The placing of certain orders (e.g. 'stop-loss' orders, where permitted under local law, or 'stop-limit' orders) which are intended to limit losses to certain amounts may not be effective because market conditions may make it impossible to execute such orders. Strategies using combinations of positions, such as 'spread' and 'straddle' positions may be as risky as taking simple 'long' or 'short' positions.

Options

3. Variable degree of risk

Transactions in options carry a high degree of risk. Purchasers and sellers of options should familiarize themselves with the type of option (i.e. put or call) which they contemplate trading and the associated risks. You should calculate the extent to which the value of the options must increase for your position to become profitable, taking into account the premium and all transaction costs.

The purchaser of options may offset or exercise the options or allow the options to expire. The exercise of an option results either in a cash settlement or in the purchaser acquiring or delivering the underlying interest. If the option is on a future, the purchaser will acquire a futures position with associated liabilities for margin (see the section on Futures above). If the purchased options expire worthless, you will suffer a total loss of your investment which will consist of the option premium plus transaction costs. If you are contemplating purchasing deep-out-of-the-money options, you should be aware that the chance of such options becoming profitable ordinarily is remote.

Selling ('writing' or 'granting') an option generally entails considerably greater risk than purchasing options. Although the premium received by the seller is fixed, the seller may sustain a loss well in excess of that amount. The seller will be liable for additional margin to maintain the position if the market moves unfavorably. The seller will also be exposed to the risk of the purchaser exercising the option and the seller will be obligated to either settle the option in cash or to acquire or deliver the underlying interest. If the option is on a future, the seller will acquire a position in a future with associated liabilities for margin (see the section on Futures above). If the option is 'covered' by the seller holding a corresponding position in the underlying interest or a future or another option, the risk may be reduced. If the option is not covered, the risk of loss can be unlimited.

Certain exchanges in some jurisdictions permit deferred payment of the option premium, exposing the purchaser to liability for margin payments not exceeding the amount of the premium. The purchaser is still subject to the risk of losing the premium and transaction costs. When the option is exercised or expires, the purchaser is responsible for any unpaid premium outstanding at that time.

Additional risks common to futures and options

4. Terms and conditions of contracts

You should ask the firm with which you deal about the terms and conditions of the specific futures or options which you are trading and associated obligations (e.g. the circumstances under which you may become obligated to make or take delivery of the underlying interest of a futures contract and, in respect of options, expiration dates and restrictions on the time for exercise). Under certain circumstances the specifications of outstanding contracts (including the exercise price of an option) may be modified by the exchange or clearing house to reflect changes in the underlying interest.

5. Suspension or restriction of trading and pricing relationships

Market conditions (e.g. illiquidity) and/or the operation of the rules of certain markets (e.g. the suspension of trading in any contract or contract month because of price limits or "circuit breakers") may increase the risk of loss by making it difficult or impossible to effect transactions or liquidate/offset positions. If you have sold options, this may increase the risk of loss.

Further, normal pricing relationships between the underlying interest and the future, and the underlying interest and the option may not exist. This can occur when, for example, the futures contract underlying the option is subject to price limits while the option is not. The absence of an underlying reference price may make it difficult to judge "fair" value.

6. Deposited cash and property

You should familiarize yourself with the protections accorded money or other property you deposit for domestic and foreign transactions, particularly in the event of a firm insolvency or bankruptcy. The extent to which you may recover your money or property may be governed by specific legislation or local rules. In some jurisdictions, property which had been specifically identifiable as your own will be pro-rated in the same manner as cash for purposes of distribution in the event of a shortfall.

7. Commission and other charges

Before you begin to trade, you should obtain a clear explanation of all commission, fees and other charges for which you will be liable. These charges will affect your net profit (if any) or increase your loss.

8. Transactions in other jurisdictions

Transactions on markets in other jurisdictions, including markets formally linked to a domestic market, may expose you to additional risk. Such markets may be subject to regulation which may offer different or diminished investor protection. Before you trade you should enquire about any rules relevant to your particular transactions. Your local regulatory authority will be unable to compel the enforcement of the rules of regulatory authorities or markets in other jurisdictions where your transactions have been effected. You should ask the firm with which you deal for details about the types of redress available in both your home jurisdiction and other relevant jurisdictions before you start to trade.

9. Currency risks

The profit or loss in transactions in foreign currency-denominated contracts (whether they are traded in your own or another jurisdiction) will be affected by fluctuations in currency rates where there is a need to convert from the currency denomination of the contract to another currency.

10. Trading facilities

Most open-outcry and electronic trading facilities are supported by computer-based component systems for the order-routing, execution, matching, registration or clearing of trades. As with all facilities and systems, they are vulnerable to temporary disruption or failure. Your ability to recover certain losses may be subject to limits on liability imposed by the system provider, the market, the clearing house and/or member firms. Such limits may vary: you should ask the firm with which you deal for details in this respect.

11. Electronic trading

Trading on an electronic trading system may differ not only from trading in an open-outcry market but also from trading on other electronic trading systems. If you undertake transactions on an electronic trading system, you will be exposed to risks associated with the system including the failure of hardware and software. The result of any system failure may be that your order is either not executed according to your instructions or is not executed at all.

12. Off-exchange transactions

In some jurisdictions, and only then in restricted circumstances, firms are permitted to effect off-exchange transactions. The firm with which you deal may be acting as your counterparty to the transaction. It may be difficult or impossible to liquidate an existing position, to assess the value, to determine a fair price or to assess the exposure to risk. For these reasons, these transactions may involve increased risks. Off-exchange transactions may be less regulated or subject to a separate regulatory regime. Before you undertake such transactions, you should familiarize yourself with applicable rules and attendant risks.

I hereby acknowledge that I have received and understood this risk disclosure statement.

Date

Signature of Customer

* * * * *

[The following language should be printed on a page other than the pages containing the disclosure language above and may be omitted from the required disclosure statement]

This disclosure document meets the risk disclosure requirements in the jurisdictions identified below ONLY for those instruments which are specified.

United States: commodity futures and options on commodity futures subject to the Commodity Exchange Act

[other jurisdictions: etc.]

PART 33—REGULATION OF DOMESTIC EXCHANGE-TRADED COMMODITY OPTION TRANSACTIONS

3. The authority citation for this part continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 7, 7a, 7b, 8, 9, 11, 12a, 12c, 13a, 13a-1, 13b, 19 and 21, unless otherwise noted.

4. Section 33.7 is amended by revising paragraph (a)(1)(i) as follows:

§ 33.7 Disclosure.

(a)(1) * * *

(i) Furnishes the option customer with a separate written disclosure statement as set forth in this section or another statement approved under § 1.55(c) of this chapter and set forth in appendix A to § 1.55 which the Commission finds satisfies this requirement, or includes either such statement in a booklet containing the customer account agreement and other disclosure statements required by Commission rules; *provided, however,* that if the statement contained in § 33.7 is used it must follow the statement required by § 1.55; and

* * * * *

PART 190—BANKRUPTCY RULES

5. The authority citation for part 190 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4a, 6c, 6d, 6g, 7, 7a, 12, 19, 23, and 24 and 11 U.S.C. 362, 546, 548, 556 and 761–766.

6. Section 190.10 is amended by revising paragraph (c)(1) as follows:

§ 190.10 General.

* * * * *

(c)(1) *Disclosure statement for non-cash margin.* (1) Except as provided in §§ 1.65, no commodity broker (other than a clearing organization) may accept property other than cash from or for the account of a customer to margin, guarantee, or secure a commodity contract unless, the commodity broker first furnishes the customer with the disclosure statement set forth in paragraph (c)(2) of this section in boldface print in at least 10 point type which may be provided as either a separate, written document or incorporated into the customer agreement, or with another statement approved under § 1.55(c) of this chapter and set forth in appendix A to § 1.55 which the Commission finds satisfies this requirement.

* * * * *

Issued in Washington, DC, on June 28, 1994 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 94–16119 Filed 7–1–94; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Parts 90 and 91

Revitalizing Base Closure Communities and Community Assistance

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Interim final rule; extension of comment period.

SUMMARY: On Wednesday, April 6, 1994, the Department of Defense published an interim final rule (59 FR 16123) and a proposed rule (59 FR 16157) regarding Revitalizing Base Closure Communities. Public comments on both the interim final rule and the proposed rule were required by July 5, 1994. The comment period on the interim final rule is being extended until August 5, 1994, due to the high level of interest, the complexity of the issues raised in public comments received to date and DoD's decision to hold a public hearing before publishing the final rule. The comment period on the proposed rule is not being extended and expires on July 5, 1994.

DATES: Comments on the interim final rule must now be received by August 5, 1994.

FOR FURTHER INFORMATION CONTACT: Steven Kleiman or Frank Savat, telephone 703–614–5356.

Dated: June 28, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–16117 Filed 7–1–94; 8:45 am]

BILLING CODE 5000–04–M

32 CFR Parts 383 and 389

Organizational Charters

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Final rule.

SUMMARY: The Department of Defense hereby removes 32 CFR parts 383 and 389 concerning internal organizations. These parts have served the purpose for which they were intended and are no longer valid.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: L.M. Bynum, Correspondence and Directives Directorate, 1155 Defense Pentagon, Washington, DC 20301–1155 (703–697–4111).

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 383 and 389

Organization and functions (Government agencies).

PARTS 383 AND 389—[REMOVED]

Accordingly, by the authority of 10 U.S.C. 301, 32 CFR parts 383 and 389 are removed.

Dated: June 29, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–16190 Filed 7–1–94; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AG81

Active Military Service Certified Under Section 401 of Public Law 95–202

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) has amended its regulations concerning persons who are included as having served on active duty. The need for this action results from recent decisions of the Secretary of the Air Force that the service of the group known as "U.S. Civilian Flight Crew and Aviation Ground Support Employees of Northwest Airlines, Who Served Overseas as a Result of Northwest Airline's Contract with the Air Transport Command during the Period December 14, 1941 through August 14, 1945," and the group known as "U.S. Civilian Female Employees of the U.S. Army Nurse Corps While Serving in the Defense of Bataan and Corregidor during the Period January 2, 1942 to February 3, 1945," constitutes active military service in the Armed Forces of the United States for purposes of all laws administered by VA. The effect of this action is to confer veteran status for VA benefit purposes on former members of these groups who were discharged under honorable conditions.

EFFECTIVE DATE: The effective date is December 13, 1993, the date on which the Secretary of the Air Force determined that such service constitutes active duty.

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue NW., Washington, DC 20420, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: Section 401 of Public Law 95–202 authorized the Secretary of Defense to determine whether the service of members of civilian or contractual groups shall be considered active duty for the purposes of all laws administered by VA.

A notice of certification of the following group by the Secretary of the Air Force appeared in the **Federal Register** of January 4, 1994 (59 FR 297): U.S. Civilian Flight Crew and Aviation Ground Support Employees of Northwest Airlines, Who Served Overseas as a Result of Northwest Airline's Contract with the Air Transport Command during the Period December 14, 1941 through August 14, 1945.

A notice of certification of the following group by the Secretary of the Air Force appeared in the **Federal Register** of January 4, 1994 (59 FR 298): U.S. Civilian Female Employees of the U.S. Army Nurse Corps While Serving in the Defense of Bataan and Corregidor During the Period January 2, 1942 to February 3, 1945.

VA is issuing a final rule to amend the provisions of 38 CFR 3.7(x). Because this change implements determinations

of the Secretary of the Air Force in accordance with Public Law 95–202, which are binding on VA, publication as a proposal is unnecessary.

Since a notice of proposed rulemaking is unnecessary and will not be published, this amendment is not a "rule" as defined in and made subject to the Regulatory Flexibility Act (RFA), 5 U.S.C. 601(2). In any case, this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the RFA, 5 U.S.C. 601–612. This amendment will not directly affect any small entity.

There is no affected Catalog of Federal Domestic Assistance program number.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

Approved: June 10, 1994.

Jesse Brown,

Secretary of Veterans Affairs.

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

PART 3—ADJUDICATION

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

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

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

2. In § 3.7, remove the authority citation that appears after paragraph (x)(23) and insert new paragraphs (x)(27) and (x)(28) and an authority citation to read as follows:

§ 3.7 Persons included.

* * * * *

(x) *Active military service certified as such under section 401 of Pub. L. 95–202.* * * *

(27) U.S. Civilian Flight Crew and Aviation Ground Support Employees of Northwest Airlines, Who Served Overseas as a Result of Northwest Airline's Contract with the Air Transport Command during the Period December 14, 1941 through August 14, 1945.

(28) U.S. Civilian Female Employees of the U.S. Army Nurse Corps While Serving in the Defense of Bataan and Corregidor During the Period January 2, 1942 to February 3, 1945.

(Authority: Sec. 401, Pub. L. 95–202, 91 Stat. 1450)

[FR Doc. 94–16115 Filed 7–1–94; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NJ12–2–6314; NY9–2–6315; PR2–2–6316; VI2–2–6317; FRL–5004–6]

Clean Air Act Approval and Promulgation of Title V, Section 507, Small Business Stationary Source Technical and Environmental Compliance Assistance Program for Region 2 States: New Jersey, New York, Puerto Rico, and the U.S. Virgin Islands

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing the conditional approvals to each state implementation plan (SIP) revision submitted by the States of New Jersey and the U.S. Virgin Islands, and the full approvals to each state SIP revision submitted by New York and the Commonwealth of Puerto Rico as proposed in the **Federal Register** on December 21, 1993 for the purpose of establishing State Small Business Stationary Source Technical and Environmental Compliance Assistance Programs (PROGRAMs). The implementation plans were submitted by the states to satisfy the Federal mandate of the Clean Air Act (CAA) to ensure that small businesses have access to the technical assistance and regulatory information necessary to comply with the CAA.

EFFECTIVE DATE: This action is effective on August 4, 1994.

ADDRESSES: Copies of all of the States' submittals and EPA's technical support documents are available for inspection during normal business hours at the EPA Region II Office, 26 Federal Plaza, room 505, New York, New York 10278. In addition, copies of a specific state submittal and EPA's technical support document can be found at the appropriate state office below:

New Jersey—Office of Permit Information and Assistance, New Jersey Department of Environmental Protection and Energy, 401 East State Street, Trenton, NJ 08625–0423, Attention: Chuck McCarty.

New York—Bureau of Technical Services, Air Resources Division, New York State Department of Environmental Conservation, 50 Wolf Road, Albany, NY 12233, Attention: Virginia Rest.

Puerto Rico—Air Programs Area, Puerto Rico Environmental Quality Board, Eurobank Building, 431 Ponce de Leon Avenue, Hato Rey, PR 00910, Attention: Francisco Claudio.

The U.S. Virgin Islands—Virgin Islands Department of Planning and Natural Resources, Division of Environmental Protection, Building 111, Apartment 114, Water Gut Homes, Christiansted, St. Croix, VI 00820, Attention: Benjamin Nazario.

FOR FURTHER INFORMATION CONTACT: Steven C. Riva, Chief, Permitting and Toxics Support Section, at the above EPA address or at telephone number (212) 264–9356.

SUPPLEMENTARY INFORMATION:

I. Background

Implementation of the provisions of the Clean Air Act (CAA), as amended in 1990, will require regulation of many small businesses so that areas may attain and maintain the national ambient air quality standards (NAAQS) and reduce the emission of air toxics. Small businesses frequently lack the technical expertise and financial resources necessary to evaluate such regulations and to determine the appropriate mechanisms for compliance. In anticipation of the impact of these requirements on small businesses, the CAA requires that states adopt a Small Business Stationary Source Technical and Environmental Compliance Assistance Program (PROGRAM), and submit this PROGRAM as a revision to the Federally approved SIP. In addition, the CAA directs the Environmental Protection Agency (EPA) to oversee these small business assistance programs and report to Congress on their implementation The requirements for establishing a PROGRAM are set out in section 507 of Title V of the CAA. In February 1992, EPA issued Guidelines for the Implementation of Section 507 of the 1990 Clean Air Act Amendments (Final Guidelines) in order to delineate the federal and state roles in meeting the new statutory provisions and as a tool to provide further guidance to the states on submitting acceptable SIP revisions.

The States of New Jersey, New York, Puerto Rico, and the U.S. Virgin Islands have submitted SIP revisions to EPA in order to satisfy the requirements of section 507. In order to gain full approval, the state submittal must provide for each of the following PROGRAM components: (1) The establishment of a Small Business Assistance Program (SBAP) to provide technical and compliance assistance to small businesses; (2) the establishment of a State Small Business Ombudsman to represent the interests of small businesses in the regulatory process;

and (3) the creation of a Compliance Advisory Panel (CAP) to determine and report on the overall effectiveness of the SBAP.

EPA proposed to conditionally approve New Jersey's and the U.S. Virgin Islands' SIPs and fully approve New York's and Puerto Rico's SIPs for the establishment of State PROGRAMs on December 21, 1993 (58 FR 67383). A detailed discussion of each state's PROGRAM and EPA's evaluations of the PROGRAMs is contained in the above cited **Federal Register**.

In addition, a thirty day public comment period was provided in the December 21, 1993 **Federal Register**. Comments were received only on New York's PROGRAM. For New Jersey, Puerto Rico, and the U.S. Virgin Islands, no comments were received.

II. Summary of Submittals

A. New Jersey

New Jersey has met all of the requirements of section 507 of the CAA by submitting a SIP revision on January 11, 1993 that implements all required PROGRAM elements or delineates milestone dates for when any remaining PROGRAM elements will be enacted by November 15, 1994. The final plan was adopted by the New Jersey Department of Environmental Protection and Energy (DEPE) on January 11, 1993.

New Jersey has met the first PROGRAM component by locating the SBAP within DEPE's Office of Permit Information and Assistance and by committing in its SIP to meet the six requirements set forth in section 507(a) of the CAA. New Jersey has met the second PROGRAM component and the seventh requirement of section 507(a) of the CAA by designating the New Jersey Department of Commerce and Economic Development, Office of Business Advocacy, to be the Small Business Ombudsman's Office. To meet the third PROGRAM component and section 507(e) of the CAA, New Jersey will enact legislation in order to authorize the establishment of a CAP, and members to the CAP will be appointed no later than November 15, 1994.

EPA finds that New Jersey presently lacks the requisite authority to establish a CAP. Therefore, EPA is conditionally approving New Jersey's section 507 program. Full approval will be granted once authority to establish a CAP has been enacted and submitted as a SIP revision.

B. New York

New York has met all of the requirements of section 507 of the CAA by submitting a SIP revision on January 11, 1993 that implements all required PROGRAM elements or delineates milestone dates for when any remaining PROGRAM elements will be enacted by November 15, 1994. A copy of New York's adopted legislation authorizing the PROGRAM was sent as a supplement to the SIP on August 26, 1993. The final plan was adopted by the New York State Department of Environmental Conservation (DEC) on January 11, 1993.

New York has met the first PROGRAM component by locating the SBAP within the New York State Environmental Facilities Corporation (EFC) with oversight provided by DEC's Small Business Section. New York has also committed in its SIP to meet the six requirements set forth in section 507(a) of the CAA for the Small Business Assistance Program. New York has met the second PROGRAM component and the seventh requirement of section 507(a) of the CAA by designating the New York State Department of Economic Development, Division of Small Business, to be the Small Business Ombudsman's Office. To meet the third PROGRAM component and section 507(e) of the CAA, New York has enacted legislation which authorizes the duties of the CAP and the appointment of members. Because New York has met all requisite requirements and has the authority to implement all PROGRAM elements, EPA is approving New York's section 507 program. However, New York still needs to appoint members to the CAP, which must occur no later than November 15, 1994.

EPA received two comments on New York's revised SIP during the 30 day public comment period. The comments have been evaluated by EPA, and a summary of the comments and EPA's responses are set forth below.

Comment #1: The Environmental Facilities Corporation (EFC), New York's SBAP Office, commented that New York's PROGRAM could be strengthened if the following changes were made to the SIP: (1) The SBAP is evaluated by the CAP only and not by the state Ombudsman; and (2) the SBAP is able to address the CAP directly as its own representative instead of the Ombudsman acting as the representative of the SBAP before the CAP. EFC believes that in order for the PROGRAM to function most effectively, the Ombudsman and SBAP must be partners with a mutually beneficial relationship. However, this equal partnership is disturbed under New York's PROGRAM because: the Ombudsman has evaluative power over the SBAP; and the SBAP does not have the power to represent itself, its program and its efforts directly to the CAP, but is indirectly represented by a third voice, the Ombudsman.

Response: The two suggestions raised by EFC have been carefully considered by EPA and DEC, and EPA is providing the following specific responses.

With regards to the first suggestion, EPA disagrees with the concept of a state Ombudsman not evaluating the SBAP. In EPA's Final Guidelines, EPA delineates several suggested duties of an Ombudsman's office. Two of the duties include: conducting independent evaluations of all aspects of the SBAP; and periodically reviewing the work and services provided by the SBAP with trade associations and small business representatives. One of EPA's criteria in determining whether the state office chosen as Ombudsman can adequately serve in its duties is whether the Ombudsman's office has been granted sufficient independent authority to identify problems and make recommendations as they relate to the implementation of the SBAP. New York has met EPA's criteria by granting the Ombudsman the above evaluative roles. Furthermore, the Ombudsman's office, in its role as the representative of small businesses, is the place where small businesses go if they have grievances regarding the SBAP or are not getting the necessary technical assistance. The Ombudsman must, therefore, have the authority to make recommendations on how the SBAP can be more effective. Thus, EPA believes New York's SIP should not be revised to remove the Ombudsman's ability to evaluate the SBAP as such an evaluative role is imperative for the Ombudsman's Office to be a true representative of the small business community.

With regards to the second suggestion, New York had always intended that the SBAP could present itself, its program and its efforts directly to the CAP. The SIP also allows for each small business office (including the SBAP, Ombudsman, and DEC) to provide input to the CAP in the form of progress reports, pending issues and proposed actions for the CAP to use during its quarterly or semiannual meetings. Nevertheless, in order to alleviate any confusion, New York submitted a supplement to its SIP which clarifies what New York meant when stating that the "Ombudsman will serve as the representative of the SBAP to the Compliance Advisory Panel." The word "representative" in this phrase means "overall evaluator". In other words, the Ombudsman will provide the CAP with an overall evaluation of the SBAP. The word "representative" is not meant to

infer that the Ombudsman will act as the agent of the SBAP before the CAP. The supplement further clarifies that the SBAP can present itself before the CAP to explain its accomplishments, make recommendations, and express any program needs.

EPA finds that the structure as provided in New York's SIP is acceptable based on section 507 of the CAA and EPA's *Final Guidelines*. Therefore, EPA is finalizing its approval of New York's PROGRAM.

Comment #2: The Erie County Environmental Compliance Services Program commented that New York's SBAP should be encouraged to utilize the services of local agencies that already provide assistance to small businesses in the State. The Erie County program, as well as several other local programs throughout New York State, already successfully provide many of the services/functions in rendering technical assistance to small businesses as proposed for the SBAP. The Erie County program endorses that local programs continue to receive state and federal funds, including funds to be supported by Title V fees, so that the local programs can work with the SBAP on technical assistance to the small business community.

Response: EPA supports Erie County's endorsement that New York use existing local infrastructures as a means to reach out to the small business community. New York also endorses the concept. One reason DEC chose EFC as the SBAP is that EFC has the ability to subcontract with local agencies. EFC fully intends to limit the size of its in-house staff working on the SBAP and will use existing local programs to perform audits and conduct other field activities where the scope and volume of those activities exceed EFC's in-house staff capacity.

C. Puerto Rico

Puerto Rico has met all of the requirements of section 507 of the CAA by submitting a SIP revision on November 16, 1992 that implements all required PROGRAM elements or delineates milestone dates for when any remaining PROGRAM elements will be enacted by November 15, 1994. Supplemental information was sent on January 14, 1993 and October 25, 1993, which included Puerto Rico's adopted legislation authorizing the PROGRAM. The final plan was adopted by the Puerto Rico Environmental Quality Board (EQB) on November 4, 1992.

Puerto Rico has met the first PROGRAM component by locating the SBAP within EQB's Planning Division and committing in its SIP to meet the six requirements set forth in section 507(a) of the CAA. Puerto Rico has met the second PROGRAM component and the seventh requirement of section 507(a) of the CAA by recommending that the Governor choose the existing Citizen's Ombudsman's, the Puerto Rico Citizen's Investigating Official as Puerto Rico's Ombudsman's Office. Legislation has been enacted which provides authority for the Ombudsman's duties. To meet the third PROGRAM component and section 507(e) of the CAA, Puerto Rico has enacted legislation which authorizes the duties of the CAP and the appointment of members. Because Puerto Rico has met all the requisite requirements and has the authority to implement all PROGRAM elements, EPA is approving Puerto Rico's section 507 program. However, Puerto Rico still needs to have an Ombudsman's Office in place and appoint members to the CAP, which must occur no later than November 15, 1994.

D. The U.S. Virgin Islands

The U.S. Virgin Islands has met all of the requirements of section 507 of the CAA by submitting a SIP revision on January 15, 1993 that implements all required PROGRAM elements or delineates milestone dates for when any remaining PROGRAM elements will be enacted by November 15, 1994. The final plan was adopted by the Virgin Islands Department of Planning and Natural Resources (DPNR) on January 14, 1993.

The U.S. Virgin Islands has met the first PROGRAM component by locating the SBAP within DPNR's Division of Environmental Protection and by committing in its SIP to meet the six requirements set forth in section 507(a) of the CAA. The U.S. Virgin Islands has met the second PROGRAM component and the seventh requirement of section 507(a) of the CAA by designating the Virgin Islands Small Business Development Agency to be the Small Business Ombudsman's Office. The Ombudsman's Office will be assisted by the Small Business Development Center of the University of the Virgin Islands. To meet the third PROGRAM component and section 507(e) of the CAA, the U.S. Virgin Islands will enact legislation to authorize the establishment of a CAP, and members to the CAP will be appointed no later than November 15, 1994.

EPA finds that the U.S. Virgin Islands presently lacks the requisite authority to establish a CAP. Therefore, EPA is conditionally approving the U.S. Virgin Islands' section 507 program. Full approval will be granted once authority to establish a CAP has been enacted and submitted as a SIP revision.

III. Final Action

EPA is conditionally approving the SIP revisions submitted by the States of New Jersey and the U.S. Virgin Islands, and fully approving the SIP revisions submitted by New York and Puerto Rico. The revisions were made to satisfy the requirements of section 507 of the CAA.

Because New Jersey and the U.S. Virgin Islands have made commitments that EPA believes meet the requirements necessary for EPA to grant conditional approval, EPA is granting a conditional approval under section 110(k)(4) of the Act. New Jersey and the U.S. Virgin Islands must meet their commitment to have their programs fully operational by November 15, 1994 and submit these requirements to EPA by that date. If New Jersey or the U.S. Virgin Islands fails to adopt or submit any of these requirements to EPA within this time frame, this approval will become a disapproval on that date. EPA will notify the State by letter that this action has occurred. At that time, this commitment will no longer be a part of the approved New Jersey or U.S. Virgin Islands SIP. EPA subsequently will publish a notice in the notice section of the **Federal Register**. If the state adopts and submits these requirements to EPA within the applicable time frame, the conditionally approved submission will remain a part of the SIP until EPA takes final action approving or disapproving the new submittal. If EPA disapproves the new submittal, the conditionally approved Small Business Plan will also be removed from the SIP. If EPA approves the submittal, those newly approved rules will become a part of the SIP and will modify or replace the commitment and the Small Business Plan on which the conditional approval is based.

If the conditional approval is converted to a disapproval, the sanctions clock under section 179(a) will begin. This clock will begin at the time EPA issues the final disapproval or on the date the State fails to meet its commitment. In the latter case, EPA will notify the State by letter that the conditional approval has been converted to a disapproval and that the sanctions clock has begun. If the State does not submit and EPA does not approve the rule on which the disapproval was based within 18 months of the disapproval, EPA must impose one of the sanctions under section 179(b)—highway funding restrictions or the offset sanction. In addition, the final disapproval triggers

the federal implementation plan (FIP) requirement under section 110(c).

This action has been classified as a Table 3 Action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225) as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. A future notice will inform the general public of these tables. On January 6, 1989 the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years. The EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. The OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request. This request continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

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

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

By today's action, EPA is conditionally or fully approving four (4) State programs created for the purpose of assisting small businesses in complying with existing statutory and regulatory requirements. The programs being conditionally or fully approved today do not impose any new regulatory burden on small businesses; these are programs under which small businesses may elect to take advantage of assistance provided by the state. Therefore, because the EPA's conditional or full approvals of these four programs do not impose any new regulatory requirements on small businesses, EPA certifies that this action does not have a significant economic impact on any small entities affected.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit within 60 days from date of publication. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Small business assistance program.

Dated: June 10, 1994.

William J. Muszynski,

Acting Regional Administrator.

40 CFR Part 52 is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401–7671q.

Subpart FF—New Jersey

2. Section 52.1607 is added to read as follows:

§ 52.1607 Small business technical and environmental compliance assistance program.

On January 11, 1993, the New Jersey Department of Environmental Protection and Energy submitted a plan for the establishment and implementation of a Small Business Stationary Source Technical and Environmental Compliance Assistance Program for incorporation in the New Jersey state implementation plan. This plan satisfies the requirements of section 507 of the Clean Air Act, and New Jersey must implement the program as approved by EPA.

Subpart HH—New York

3. Section 52.1690 is added to read as follows:

§ 52.1690 Small business technical and environmental compliance assistance program.

On January 11, 1993, the New York State Department of Environmental Conservation submitted a plan for the establishment and implementation of a Small Business Stationary Source Technical and Environmental Compliance Assistance Program for incorporation in the New York state implementation plan. This plan meets the requirements of section 507 of the Clean Air Act, and New York must implement the program as approved by EPA.

Subpart BBB—Puerto Rico

4. Section 52.2732 is added to read as follows:

§ 52.2732 Small business technical and environmental compliance assistance program.

On November 16, 1992, the Puerto Rico Environmental Quality Board submitted a plan for the establishment and implementation of a Small Business Stationary Source Technical and Environmental Compliance Assistance Program for incorporation in the Puerto Rico state implementation plan. This plan meets the requirements of section 507 of the Clean Air Act, and Puerto Rico must implement the plan as approved by EPA.

Subpart CCC—Virgin Islands

5. Section 52.2782 is added to read as follows:

§ 52.2782 Small business technical and environmental compliance assistance program.

On January 15, 1993, the Virgin Islands Department of Planning and Natural Resources submitted a plan to establish and implement a Small Business Stationary Source Technical and Environmental Compliance Assistance Program for incorporation in the Virgin Islands state implementation plan. This plan meets the requirements of section 507 of the Clean Air Act, and the U.S. Virgin Islands must implement the program as approved by EPA.

[FR Doc. 94–16128 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 372

[OPPTS–400073B; FRL–4864–8]

Glycol Ethers Category; Toxic Chemical Release Reporting; Community Right-to-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is redefining the glycol ethers category list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). EPA is changing the present definition of the glycol ethers category

to exclude the high molecular weight glycol ethers that do not, in EPA's judgement, meet the criteria set out in EPCRA section 313(d). This redefinition of the glycol ethers category, which is based on EPA's review of available human health data on short-chain length glycol ethers, eliminates the EPCRA section 313 reporting requirements for those glycol ethers known as surfactant glycol ethers.

EFFECTIVE DATE: This rule is effective June 28, 1994.

FOR FURTHER INFORMATION CONTACT: Maria J. Doa, Petitions Coordinator, 202–260–9592, for specific information regarding this final rule. For further information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Information Hotline, Environmental Protection Agency, Mail Stop 5101, 401 M St., SW., Washington, DC 20460, Toll free: 800–535–0202, Toll free TDD: 800–553–7672.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

This action is issued under section 313(d) of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11023, "EPCRA"). EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986.

B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using toxic chemicals to report their environmental releases of such chemicals annually. Beginning with the 1991 reporting year, such facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act (42 U.S.C. 13106). Section 313 established an initial list of toxic chemicals that was comprised of more than 300 chemicals and 20 chemical categories. Section 313(d) authorizes EPA to add chemicals to or delete chemicals from the list, and sets forth criteria for these actions. Under section 313(e), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA has added to and deleted chemicals from the original statutory list.

EPA issued a statement of petition policy and guidance in the **Federal Register** of February 4, 1987 (52 FR 3479), to provide guidance regarding the recommended content and format for petitions. On May 23, 1991 (56 FR 23703), EPA published guidance regarding the recommended content of petitions to delete individual members of the section 313 metal compound categories.

II. Effective Date

This action becomes effective immediately. Thus, the last year in which facilities had to report releases of high molecular weight glycol ethers now excluded from the list was 1993, covering releases that occurred in 1992. The effect of this category redefinition is that, since the high molecular weight glycol ethers being excluded from the category will not be on the section 313 list when facilities report in 1994 for releases that occurred in 1993, these reports and all subsequent reports need not include release data for these glycol ethers. Facilities will therefore not have to collect release information for any releases of the excluded glycol ethers that occurred during the 1993 reporting year or for any releases that occur in the future.

Section 313(d)(4) provides that "[a]ny revision [to the section 313 list] made on or after January 1 and before December 1 of any calendar year shall take effect beginning with the next calendar year. Any revision made on or after December 1 and before January 1 shall take effect beginning with the calendar year following the next calendar year." The Agency interprets this delayed effective date provision to apply only to actions that add chemicals to the section 313 list. For deletions, the Agency may, in its discretion, make such actions immediately effective. An immediate effective date is authorized, in these circumstances, under 5 U.S.C. section 553(d)(1) since a deletion from the section 313 list relieves a regulatory restriction.

The Agency believes that the purpose behind the section 313(d)(4) effective date provision is to allow facilities adequate planning time to incorporate newly added chemicals to their Toxic Release Inventory (TRI) release data collection processes. A facility would not need additional planning time to not report releases of a given chemical. Thus, a reasonable construction of section 313(d)(4), given the overall purpose and structure of EPCRA — to provide the public with information about chemicals which meet the criteria for inclusion on the section 313 list — is to apply the delayed effective date requirement only to additions to the list. Where the Agency has determined, as it has with the excluded glycol ethers, that a chemical does not satisfy the criteria of section 313(d)(2)(A)–(C), no purpose is served by requiring facilities to collect release data or file release reports for that chemical, or, therefore, by leaving that chemical on the section 313 list for any additional period of time. Nothing in the legislative history suggests that section 313(d)(4) was intended to apply to deletions as well as additions; indeed, such a construction would be incongruous, since deleted chemicals, by definition, do not satisfy the criteria for being on the section 313 list and their deletion from that list should not be delayed in the absence of any compelling reason to the contrary. This construction of section 313(d)(4) is also consistent with previous rules deleting chemicals from the section 313 list. Indeed, the Agency has not given any of its rules deleting chemicals from the section 313 list the delayed effective dates specified in section 313(d)(4).

EPA has not deleted all glycol ethers from reporting requirements under EPCRA section 313. Reporting will still be required for those glycol ethers which meet the revised definition.

III. Description of the EPCRA Section 313 Glycol Ethers Category

In the **Federal Register** of July 6, 1993 (58 FR 36180), EPA issued a proposed rule to redefine the glycol ethers category on the EPCRA section 313 list of toxic chemicals. EPA has evaluated the current scope of the section 313 glycol ethers category and believes that it is overly broad. The existing category includes substances that traditionally have not been considered glycol ethers. Also, it is apparent that this category contains members that do not meet the EPCRA section 313(d)(2) criteria for listing. EPA has reviewed the current glycol ethers category and is redefining it to exclude the surfactant glycol ethers. Surfactant glycol ethers are those glycol ethers with pendant alkyl groups which typically consist of eight or more carbon atoms (i,e., high molecular weight glycol ethers). However, EPA does not believe that the category can be more narrowly defined at this time.

EPA's revised glycol ethers category for which section 313 reporting is required, consists of those glycol ethers which meet the following definition:

Certain Glycol Ethers:
R - $(OCH_2CH_2)_n$ - OR'
Where:
n = 1, 2, or 3;
R = alkyl C7 or less, or
R = phenyl or alkyl substituted phenyl;
R' = H or alkyl C7 or less; or
OR' consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.

IV. Rationale for Redefinition

EPA's concerns for the included chemicals is based on a review of

available human health data on short-chain length glycol ethers. Specifically, EPA believes that these chemicals meet the criterion of EPCRA section 313(d)(2)(B) because the individual members of this category can be reasonably anticipated to cause one or more of the following effects: Kidney toxicity, liver toxicity, adverse blood effects, adverse central nervous system effects, reproductive effects, and developmental effects. EPA believes that the category can be redefined to exclude those glycol ethers known as surfactant glycol ethers because these high molecular weight glycol ethers do not meet the listing criteria in section 313(d)(2)(A) or (B). None of the chemicals in the current glycol ethers category meet the toxicity criterion of section 313(d)(2)(C) based on their ecotoxicity. EPA's rationale for this redefinition is detailed in the proposed rule and is based on the Agency's review of various relevant materials.

V. Response to Comments

EPA received 11 comments on the proposed rule, all in support of the proposed redefinition of the glycol ethers category. However, several of the commenters expressed the opinion that the proposed rule does not narrow the definition sufficiently, and that EPA should consider a further narrowing of the definition in the future. As discussed below, EPA does not believe that it currently has sufficient data to further narrow the category definition.

Two commenters, the Chemical Manufacturers Association (CMA), Propylene Glycol Ethers Panel, and CMA Ethylene Glycol Ethers Panel, stated that the name of the category should be changed to "certain glycol ethers" to more accurately characterize the chemicals that are within the category. EPA has incorporated this comment, since this category does not consist of all chemicals that contain the glycol ether functionality.

One commenter, General Electric, suggested that the definition should not identify reportable glycol ethers by molecular structure. Instead, the commenter recommended listing the glycol ethers of concern individually, and identifying those which must be reported on an individual basis. All remaining glycol ethers would then be reported in an aggregate form. EPA believes this approach to defining the category is inappropriate and unnecessary. EPA has identified by molecular formula a specific group of glycol ethers having a common structure that pose similar hazards. EPA currently believes that the most appropriate way to report on this group of glycol ethers is in aggregate by category. A listing of glycol ethers as proposed by the commenter may exclude from reporting certain glycol ethers within the scope of the definition in this rulemaking that meet the section 313(d)(2) criterion. Therefore, EPA is adopting the redefinition of the glycol ethers category based on a molecular structure formula. A reporting facility must make aggregate reporting threshold and estimated release determinations for all glycol ethers in the category.

The Soap and Detergent Association proposed that the revised definition exclude sulfonate in the category of OR' because "carbon sulfur bonds are not easily broken and, therefore, sulfonates are not readily hydrolyzable from surfactants." EPA proposed the inclusion of sulfonate not because of the possible reaction at the carbon sulfur bond in the sulfonate, e.g., desulfonation of aromatic sulfonates, but rather because the sulfonate ion is a reactive leaving group and thus can reasonably be anticipated to be hydrolyzed to yield a glycol ether of concern. Specifically hydrolysis of R-$(OCH_2CH_2)_nOSO_2R''$ (where R'' is any organic substituent) yields R-$(OCH_2CH_2)_nOH$ and R''SO_2OH. Therefore, EPA reaffirms its inclusion of sulfonate as an appropriate member in the category of OR'.

The Chemical Manufacturers Association stated that the category should be limited to four specific ethylene glycol ether solvents: 2-Methoxyethanol, 2-ethoxyethanol, and their acetates. As stated in the proposed rule, with respect to the glycol ethers and developmental effects, there is evidence that the toxicity is reduced going from the methyl to the butyl ether. However, data for other toxic effects on glycol ethers with pendant alkyl groups of one to seven carbons or a phenyl group do not indicate a trend towards increased toxicity based on chain length for other toxic effects. Low molecular weight ethylene glycol ethers disturb the hemopoiesis and the blood picture at low doses. Hemolysis has been reported in varying degrees for ethylene glycol ethers of one to five carbons in the alkyl chain. The optimum alkyl chain length for hemolysis is four carbons. 2-Phenoxyethanol has also been found to cause intravascular hemolysis. Therefore, the concerns for ethylene glycol ethers are not limited to the four specific compounds mentioned by the commenter.

In the proposed rule, EPA requested comment on whether the definition of R' should include only straight chained alkyl groups of seven of fewer carbons or both straight and branched alkyl groups of seven or fewer carbons. No comments on this issue were received. Therefore, the definition of R' will include both straight and branched alkyl groups of seven or fewer carbons.

Rochester Midland, Soap and Detergent Association, Henkel Corporation, and Union Carbide Corporation asked that the definition also exclude alkylated phenols containing seven or more carbon atoms. As stated in the proposed rule, 2-phenoxyethanol is known to cause hemolysis. No data have been found for alkyl substituted phenoxyethanol derivatives. Henkel Corporation stated that "[t]he C_8, C_9, and C_{12} alkyl phenol ethoxylates have also been used for many years as surfactants. There is no evidence that they present adverse human effects such as those which caused the listing of the glycol ether category or would otherwise meet the section 313 criteria." However, this commenter did not supply data to substantiate this assertion. The Soap and Detergent Corporation provided two studies to support its position (Smyth and Calandra, 1969; Dudek and Ribelin, 1988). Neither of these studies specifies the composition of the test material by number of ethylene oxide units. The commenter did provide the typical weight percent of the test substances as sold in commerce. Even if EPA assumed these typical compositions represent the test materials of these two studies, the dose levels presented in the studies would not be considered adequate to establish the lack of toxicity associated with ethylene glycol ethers with alkyl groups consisting of seven or greater carbon atoms.

Because only phenoxyethanol has been tested for systemic toxicity, change in the glycol ethers category definition which would exclude alkylphenol ethoxylates is not supportable, based on the available data. To evaluate the alkylphenol ethoxylates subcategory of the ethylene glycol ether category, EPA would require subchronic toxicity data for one or more specific members of the category (e.g., 2-nonylphenoxyethanol). In the absence of these data, the Agency believes that the glycol ethers category should continue to include these substances.

General Electric contended that individual glycol ethers should be listed in lieu of a category because EPCRA section 313 "clearly states that additions to the EPCRA section 313 list must be done on a chemical-by-chemical basis. Each statutory provision that deals with revising the section 313 list speaks only in terms of a chemical-by-chemical basis, and EPCRA is silent on the issue of regulating by chemical categories."

The Agency believes that the statutory authority to add "a chemical" to the list may be reasonably interpreted to include the authority to add groups or categories of chemicals to the list, particularly in light of the fact that the original list adopted by Congress in section 313(c) of EPCRA included 20 chemical categories. These consist mostly of metal compounds categories, but also include categories of organic chemicals, such as glycol ethers (as noted in the proposed rule, Congress listed this category without a delimiting definition).

General Electric further contended that Congress listed "glycol ethers" in addition to the two individually listed glycol ethers, "2-methoxyethanol" and "2-ethoxyethanol," to allow facilities the option of aggregating the releases of the two individually listed glycol ether chemicals and filing one TRI Form R report for "glycol ether" rather than two separate Form R reports. EPA does not accept this interpretation of Congress' intent in listing 20 chemical categories on the original EPCRA section 313(c) list of chemicals subject to TRI reporting. There is no clear statement of Congressional intent to adopt the type of "optional" reporting scheme advocated by General Electric. Indeed, the legislative history cited by General Electric supports EPA's current interpretation and implementation of EPCRA's reporting structure, i.e., persons manufacturing, processing, or otherwise using more than one member of a chemical category above the applicable reporting threshold may report the releases of all such chemicals, in the aggregate, on a single Form R report, rather than listing data separately for each chemical in the group.

Furthermore, contrary to General Electric's contention, several of the original chemical categories did not have corresponding "individual" chemicals listed on the original (CAS number specific) section 313(c) list. In their comments, General Electric acknowledged this to be the case only with regard to the polybrominated biphenyls (PBBs) category. However, there was no individual listing for any barium compounds, cadmium compounds, chromium compounds, or several other metal compounds in the original list transmitted to EPA by Congress. See 53 FR 4500; February 16, 1988. Taken to its logical conclusion, General Electric's interpretation would result in no reporting of any members of the PBBs category unless and until EPA listed individual members of that category. EPA does not believe that this would be consistent with Congress' intent in listing this category on the initial section 313(c) list. If Congress had intended to include category listings as an optional method of reporting individually listed chemicals, it could have clearly stated so in the statute. At a minimum, some members of all the listed chemical categories would have been included in the CAS number specific list. In sum, EPA believes that its interpretation of the category reporting structure is a reasonable reading of EPCRA.

General Electric objected to the continued listing of a glycol ethers category because categories are difficult for EPA to administer and/or for the public and industry to understand. In addition, the commenter contended that industry compliance with reporting and supplier notification requirements is more difficult for categories, such as glycol ethers, because facilities are not provided with discrete chemical names and Chemical Abstract Service (CAS) registry numbers. The commenter contended that these problems are magnified in the case of the glycol ethers category because the category is defined by molecular structure formula.

Since the glycol ethers category consists of chemicals that are similar chemically and in potential effect, EPA believes that this category will not be difficult for the public or industry to understand or for the Agency to administer. The Agency will work with the public and the regulated community to develop, as appropriate, any interpretations and guidance the Agency determines are necessary to facilitate accurate reporting for the "certain glycol ethers" category. The Agency does not believe that the glycol ethers category is unique in that it is defined by molecular structure formula. All of the metal compound categories are defined based on molecular structure formula, i.e., to be considered a member of a metal compound category, the compound must consist of the parent metal and at least one substituent group. Both the chlorophenols and cyanide compound categories are defined by molecular structure formulas on the EPCRA section 313 list. EPA believes that defining the category by molecular structure formula ensures that all members of the category that meet the EPCRA section 313(d)(2) criteria are included and thus reportable.

Three commenters, the Soap and Detergent Association, Proctor and Gamble Co., and Union Carbide contended that EPA should be consistent between EPCRA and TSCA on its treatment of identical materials. Union Carbide cited the TSCA section 8(b) Inventory provisions. EPA believes that the differing treatment of glycol ether species with a low degree of ethoxylation under EPCRA and TSCA is appropriate given the differing purposes and standards of TSCA section 8(b) and EPCRA section 313. TSCA is concerned with the regulation of unreasonable risks to human health and the environment posed by chemical substances and mixtures in commerce; the section 8(b) Inventory, with few exceptions, provides a list of those chemical substances and mixtures. For purposes of developing an inventory of chemical substances in commerce, it is less important to specify whether those substances consist of a discrete species, e.g., chloroform, or a species with a range of molecular weights. EPCRA's goal is to provide the general public with a broad range of information on releases of certain chemicals.

Under TSCA, for example, glycol ether surfactant "mixtures" are considered as a single entity for purposes of entry on the Inventory; however, for purposes of reviewing the potential health or environmental unreasonable risks posed by activities involving such chemical substances, the impacts of their various components would be considered. Because the intent of EPCRA section 313 is community right-to-know, EPA wants to ensure that the public has access to information on each listed toxic chemical or chemical category to which the public could be exposed, regardless of whether it is in a mixture. Therefore, where a surfactant contains species with a low degree of ethoxylation that fit the glycol ether category definition, EPA requires that those chemicals be reported.

Union Carbide also contended that "[a]s a legal matter, the current and proposed definitions exclude polymers from the category of glycol ethers. Since polymers potentially include their low molecular weight species (n = 1, 2, 3), the exemption for polymers precludes the need to report low molecular weight species under [s]ection 313."

EPA disagrees with Union Carbide's conclusion regarding species with low degrees of ethoxylation. The proposed definition being finalized today continues to exclude polymer molecules (i.e., those molecules which include at least four covalently linked subunits at least two of which are internal subunits), and to include low molecular weight glycol ethers with a low degree of ethoxylation. The change in regulatory text deleting the phrase "polymers are excluded from this category," does not change EPA's position regarding the scope of the glycol ethers category.

One commenter, the Cosmetic, Toiletry, and Fragrance Association, stated support for the proposal to change the definition of glycol ethers on other EPA lists. Today's action is not intended, and should not be inferred to affect the definition or regulatory requirements for glycol ethers under any statute or EPA program other than the Toxic Release Inventory reporting requirements under EPCRA section 313 and the Pollution Prevention Act section 6607. Specifically, the redefinition of glycol ethers on the EPCRA section 313 list does not in any way alter their definition under section 112(b) of the Clean Air Act (CAA), 42 U.S.C. section 7412(b) as amended, or, by virtue of their status as "hazardous air pollutants" (HAP) under the CAA, as "hazardous substances" under section 101(14) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C section 9601(14).

VI. Rulemaking Record

The record supporting this final rule is contained in the docket number OPPTS–400073B. All documents, including an index of the docket, are available for viewing and photocopying in the TSCA Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office, from noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA NCIC is located at EPA Headquarters, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

VII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Section 3(f) of the Order defines a "significant regulatory action" as an action likely to lead to a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, it has been determined that this final rule is not "significant" and therefore not subject to OMB review.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires each Federal agency to perform a Regulatory Flexibility Analysis for all rules that are likely to have a "significant impact on a substantial number of small entities."

40 CFR part 372 exempts certain small businesses (specifically, those facilities with fewer than 10 full-time employees) from reporting. This exclusion exempts about one-half of all manufacturing facilities in Standard Industrial Classification (SIC) codes 20 through 39 from section 313 reporting. Additionally, facilities which manufacture or process less than 25,000 pounds or otherwise use less than 10,000 pounds of these chemicals annually are not required to report for these chemicals. Thus, many small facilities will not incur any regulatory costs in association with this rule. Small businesses are not expected to be adversely affected by this rule, since the rule would increase the likelihood that they would not be required to report glycol ether releases. Therefore, EPA certifies that this rule is not likely to significantly impact small entities.

C. Paperwork Reduction Act

There are no unique reporting requirements associated with this final rule because it redefines the glycol ethers category to exclude certain high molecular weight glycol ethers from reporting under section 313. Reporting of chemicals that are subject to section 313 has been approved by OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and has been assigned the OMB control number 2070–0093.

The public reporting burden for section 313 chemicals is estimated to average 43 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This rule's redefinition will reduce the number of responses required, thus reducing overall burden.

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, Toxic chemicals.

Dated: June 28, 1994.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 372 is amended as follows:

PART 372—[AMENDED]

1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

2. In § 372.65(c) by amending the category, glycol ethers to read as follows:

§ 372.65 Chemicals and chemical categories to which the part applies.

* * * * *

(c) * * *

Category Name	Effective Date
* * * * *	
Certain Glycol Ethers	1/1/95
$R - (OCH_2CH_2)_n - OR'$	
Where:	
n = 1, 2, or 3;	
R = alkyl C7 or less; or	
R = phenyl or alkyl substituted phenyl;	
R' = H or alkyl C7 or less; or	
OR' consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.	

Category Name	Effective Date
* * * * *	

[FR Doc. 94–16173 Filed 6–29–94; 1:07 pm]
BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 93–99; RM–8202 and RM–8304]

Radio Broadcasting Services; Ashland, Moberly, Monroe City, Rolla, and Wheeling, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 288C2 for Channel 288C3 at Moberly, Missouri, and modifies the license for Station KZZT(FM) to specify operation on Channel 288C2 in response to a petition filed by FM 105, Inc. See 58 FR 25593, April 27, 1993. The coordinates for Channel 288C2 at Moberly are 39–25–45 and 92–22–49. The counterproposal filed by Sobocomo Radio, Inc. (RM–8304), proposing the substitution of Channel 291C1 for Channel 291C2, Ashland, Missouri, substitution of Channel 276C3 for Channel 292A, Rolla, Missouri, substitution of Channel 298A for Channel 292A, Monroe City, Missouri, and change of reference coordinates for Channel 290A, Wheeling, Missouri, was dismissed. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 11, 1994.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 93–99, adopted June 15, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street NW., Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by removing Channel 288C3 and adding Channel 288C2 at Moberly.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–16130 Filed 7–1–94; 8:45 am]
BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 93–269; RM–8319]

Radio Broadcasting Services; Denison and Pilot Point, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Davis Family Trust, reallocates Channel 285C2 from Denison, Texas, to Pilot Point, Texas, and modifies Station KTCY–FM's construction permit to specify Pilot Point as its community of license. *See* 58 FR 58672, November 3, 1993. Channel 285C2 can be allotted to Pilot Point in compliance with the Commission's minimum distance separation requirements with a site restriction of 16.0 kilometers (9.9 miles) north to accommodate Davis' desired site. The coordinates for Channel 285C2 at Pilot Point are North Latitude 33–32–20 and West Longitude 96–57–15. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 11, 1994.

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–269, adopted June 14, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, D.C. 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas is amended by adding Pilot Point, Channel 285C2 and removing Channel 285C2 at Denison.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–16131 Filed 7–1–94; 8:45 am]
BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 93–271; RM–8345]

Television Broadcasting Services; Walla Walla, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Spectrum Communications, Inc., substitutes VHF television Channel 9+ for vacant UHF Channel 14 – at Walla Walla, Washington, as its first local television broadcast service. See 58 FR 58672, November 3, 1993. Channel 9+ can be substituted at Walla Walla in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 9+ are North Latitude 46–04–12 and West Longitude 118–19–48. Since Walla Walla is located

within 400 kilometers (250 miles) of the U.S.-Canadian border, concurrence of the Canadian government has been received. With this action, this proceeding is terminated.

EFFECTIVE DATE: August 11, 1994.

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 93–271 adopted June 15, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.606 [Amended]

2. Section 73.606(b), the Table of TV Allotments under Washington, is amended by removing Channel 14– and adding Channel 9+ at Walla Walla.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–16132 Filed 7–1–94; 8:45 am]

BILLING CODE 6712–01–M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1056

Transportation of Household Goods in Interstate or Foreign Commerce

AGENCY: Interstate Commerce Commission.

ACTION: Technical amendments.

SUMMARY: In order to update the Interstate Commerce Commission's regulations, as set forth in Title 49, Chapter X, Part 1056, of the Code of Federal Regulations, several technical amendments are necessary, as set forth below.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: Neil S. Llewellyn, (202) 927–5520, Patricia A. Burke, (202) 927–5520, (TDD for hearing impaired: (202) 927–5721).

SUPPLEMENTARY INFORMATION:

List of Subjects in 49 CFR Part 1056

Advertising, Consumer protection, Freight, Insurance, Motor Carriers, Moving of household goods, Reporting and recordkeeping requirements.

For the reasons set forth above, Title 49, Chapter X, Part 1056 is amended as follows:

PART 1056—TRANSPORTATION OF HOUSEHOLD GOODS IN INTERSTATE OR FOREIGN COMMERCE

1. The authority citation for Part 1056 continues to read as follows:

Authority: 49 U.S.C. 10321, 11109, 11110 and 5 U.S.C. 553.

2. In Part 1056, the words, "OCP–100", "OCP–101", "Office of Consumer Protection", and "Office of Compliance and Consumer Assistance" are revised to read "OCE–100", "OCE–101", and "Office of Compliance and Enforcement" everywhere they appear.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 94–16227 Filed 7–1–94; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 675

[Docket No. 931100–4043; I.D. 062994A]

Groundfish of the Bering Sea and Aleutian Islands Area

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

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for Atka mackerel in the Western Aleutian District of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the total allowable catch (TAC) of Atka mackerel specified for this District.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), June 30, 1994, until 12 midnight, A.l.t., December 31, 1994.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, 907–586-7228.

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

In accordance with § 675.20(a)(7)(ii), the Atka mackerel TAC for the Western Aleutian District was established by the final 1994 initial specifications of groundfish for the BSAI (59 FR 7656, February 16, 1994) as 8,500 metric tons (mt).

The Director, Alaska Region, NMFS (Regional Director), has determined, in accordance with § 675.20(a)(8), that the Atka mackerel TAC specified for the Western Aleutian District soon will be reached. Therefore, the Regional Director has established a directed fishing allowance of 8,000 mt after determining that 500 mt will be taken as incidental catch in directed fishing for other species in the Western Aleutian District. Consequently, NMFS is prohibiting directed fishing for Atka mackerel in the Western Aleutian District, effective from 12 noon A.l.t., June 30, 1994, until 12 midnight, A.l.t., December 31, 1994.

Directed fishing standards for applicable gear types may be found in the regulations at § 675.20(h).

Classification

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

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

Dated: June 29, 1994.

David S. Crestin,

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

[FR Doc. 94–16215 Filed 6–29–94; 3:39 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 59, No. 127
Tuesday, July 5, 1994

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 575

RIN 3206–AF86

Recruitment and Relocation Bonuses and Retention Allowances

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing proposed regulations to provide agencies with greater flexibility in paying recruitment and relocation bonuses and retention allowances (the 3 R's). The proposed regulations revise certain requirements in the current regulations to maximize agency discretion in using these flexibilities. The 3 R's were authorized by the Federal Employees Pay Comparability Act of 1990 (FEPCA).

DATES: Comments must be received on or before August 4, 1994.

ADDRESSES: Comments may be sent or delivered to Donald J. Winstead, Acting Assistant Director for Compensation Policy, Personnel Systems and Oversight Group, Office of Personnel Management, Room 6H31, 1900 E Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Belva MacDonald or Lee Kara, (202) 606–1413.

SUPPLEMENTARY INFORMATION: On August 19, 1992, OPM published final regulations at 57 FR 37394 to authorize the payment of recruitment and relocation bonuses and retention allowances (the 3 R's) under the Federal Employees Pay Comparability Act of 1990 (FEPCA). These regulations finalized interim regulations that were published on March 28, 1991 (56 FR 12833). Overall, use of the 3 R's has been limited.

In a memorandum to the Interagency Advisory Group on October 24, 1991, OPM advised agencies to consider using the 3 R's before requesting new or increased special salary rates under 5 U.S.C. 5305. In most situations, the use of the 3 R's to solve staffing problems will be less expensive than special rates. Special rates are basic pay for such purposes as retirement benefits, premium pay, and promotions, whereas the 3 R's are not basic pay for any purposes. The 3 R's are also generally less expensive than superior qualifications appointments. Superior qualifications appointments, like special salary rates, have a lasting effect on future pay entitlements.

When necessary, the 3 R's may be used in combination with special salary rates and superior qualifications appointments. However, payment of one of the 3 R's alone may be the most appropriate solution for a staffing problem. For example, a candidate may prefer a lump-sum payment to address his or her immediate needs instead of an increase in basic pay that would be received in relatively small amounts over a long period of time.

Agencies have found it difficult to use the 3 R's and have requested changes in the current regulations. OPM also has approved variations to the requirements bonus regulations. (This is discussed below under appointments required for recruitment bonus purposes.) OPM is proposing the regulatory changes discussed below to increase agencies' discretion in administering the 3 R's.

Recruitment Bonuses

Candidate quality. In §§ 575.101, 575.104(b)(2), 575.104(c)(1) and (c)(2) (i) and (iii), and 575.108(b), the current regulations allow payment of a recruitment bonus only when, in the absence of such a bonus, agencies would encounter difficulty in filling the position with a *high quality candidate.* Same agencies' recruitment needs are not limited to high quality candidates. Therefore, they have not considered offering recruitment bonuses before requesting approval of special salary rates. (OPM approval of special rates is not dependent upon the recruitment of high quality candidates.) The proposed regulations would allow an agency to pay a recruitment bonus to any qualified candidate the agency wishes to recruit for a difficult-to-fill position. The agency would determine the level of candidate quality it needs to target.

Length of appointment and service agreement. In § 575.103, the current definition of "employee" for recruitment bonus purposes requires an appointment of at least 2 years. The proposed regulations would delete the language regarding the minimum length of appointment; however, since, in § 575.106(b), the proposed regulations require a service agreement of at least 6 months, any appointment would have to be at least that long. Currently, a minimum 12-month service agreement is required. Reducing the requirement to 6 months would give agencies more flexibility.

Break-in service. To meet the current definition of "newly appointed" in § 575.103, a candidate with prior Federal Government service must have a break in service of at least 1 year. The proposed regulations would reduce this break-in-service restriction to 90 days. This parallels the 90-day-break-in-service restriction for superior qualifications appointments in § 531.203(b)(2). It allows agencies to consider paying a recruitment bonus in more circumstances as an alternative to paying advanced in-hire rates for superior qualifications.

The proposed regulations add two authorized exceptions to the break-in-service rule in § 575.103. The first is a permanent appointment that follows a provisional appointment (as defined in § 316.403). The second is an appointment that follows a temporary appointment, provided the temporary appointment was neither full-time nor the principal employment of the candidate. This would allow agencies to pay recruitment bonuses in situations like those approved by OPM as variations to the current regulations. Under the variations, bonuses were paid to medical officers who served in temporary appointments prior to being offered permanent appointments. The medical officers did not meet the break-in-service requirement under current regulations. OPM determined that payment of recruitment bonuses was appropriate because the temporary positions were neither full-time nor the candidates' principal employment. Also, the inability of the hiring officials to take advantage of such opportunities would have resulted in lengthy recruitment efforts to find qualified candidates with the required specialized skills. (These variations were reported in former Federal Personnel Manual Bulletins 575–4, April 20, 1993; 575–5, October 25, 1993; and 575–6, November

12, 1993; and in OPM's Provisional Notice No. 575–1, May 25, 1994.)

Written determination. In § 575.104(c)(1), the current regulations for recruitment bonuses require a written determination made on a case-by-case basis for each employee. The proposed regulations would allow an agency to make a single written determination applicable to a group of candidates for positions that the agency targets as difficult to fill. This would not require OPM's prior approval.

Reporting requirement. In § 575.108(b), the current regulations for recruitment bonuses require an annual written report by each agency on its use of recruitment bonuses. The proposed regulations would remove this requirement. However, each agency would retain responsibility for monitoring its use of recruitment bonuses.

Relocation Bonuses

Candidate quality. In §§ 575.201, 575.204 (c)(1) and (c)(2) (i) and (iii), and 575.208(b), the current regulations allow payment of a relocation bonus only when, in the absence of such a bonus, difficulty would be encountered in filling the position with a "high quality candidate." As for recruitment bonuses (discussed above), payment of relocation bonuses should be considered before requesting approval of special salary rates for difficult-to-fill positions. The proposed regulations would allow an agency to pay a relocation bonus to any employee the agency wishes to relocate to a position that would otherwise be difficult to fill.

Length of appointment. In § 575.203, the current definition of "employee" for relocation bonus purposes requires an appointment of at least 2 years. The proposed regulation would allow the employee's appointment to be any length of time determined appropriate by the agency. Also, the proposed definition would make a technical change to clarify that a relocation bonus may be paid to an employee whose duty station is changed to a different commuting area permanently as well as temporarily.

Written determination. In § 575.204(d), the current regulations provide for exceptions to case-by-case approvals of relocation bonuses with prior OPM approval. The proposed regulations would allow such exceptions without prior OPM approval.

Reporting requirement. In § 575.208(b), the current regulations for relocation bonuses require an annual written report by each agency on its use of relocation bonuses. The proposed regulations would remove this requirement.

Retention Allowances

Length of appointment. In § 575.303, the current definition of "employee" for retention allowance purposes requires an appointment of at least 2 years. The proposed regulations would allow the employee's appointment to be any length of time determined appropriate by the agency.

Length of service. In § 575.304(a), the current regulations permit payment of a retention allowance only to an employee who (1) has completed 1 year of continuous service with the agency immediately prior to such payment, or (2) has completed a period of employment established under a service agreement for a recruitment or relocation bonus. the proposed regulations would allow an agency to pay a retention allowance to an employee with less than 1 year of continuous service. However, the proposed regulations continue to require that an employee under a service agreement for a recruitment or relocation bonus complete such an agreement before receiving a retention allowance.

Reason for being likely to leave. In §§ 575.304(b) and 575.305(c), the current regulations permit payment of a retention allowance to an employee only if he or she is likely to leave the Federal service for employment outside the executive, legislative, or judicial branch of the Federal Government. The proposed regulations would allow payment of a retention allowance to an employee who is likely to leave not only for employment outside the Federal Government, but for a reason other than employment, such as retirement.

Reporting requirement. In § 575.308(b), the current regulations for retention allowances require an annual written report by each agency on its use of retention allowances. The proposed regulations would remove this requirement.

Miscellaneous

In § 575.103, the definition of "commuting area" is not germane to the payment of recruitment bonuses and would be removed by the proposed regulations. (The definition would remain in § 575.203 for payment of relocation bonuses.) Finally, the proposed regulations add a new paragraph (d) in § 575.306 to clarify that a retention allowance is not pay for purposes of a lump-sum payment for annual leave under 5 U.S.C. 5551. (See Comptroller General opinion B–249816, March 8, 1993.)

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 575

Administrative practice and procedure, Government employees, Wages.

James B. King,

Director.

Accordingly, OPM is proposing to amend part 575 of title 5 of the Code of Federal Regulations as follows:

PART 575—RECRUITMENT AND RELOCATION BONUSES; RETENTION ALLOWANCES; SUPERVISORY DIFFERENTIALS

1. The authority citation for part 575 continues to read as follows:

Authority: 5 U.S.C. 1104(a)(2), 5753, 5754, and 5755; sec. 302 and 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509) 104 Stat. 1462 and 1466, respectively; E.O. 12748.

2. Section 575.101 is revised to read as follows:

§ 575.101 Purpose.

This subpart provides regulations to implement 5 U.S.C. 5753, which authorizes payment of a recruitment bonus of up to 25 percent of basic pay to a newly appointed employee or an individual to whom a written offer of employment has been made by the agency, provided there is a determination that, in the absence of such a bonus, difficulty would be encountered in filling the position.

3. In § 575.103, the definition of "commuting area" is removed, and the definitions of "employee" and "newly appointed" are revised to read as follows:

§ 575.103 Definitions.

* * * * *

Employee means an employee in or under an agency who is newly appointed or an individual who has received a written offer of employment.

* * * * *

Newly appointed refers to—

(a) The first appointment, regardless of tenure, as an employee of the Federal Government;

(b) An appointment as an employee of the Federal Government following a break in service of at least 90 days from

the candidate's last period of Federal employment other than—

(1) Employment in a cooperative work-study program under a Schedule B appointment made in accordance with § 213.3202 of this chapter;

(2) Employment under the Stay-in-School program, in accordance with § 213.3102(w) of this chapter;

(3) Employment as a law clerk trainee under § 213.3102(e) of this chapter;

(4) Employment while a student during school vacations under a short-term temporary appointing authority;

(5) Employment under a provisional appointment designated under § 316.403 if the new appointment is permanent and immediately follows the provisional appointment; or

(6) Employment under a temporary appointment that is neither full-time nor the principal employment of the candidate.

* * * * *

4. In § 575.104, paragraphs (b)(2), (c)(1), and (c)(2) (i) and (iii) are revised to read as follows:

§ 575.104 Agency recruitment bonus plans; higher level review and approval; and criteria for payment.

* * * * *

(b)(2) When necessary to make a timely offer of employment, a higher level official may establish criteria for offering recruitment bonuses in advance and authorize the recommending official to offer a recruitment bonus (in any amount within a pre-established range) to any candidate without further review or approval.

(c) *Criteria for payment.* (1) Each bonus paid under this subpart shall be based on a written determination that, in the absence of such a bonus, the agency would encounter difficulty in filling the position. Such a determination shall be made before any employee actually enters on duty in the position for which he or she was recruited. An agency may target groups of positions that have been difficult to fill in the past or that may be difficult to fill in the future and may make the required written determination to offer a recruitment bonus on a group basis.

(2) * * *

(i) The success of recent efforts to recruit candidates for similar positions, including indicators such as offer acceptance rates, the proportion of positions filled, and the length of time required to fill similar positions;

* * * * *

(iii) Labor-market factors that may affect the ability of the agency to recruit candidates for similar positions now or in the future;

* * * * *

5. Section 575.106 is revised to read as follows:

§ 575.106 Service agreement.

(a) Before a recruitment bonus may be paid, an agency shall require that the employee sign a written service agreement to complete a specified period of employment with the appointing agency (or successor agency in the event of a transfer of function).

(b) The minimum period of employment to be established under a service agreement for a recruitment bonus shall be 6 months.

6. Section 575.108 is revised to read as follows:

§ 575.108 Internal monitoring.

Each agency shall monitor the use of recruitment bonuses to ensure that its recruitment bonus plan conforms to the requirements established under this subpart and that the payment of recruitment bonuses conforms to the criteria established under this subpart.

7. Section 575.201 is revised to read as follows:

§ 575.201 Purpose.

This subpart provides regulations to implement 5 U.S.C. 5753, which authorizes payment of a relocation bonus of up to 25 percent of basic pay to an employee who must relocate to accept a position in a different commuting area, provided there is a determination that, in the absence of such a bonus, difficulty would be encountered in filing the position.

8. In § 575.203, the definitions of "employee" and "service agreement" are revised to read as follows:

§ 575.203 Definitions.

* * * * *

Employee means an employee in or under an agency who is appointed to a position in a different commuting area or whose duty station is changed permanently or temporarily to a different commuting area.

* * * * *

Service agreement means a written agreement between an agency and an employee under which the employee agrees to a specified period of employment with the agency at the new duty station to which relocated in return for payment of a relocation bonus.

9. In § 575.204, paragraphs (c)(1), (c)(2)(i), (c)(2)(iii), and (d) are revised to read as follows:

§ 575.204 Agency relocation bonus plans; higher level review and approval; criteria for payment; and exceptions to case-by-case approval.

* * * * *

(c) *Criteria for payment.* (1) Each bonus paid under this subpart shall be based on a written determination that, in the absence of such a bonus, the agency would encounter difficulty in filling the position. Each such determination shall be made before the employee actually enters on duty in the position to which he or she was relocated. An agency may target groups of positions that have been difficult to fill in the past or that may be difficult to fill in the future. However, except as provided in paragraph (d) of this section, any determination to pay a bonus shall be made on a case-by-case basis for each employee.

(2) * * *

(i) The success of recent efforts to recruit candidates for similar positions, including indicators such as offer acceptance rates, the proportion of positions filled, and the length of time required to fill similar positions;

* * * * *

(iii) Labor market factors that may affect the ability of the agency to recruit candidates for similar positions now or in the future; and

* * * * *

(d) *Exceptions to case-by-case approval.* The head of an agency may authorize the payment of a relocation bonus to any employee whose rating of record is at least fully successful without the requirement for case-by-case approval when—

(1) The employee is a member of a specified group of employees subject to a mobility agreement, and the head of an agency determines that relocation bonuses are necessary to ensure the agency's ability to retain employees subject to such an agreement; or

(2) A major organizational unit of an agency is relocated to a different commuting area, and the head of an agency determines that relocation bonuses are necessary for specified groups of employees to ensure the continued operation of that unit without undue disruption of an activity or function that is deemed essential to the agency's mission and/or without undue disruption of service to the public.

10. Section 575.206 is revised to read as follows:

§ 575.206 Service agreement.

Before a relocation bonus may be paid, an agency shall require that the employee sign a written service agreement to complete a specified period of employment with the appointing agency (or the successor agency in the event of a transfer of function) at the new duty station.

11. Section 575.208 is revised to read as follows:

§ 575.208 Internal monitoring.

Each agency shall monitor the use of relocation bonuses to ensure that its relocation bonus plan conforms to the requirements established under this subpart and that the payment of relocation bonuses conforms to the criteria established under this subpart.

12. In § 575.303, the definition of "employee" is revised to read as follows:

§ 575.303 Definitions.

* * * * *

Employee means an employee in or under an agency.

* * * * *

13. In § 575.304, paragraphs (a) and (b) are revised to read as follows:

§ 575.304 Conditions for payment.

(a) If applicable, an agency may pay a retention allowance to an employee only if the employee has completed a period of employment established under the service agreement required for payment of a recruitment bonus under subpart A of this part or a relocation bonus under subpart B of this part, whichever occurs later.

(b) An agency may pay a retention allowance to an employee if the employee is likely to leave the Federal service for any reason.

* * * * *

14. In § 575.306, a new paragraph (d) is added to read as follows:

§ 575.306 Payment of retention allowance.

* * * * *

(d) A retention allowance is not pay for purposes of a lump-sum payment for annual leave under 5 U.S.C. 5551.

15. Section 575.308 is revised to read as follows:

§ 575.308 Internal monitoring.

Each agency shall monitor the use of retention allowances to ensure that its retention allowance plan conforms to the requirements established under this subpart and that the payment of retention allowances conforms to the criteria established under this subpart.

[FR Doc. 94–16127 Filed 7–1–94; 8:45 am]

BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 317

[Docket No. 93–030E]

RIN 0583–AB74

Nutrition Labeling of Ground Beef and Hamburger

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Extension of comment period.

SUMMARY: On May 24, 1994, the Food Safety and Inspection Service (FSIS) published a proposed rule (59 FR 26916) to amend the Federal meat inspection regulations by permitting percentage labeling for lean and fat on ground beef and hamburger, provided such product labeling contains nutrition information. FSIS has received a request to extend the comment period on the proposed rule so that additional data and information can be provided. FSIS has determined that the request should be granted and, therefore, is extending the comment period on the proposed rule for 45 days. FSIS is continuing to evaluate the effect that this extension will have on issues such as the survey for significant participation for voluntary nutrition labeling and the approval of labeling for ground beef and hamburger pending the outcome of this rulemaking.

DATES: Comments must be received on or before August 22, 1994.

ADDRESSES: Submit written comments in triplicate to: Diane Moore, Docket Clerk, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 3171–S, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Mr. Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 254–2565.

SUPPLEMENTARY INFORMATION: On May 24, 1994, FSIS published in the **Federal Register** a proposed rule (59 FR 26916) to amend the Federal meat inspection regulations by permitting percentage labeling for lean and fat on ground beef and hamburger, provided such product labeling contains nutrition information. The proposed rule would provide increased flexibility in the labeling of ground beef and hamburger, and would also allow consumers to readily identify and differentiate between the varying lean/fat percentages of these products.

Interested persons were given until July 8, 1994, in which to comment on the proposed rule. FSIS has received a request from a consumer interest group to extend the comment period on the proposed rule to allow additional time for consumer survey data to be gathered and submitted. FSIS noted in its proposed rule on percentage labeling for lean/fat on ground beef and hamburger (59 FR 26916) that it had not assessed whether multiple uses of the term "percent lean" might result in consumer misunderstanding that would limit informed consumer choice. The consumer survey will provide information on consumer perceptions of the terms "lean," "extra lean," "percent lean," "reduced fat," and "percent daily value." FSIS is interested in receiving such data to assist in its efforts to develop comprehensive nutrition labeling regulations that will help consumers make informed purchasing decisions. FSIS believes that it would be a disservice to consumers and industry for FSIS to deny an opportunity for further input into a decision on the labeling of ground beef and hamburger. Therefore, FSIS is extending the comment period on the proposed rule for 45 days so that any labeling decision resulting from its proposed rule reflects the greatest amount of data and information available on this important issue. FSIS is continuing to evaluate the effect that this extension will have on issues such as the survey for significant participation for voluntary nutrition labeling and the approval of labeling for ground beef and hamburger pending the outcome of this rulemaking.

Done at Washington, DC, on: June 27, 1994.

William J. Hudnall,

Acting Administrator, Food Safety and Inspection Service.

[FR Doc. 94–16108 Filed 7–1–94; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94–NM–67–AD]

Airworthiness Directives; Raytheon Corporate Jets Model BAe 125–1000A Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Raytheon Corporate Jets Model

BAe 125–1000A series airplanes. This proposal would require modification of the galley feeder cables and toilet services fuse. This proposal is prompted by a report that the gauge size of the existing galley feeder cable is not compatible with the rating of the currently used toilet services fuse. The actions specified by the proposed AD are intended to ensure that the subject cables are compatible with the toilet services fuse in order prevent overheating of the cables, which could result in smoke and fire in the cabin.

DATES: Comments must be received by September 22, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–67–AD, 1601 Lind Avenue SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Raytheon Corporate Jets, Inc., Customer Support Department, Adams Field, P.O. Box 3356, Little Rock, Arkansas 72203. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (206) 227–1112; fax (206) 227–1100.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 94–NM–67–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–67–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain Raytheon Corporate Jets Model BAe 125–1000A series airplanes. The CAA advises that the gauge size of the galley feeder cables installed on these airplanes is not compatible with the rating of the toilet services fuses. In the event of a fault condition, the incompatibility of these items could result in the cables becoming overheated, which could lead to the generation of smoke and fire in the cabin. There have been no in-service incidents of such faults or consequent smoke and fire, however.

Hawker-Raytheon Corporate Jets has issued Service Bulletin SB.25–75–25A698A&B, dated February 10 1994, that describes procedures for installing Modification 25A698A&B on airplanes that were furnished with an "open plan" galley. This modification consists of changing the gauge size of the galley feeder cables (from fuses F1 and F2 on panel WFA to the left and right galley) from size 10 to size 8; changing the toilet services fuse F3 from 50A to 30A amperage; and adding a new 20A fuse to the left and right galley.

Hawker-Raytheon Corporate Jets also has issued Service Bulletin SB.25–75–25A699A, dated February 10 1994, that describes procedures for installing Modification 25A699A on airplanes that were furnished with a "traditional" galley. This modification consists of changing the gauge size of the galley feeder cables (from fuses F1 and F2 on panel WFA to the galley) from size 10 to size 8; changing the toilet services fuse F3 from 50A to 30A amperage; and adding a new 20A fuse to the galley.

The CAA classified both of these service bulletins as mandatory.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require modification of the galley feeder cables and toilet services fuses. The actions would be required to be accomplished in accordance with the service bulletins described previously.

The FAA estimates that 4 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 16 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Required parts would cost approximately $500 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $5,520, or $1,380 per airplane.

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

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant

economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

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

Raytheon Corporate Jets, Inc.: Docket 94–NM–67–AD.

Applicability: Model BAe 125–1000A series airplanes; as listed in Hawker-Raytheon Corporate Jets Service Bulletin SB.25–76–25A698A&B, dated February 10, 1994, and Hawker-Raytheon Corporate Jets Service Bulletin SB.25–76–25A699A, dated February 10, 1994; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent smoke and fire in the cabin due to overheating of galley cables, accomplish the following:

(a) For airplanes listed in Hawker-Raytheon Corporate Jets Service Bulletin SB.25–76–25A698A&B, dated February 10, 1994: Within 100 hours time-in-service after the effective date of this AD, install Modification 25A698A&B in accordance with that service bulletin.

(b) For airplanes listed in Hawker-Raytheon Corporate Jets Service Bulletin SB.25–76–25A699A, dated February 10, 1994: Within 100 hours time-in-service after the effective date of this AD, install Modification 25A699A in accordance with that service bulletin.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

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

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

Issued in Renton, Washington, on June 28, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–16158 Filed 7–1–94; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[IA–78–93]

RIN 1545–AS58

Accuracy-Related Penalty; Hearing

AGENCY: Internal Revenue Service, Treasury.

ACTION: Change of location of public hearing.

SUMMARY: This document changes the location of the public hearing on proposed regulations relating to accuracy-related penalty under chapter 1 of the Internal Revenue Code.

DATES: The public hearing is being held on Tuesday, July 12, 1994, beginning at 10 a.m.

ADDRESSES: The public hearing originally scheduled in the IRS Auditorium, Seventh floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC, is changed to room 3718, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of public hearing appearing in the **Federal Register** on Thursday, March 17, 1994 (59 FR 12563), announced that a public hearing relating to proposed regulations under section 6662 of the Code by section 13251 of OBRA 1993 will be held Tuesday, July 12, 1994, beginning at 10 a.m. in the IRS Auditorium, Seventh floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC and that requests to speak and outlines of oral comments should be received by Tuesday, June 21, 1994. The proposed regulations were published in the **Federal Register** on Thursday, March 17, 1994 (59 FR 12563).

The location of the public hearing has changed. The hearing is being held in room 3718 on Tuesday, July 12, 1994, beginning at 10 a.m. The requests to speak and outlines or oral comments must have been received by Tuesday, June 21, 1994. Because of controlled access restrictions, attenders cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

Copies of the agenda are available free of charge at the hearing.

Cynthia E. Grigsby,

Chief, Regulations Unit Assistant Chief Counsel (Corporate).

[FR Doc. 94–16217 Filed 7–1–94; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF EDUCATION

Office of Postsecondary Education

34 CFR Chapter VI

Direct Student Loan Regulations Negotiated Rulemaking Advisory Committee: Meeting

AGENCY: Direct Student Loan Regulations Negotiated Rulemaking Advisory Committee, Department of Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the date and location of the forthcoming meeting of the Direct Student Loan Regulations Negotiated Rulemaking Advisory Committee. This notice also describes the functions of the committee, Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATES July 7–8, 1994 from 9 a.m. to 5 p.m.

ADDRESSES: The Crystal Gateway Marriot, 1700 Jefferson Davis Highway, Arlington, VA, (703) 920–3230.

FOR FURTHER INFORMATION CONTACT: Jennifer Peck, Office of the Assistant Secretary for Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW. (Room 4082, ROB–3), Washington, D.C. 20202–5100, Telephone: (202) 708–5547. Individuals

who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Director Student Loan Regulations Negotiated Rulemaking Advisory Committee is established by Sections 422 and 457 of the Higher Education Act of 1965, as amended by the Student Loan Reform Act of 1993 (Pub. L. 103–66; 20 U.S.C. 1087g). The Committee is also established in accordance with the provisions of the Negotiated Rulemaking Act (Pub. L. 101–648, as amended; 5 U.S.C. 561). The advisory Committee is established to provide advice to the Secretary on the standards, criteria, procedures, and regulations governing the District Student Loan Program beginning with academic year 1995–1996. The Direct Student Loan Program is authorized by the Student Loan Reform Act of 1993. The Act authorizes the Secretary of Education to enter into agreements with selected institutions of higher education. These agreements will enable the institutions to originate loans to eligible students and eligible parents of such students.

The meeting is open to the public. The agenda will include the following:

—Initial counseling

—Late disbursements

—Service choice

—Economic hardship

—Income contingent loan repayment

This notice is being published less than 15 days in advance of the meeting because it was scheduled at the end of the June negotiating session.

Records are kept of all Committee proceedings and are available for public inspection at the Office of the Assistant Secretary for Postsecondary Education, Room 4082, ROB–3, 7th and D Streets SW., Washington, DC from the hours of 9 a.m. and 5 p.m. weekdays, except Federal holidays.

Dated: June 28, 1994

David A. Longanecker,

Assistant Secretary, Office of Postsecondary Education, U.S. Department of Education.

[FR Doc. 94–16121 Filed 7–1–94; 8:45 am]

BILLING CODE 4000–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OAQPS #CA21–6–6291; FRL–5007–1]

Approval and Promulgation of Implementation Plans; California

State Implementation Plan Revision; Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) for ozone. The revisions concern the control of oxides of nitrogen (NO_x) from electric utilities and stack monitoring requirements for making compliance determinations in Ventura County. The intended effect of proposing approval of these rules is to regulate emissions of NO_x in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). EPA's final action on this notice of proposed rulemaking will incorporate these rules into the federally approved SIP. EPA has evaluated each of these rules and is proposing to approve them under provisions of the CAA regarding EPA actions on SIP submittals, SIPs for national primary and secondary ambient air quality standards, and plan requirements for nonattainment areas.

COMMENTS: Comments on this proposed action must be received in writing on or before August 4, 1994.

ADDRESSES: Comments may be mailed to: Daniel A. Meer, Chief, Stationary Source Rulemaking (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

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

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

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95812.

Ventura County Air Pollution Control District, Rule Development Section, 702 County Square Drive, Ventura, CA 93003.

FOR FURTHER INFORMATION CONTACT: Wendy Colombo, Stationary Source Rulemaking, (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105 Telephone: (415) 744–1202.

SUPPLEMENTARY INFORMATION:

Background:

On November 15, 1990, the Clean Air Act Amendments of 1990 (CAA) were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. The air quality planning requirements for the reduction of NO_x emissions through reasonably available control technology (RACT) are set out in section 182(f) of the CAA. On November 25, 1992, EPA published a notice of proposed rulemaking entitled "State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule," (the NO_x Supplement) which describes the requirements of section 182(f). The November 25, 1992, notice should be referred to for further information on the NO_x requirements and is incorporated into this document by reference.

Section 182(f) of the Clean Air Act requires States to apply the same requirements to major stationary sources of NO_x ("major" as defined in section 302 and sections 182(c), (d), and (e)) as are applied to major stationary sources of volatile organic compounds (VOCs), in moderate or above ozone nonattainment areas. Ventura County is classified as a severe nonattainment area for ozone,[1] therefore subject to the RACT requirements of section 182(b)(2), cited above.

Section 182(b)(2) requires submittal of RACT rules for major stationary sources of VOC emissions (not covered by a pre-enactment control technologies guidelines (CTG) document or a post-enactment CTG document) by November 15, 1992. There were no NO_x CTGs issued before enactment and EPA has not issued a CTG document for any NO_x sources since enactment of the CAA. The RACT rules covering NO_x sources and submitted as SIP revisions are expected to require final installation of the actual NO_x controls by May 31, 1995 for those sources where installation by that date is practicable.

[1] Ventura County was designated nonattainment and classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 55 FR 56694 (November 6, 1991).

This document addresses EPA's proposed action for Ventura County Air Pollution Control District (VCAPCD), Rule 59, Electrical Power Generating Equipment—Oxides of Nitrogen Emissions and Rule 103, Stack Monitoring. Rule 59 and Rule 103 were respectively adopted by VCAPCD on September 15, 1992 and June 4, 1991. The California Air Resources Board (CARB) submitted these revisions to EPA on November 18, 1993 and October 25, 1991, respectively. The submissions were found to be complete on December 23, 1993 (Rule 59) and December 18, 1991 (Rule 103), pursuant to EPA's completeness criteria that are set forth in 40 CFR Part 51 Appendix V,[2] and are being proposed for approval into the SIP.

NO_X emissions contribute to the production of ground level ozone and smog. Rule 59 limits nitrogen oxide emissions from utility boilers in Ventura County, while Rule 103 specifies stack monitoring requirements. The rules were adopted as part of Ventura County's efforts to achieve the National Ambient Air Quality Standards (NAAQS) for ozone and in response to the CAA requirements cited above. The following is EPA's evaluation and proposed action for these rules.

EPA Evaluation and Proposed Action

In determining the approvability of a NO_X rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption and Submittal of Implementation Plans). The EPA interpretations of these requirements, which form the basis for this action, appear in the NO_X Supplement and various other EPA policy guidance documents.[3] Among these provisions is the requirement that a NO_X rule must, at a minimum, provide for the implementation of RACT for stationary sources of NO_X emissions.

For the purposes of assisting state and local agencies in developing NO_X RACT rules, EPA prepared the NO_X Supplement to the General Preamble, cited above (57 FR 55620). In the NO_X Supplement, EPA provides guidance on how RACT should be determined for major stationary sources of NO_X emissions. While most of the guidance issued by EPA on what constitutes RACT for stationary sources has been directed towards application for VOC sources, much of the guidance is also applicable to RACT for stationary sources of NO_X (see section 4.5 of the NO_X Supplement). In addition, pursuant to section 183(c), EPA is issuing alternative control techniques documents (ACTs), that identify alternative controls for all categories of stationary sources of NO_X. The ACT documents will provide information on control technology for stationary sources that emit or have the potential to emit 25 tons per year or more of NO_X. However, the ACTs will not establish a presumptive norm for what is considered RACT for stationary sources of NO_X. In general, the guidance documents cited above, as well as other relevant and applicable guidance documents, have been issued by EPA to ensure that submitted NO_X RACT rules are fully enforceable and strengthen or maintain the SIP.

The current SIP-approved version of Rule 59, Electrical Power Generating Equipment—Oxides of Nitrogen Emissions, has four parts: "A" regarding emission limits; "B" regarding applicability; "D" regarding definitions (approved on June 6, 1980); and "C" regarding exceedance provisions (approved into the SIP on April 11, 1983). The significant changes in the September 15, 1992 version involve more stringent emission limits, fuel oil provisions, natural gas curtailment issues, 24-hour rolling average compliance determinations, start-up exemptions, and increments of progress provisions. In addition, new recordkeeping requirements, test methods, and definitions have been included.

Specifically, the rule limits NO_X emissions from boilers rated less than 2150 million British Thermal Units (MMBtu) to 0.20 pounds per megawatt-hour (lb/MW-hr) produced, and limits NO_X emissions from units greater than or equal to 2150 MMBtu to 0.10lb/MW-hr. Final compliance with these limits is required by June 4, 1996 and June 4, 1994, respectively. Interim NO_X limits are required for units burning natural gas as well as fuel oil. However, operation on any amount of fuel oil as of April 1, 1993 is prohibited except during system tests or a force majeure natural gas curtailment. Compliance with the hourly emission limits is determined using a 24-hour rolling average in which the 24 hourly measurements immediately preceding the current hour are used to calculate the average for that hour. Emissions and power production are required to be continuously monitored pursuant to Rule 103. For implementation by 1995, all the limits specified in Rule 59 are more stringent than RACT except for the pre-1996 limits established for units less than 2150MMBtu/hr. The pre-1996 limits for these units, however, meet RACT. Although all limits post-1996 are more stringent than the NO_X RACT limits for utility boilers specified in the NO_X Supplement, all additional reductions obtained beyond those attributable to RACT are assumed necessary for VCAPCD's attainment planning purposes.

A more detailed discussion of the sources controlled, the controls required, and the analysis of how these controls meet RACT can be found in the Technical Support Document (TSD) for Rule 59 and Rule 103, dated June 1994.

Rule 103, Stack Monitoring was originally adopted by VCAPCD on November 22, 1977. A revised version was approved into the SIP on October 16, 1985. The rule adopted on June 4, 1991 requires all large boilers, regardless of their use rate, to be monitored.

EPA has evaluated the submitted rules and has determined that they are consistent with the CAA, EPA regulations and EPA policy. Therefore, both VCAPCD Rule 59, Electrical Power Generating Equipment—Oxides of Nitrogen Emissions and VCAPCD Rule 103, Stack Monitoring are being proposed for approval under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

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

Regulatory Process

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

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

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

government entities with jurisdiction over populations of less than 50,000.

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

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation.

OMB has exempted this action from E.O. 12866 review.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401-7671q.

Dated: June 20, 1994.

John Wise,

Acting Regional Administrator.

[FR Doc. 94–16219 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–50–P

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40 CFR Part 52

[SIPTRAX NO. DC11–1–6222; FRL–5006–9]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Oxygenated Gasoline Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a limited approval/limited disapproval of a State Implementation Plan (SIP) revision submitted by the District of Columbia. This revision implements an oxygenated gasoline program in the District of Columbia. The intended effect of this action is to propose approval of those subsections of the District of Columbia Municipal Regulations (DCMR) which pertain to oxygenated gasoline for the limited purpose of strengthening the District of Columbia SIP which currently has no requirements for an oxygenated gasoline program. In addition, this action is intended to propose disapproval of those subsections of the DCMR which pertain to oxygenated gasoline for the limited purpose of allowing the District of Columbia the opportunity to correct the deficiencies in the regulation which result in its failure to meet all requirements of the Clean Air Act. This action is being taken under Section 110 of the Clean Air Act.

DATES: Comments must be received on or before August 4, 1994.

ADDRESSES: Comments may be mailed to Thomas J. Maslany, Director, Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107 and the District of Columbia Department of Consumer and Regulatory Affairs, 2100 Martin Luther King Ave, S.E., Washington, DC 20020.

FOR FURTHER INFORMATION CONTACT: Mrs. Kelly L. Bunker, (215) 597–4554.

SUPPLEMENTARY INFORMATION:

I. Introduction

Motor vehicles are significant contributors of carbon monoxide emissions. An important measure toward reducing these emissions is the use of cleaner-burning oxygenated gasoline. Extra oxygen enhances fuel combustion and helps to offset fuel-rich operating conditions, particularly during vehicle starting, which are more prevalent in the winter.

Section 211(m) of the Clean Air Act, 42 U.S.C. 7401 *et seq.* (the Act), requires that various states submit revisions to their SIPs, and implement oxygenated gasoline programs by no later than November 1, 1992. This requirement applies to all states with carbon monoxide nonattainment areas with design values of 9.5 parts per million or more based generally on 1988 and 1989 data. Each state's oxygenated gasoline program must require gasoline for the specified control area(s) to contain not less than 2.7 percent oxygen by weight during that portion of the year in which the areas are prone to high ambient concentrations of carbon monoxide. Under section 211(m)(2), the oxygenated gasoline requirements are to generally cover all gasoline sold or dispensed in the larger of the Consolidated Metropolitan Statistical Area (CMSA) or the Metropolitan Statistical Area (MSA) in which the nonattainment area is located. Under section 211(m)(2), the length of the control period, to be established by the EPA Administrator, shall not be less than four months in length unless a state can demonstrate that, because of meteorological conditions, a reduced control period will assure that there will be no carbon monoxide exceedances outside of such reduced period. EPA announced guidance on the establishment of control periods by area in the Federal Register on October 20, 1992.[1]

In addition to the guidance on establishment of control period by area, EPA has issued additional guidance related to the oxygenated gasoline program. On October 20, 1992, EPA announced the availability of oxygenated gasoline credit program guidelines in the Federal Register.[2] Under a credit program, marketable oxygen credits may be generated from the sale of gasoline with a higher oxygen content than is required (i.e. an oxygen content greater than 2.7 percent by weight). These oxygen credits may be used to offset the sale of gasoline with a lower oxygen content than is required. Where a credit program has been adopted, EPA's guidelines provide that no gallon of gasoline should contain less than 2.0% oxygen by weight.

EPA issued labeling regulations under section 211(m)(4) of the Act. These labeling regulations were published in the Federal Register on October 20, 1992.[3]

II. Background for this Action

EPA has determined that the 1988 and 1989 data for the Washington, DC area is invalid because of poor data quality and therefore inadequate to properly characterize the ambient concentrations of carbon monoxide (CO). Therefore, EPA used data from 1987 and 1988 to designate the Washington, DC area as a CO nonattainment area with a design

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[1] *See* "Guidelines for Oxygenated Gasoline Credit Programs and Guidelines on Establishment of Control Periods under Section 211(m) of the Clean Air Act as Amended—Notice of Availability," 57 FR 47853 (October 20, 1992).

[2] *See* note 1. EPA was issued guidelines for credit programs under section 211(m)(5) of the Act.

[3] *See* "Notice of Final Oxygenated Fuels Labeling Regulations under Section 211(m) of the Clean Air Act as Amended—Notice of Final Rulemaking," 57 FR 47769. The labeling regulations may be found at 40 C.F.R. Part 80, section 80.35.

value of 11.4 ppm.[4] Under section 211(m) of the Act, the District of Columbia was required to submit a revised SIP under section 110 and part D of title I of the Act which includes an oxygenated gasoline program for the entire District of Columbia by November 15, 1992.[5]

On October 27, 1993, the District of Columbia Department of Consumer and Regulatory Affairs submitted a revision to its SIP for an oxygenated gasoline program. The revision included additions or amendments to 20 District of Columbia Municipal Regulations (DCMR) Chapter 1, Section 199; Chapter 5, Section 500, Subsections 500.4 and 500.5; Chapter 5, Section 502, Subsection 502.18; Chapter 9, Section 904, Subsections 904.1 and 904.2. These regulatory revisions were adopted by the District of Columbia on July 16, 1993 and became effective on September 30, 1993. EPA summarizes its analysis of the state submittal below. A more detailed analysis of the state submittal is contained in a Technical Support Document (TSD) dated February 23, 1994, which is available from the Region III office, listed in the ADDRESSES section.

III. EPA's Analysis of the District of Columbia's Oxygenated Gasoline Program

As discussed above, section 211(m)(2) of the Act requires that gasoline sold or dispensed for use in the specified control areas contain not less than 2.7 percent oxygen by weight. Under section 211(m)(5), the EPA Administrator issued guidelines for credit programs allowing the use of marketable oxygen credits. The District of Columbia has elected to adopt a regulation requiring 2.7% oxygen content for each gallon of gasoline sold in a control area. The following sections of this notice address some specific elements of the state's submittal. Parties desiring more specific information should consult the TSD.

Applicability and Program Scope

Section 211(m)(2) requires oxygenated gasoline to be sold during a control period based on air quality monitoring data and established by the EPA Administrator. The District of Columbia has established the control period as November 1 to the last day of February control period which is consistent with the EPA guidance. The District of Columbia oxygenated gasoline regulations require oxygenated gasoline to be sold in the entire District of Columbia, consistent with the requirements of section 211(m)(2) of the Act. 20 DCMR Section 500, Subsection 500.4 requires all parties in the gasoline distribution network, including "carriers", to generate and maintain records detailing compliance. However, the definition of "carriers" is not found in Section 199, entitled Definitions and Abbreviations, or any other section of 20 DCMR. The lack of a definition for "carriers" compromises the enforceability of the regulation and is a deficiency under Section 110(a)(2) of the Act.

Transfer Documents

The District of Columbia has included requirements related to transfer documentation in its regulation. These transfer document requirements will enhance the enforcement of the oxygenated gasoline regulation, by providing a paper trail for each gasoline sample taken by state enforcement personnel.

Enforcement and Penalty Schedules

State oxygenated gasoline regulations must be enforceable by the state oversight agency. EPA recommends that states will visit at least 20% of regulated parties during a given control period. Inspections should consist of product sampling and record review. In addition, each state should devise a comprehensive penalty schedule. Penalties should reflect the severity of a party's violation, the compliance history of the party, as well as the potential environmental harm associated with the violation.

The District of Columbia's enforcement strategies and penalty provisions are found in 20 DCMR Chapter 1, Sections 100, 101, 102, 104 and 105. 20 DCMR Chapter 1, Sections 101 and 102 give the authority to inspect and issue notice of violations to the alleged violator. 20 DCMR Chapter 1, Section 104 provides the alleged violator the opportunity for a hearing. 20 DCMR Chapter 1, Section 105 provides penalties which include a fine of up to $5,000 per violation or imprisonment not to exceed 90 days, or both. The District of Columbia's enforcement and penalty provisions are acceptable.

Test Methods and Laboratory Review

EPA's sampling procedures are detailed in Appendix D of 40 C.F.R. Part 80. EPA has recommended that states adopt these sampling procedures. The District of Columbia has not adopted EPA sampling procedures or any other sampling procedure which would be acceptable to EPA. In addition, the District of Columbia has failed to include in its' regulation procedures for the calculation of oxygen content in the gasoline sampled. Both the lack of sampling procedures and oxygen content calculations compromise the enforceability of the regulation and are a deficiency under Section 110(a)(2) of the Clean Air Act.

Each state regulation must include a test method. EPA's guidelines recommend the use of the OFID test, although parties may elect to use ASTM–D4815–89 or another method, if approved by EPA. The District of Columbia has elected to use the ASTM–D4815–89 method which is consistent with EPA guidelines.

Labeling

EPA was required to issue federal labeling regulations under section 211(m)(4) of the Act. These regulations, published in the **Federal Register** on October 20, 1992,[6] required the following statement be posted for a per-gallon program or credit program with minimum oxygen content requirement:

"The gasoline dispensed from this pump is oxygenated and will reduce carbon monoxide pollution from motor vehicles."

The Federal regulation also specifies the appearance and placement requirements for the labels.

EPA has strongly recommended that states adopt their own labeling regulations, consistent with the Federal regulation. The District of Columbia has adopted labeling regulations consistent with the federal regulation.

EPA Analysis

EPA is proposing a limited approval of the additions or amendments to 20 DCMR Chapter 1, Section 199, definitions for the terms "blending plant", "distributor", "non-oxygenated gasoline", "oxygenate", "oxygenated gasoline", "oxygenated gasoline control period", "oxygenated gasoline control area", "refiner", "refinery", "retailer", "retail outlet", "terminal", and "wholesale purchaser consumer"; Chapter 5, Section 500, Subsections 500.4 and 500.5; Chapter 5, Section 502, Subsection 502.18; Chapter 9, Section 904, Subsections 904.1 and 904.2 into the District of Columbia SIP, which was submitted on October 27, 1993. EPA is also proposing to disapprove the additions or amendments to 20 DCMR Chapter 1, Section 199, definitions for the terms "blending plant",

[4] *See* "Designation of Areas for Air Quality Planning Purposes," 56 FR 56694 (November 6, 1991).

[5] *See* credit program guidelines at 3, wherein the November 15, 1992 SIP revision due date was specified.

[6] *See* note 3.

"distributor", "non-oxygenated gasoline", "oxygenate", "oxygenated gasoline", "oxygenated gasoline control period", "oxygenated gasoline control area", "refiner", "refinery", "retailer", "retail outlet", "terminal", and "wholesale purchaser-consumer"; Chapter 5, Section 500, Subsections 500.4 and 500.5; Chapter 5, Section 502, Subsection 502.18; Chapter 9, Section 904, Subsections 904.1 and 904.2 for the limited purpose of allowing the District of Columbia the opportunity to correct certain deficiencies. These deficiencies are located in Section 199 (lack of definition for the term "carrier") and Section 502 (lack of sampling procedure and lack of a procedure to calculate the oxygen content of the gasoline sampled). EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action.

Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Regional office listed in the *Addresses* section of this notice.

20 DCMR Section 500, Subsection 500.4 requires all parties in the gasoline distribution network, including "carriers", to generate and maintain records detailing compliance. However, the definition of "carriers" is not found in 20 DCMR Section 199, entitled Definitions and Abbreviations, or any other section of 20 DCMR. Therefore, EPA is proposing to disapprove both Section 199, because it lacks a definition for the term "carriers", and Subsection 500.4, because the term "carriers" which is used in this section is not defined in the subsection or any other section of 20 DCMR. The lack of a definition of "carriers" compromises the enforceability of the regulation and is a deficiency under Section 110(a)(2) of the Clean Air Act.

EPA's sampling procedures are detailed in Appendix D of 40 CFR Part 80. EPA has recommended that states adopt these sampling procedures. The District of Columbia has not adopted EPA sampling procedures or any other sampling procedure which would be acceptable to EPA. In addition, the District of Columbia has failed to include in its' regulation procedures for the calculation of oxygen content in the gasoline sampled. Both the lack of a sampling procedure and oxygen content calculation procedure compromise the enforceability of the regulation and are a deficiency under Section 110(a)(2) of the Clean Air Act. Therefore, EPA is proposing to disapprove 20 DCMR Section 502, Subsection 502.18 because it lacks both a sampling procedure and a procedure for calculating the oxygen content in the gasoline sampled.

Because of the above deficiencies, EPA cannot grant full approval of this rule under section 100(k)(3) and Part D. Also, because the submitted rule is not composed of separable parts which meet all the applicable requirements of the Act, EPA cannot grant partial approval of the rule under section 110(k)(3). However, EPA may grant a limited approval of the submitted rule under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited because EPA's action also contains a simultaneous limited disapproval, due to the fact that the rule does not meet the section 110(a)(2) requirement because of the noted enforcement deficiencies. Thus, in order to strengthen the SIP, EPA is proposing a limited approval of the District of Columbia's submitted additions or amendments to 20 DCMR Chapter 1, Section 199; Chapter 5, Section 500, Subsections 500.4 and 500.5; Chapter 5, Section 502, Subsection 502.18; Chapter 9, Section 904, Subsections 904.1 and 904.2 under section 110(k)(3) and 301(a) of the Act.

At the same time, EPA is also proposing a limited disapproval of this rule because it contains deficiencies under section 110(a)(2) of the Act, and, as such, the rule does not fully meet the requirements of the Act. Under section 179(a)(2), if the Administrator disapproves a submission under section 110(k) for an area designated nonattainment, based on the submission's failure to meet one or more of the elements required by the Act, the Administrator must apply one of the sanctions set forth in section 179(b) unless the deficiency has been corrected within 18 months of such disapproval. Section 179(b) provides two sanctions available to the Administrator: highway funding and offsets. The 18 month period referred to in section 179(a) will begin at the time EPA publishes final notice of this disapproval. Moreover, the final disapproval triggers the federal implementation plan (FIP) requirement under section 110(c).

III. Proposed Action

For the above stated reasons, EPA is proposing a limited approval/limited disapproval of the District of Columbia's SIP for an oxygenated gasoline program. In order to correct the deficiencies in 20 DCMR Chapter 1, Section 199; Chapter 5, Section 500, Subsections 500.4 and 500.5; Chapter 5, Section 502, Subsection 502.18; Chapter 9, Section 904, Subsections 904.1 and 904.2 which EPA is proposing as a limited disapproval, the District of Columbia must include a definition for the term "carrier", include a sampling procedure, and include procedures for the calculation of oxygen content in the gasoline sampled. If the District of Columbia submits a SIP revision which is deemed administratively and technically complete and corrects the deficiencies listed above prior to the time that EPA finalizes this action, EPA will propose full approval of the October 27, 1993 submittal and the subsequent submittal which corrects the deficiencies.

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

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

SIP approvals under sections 110 and 301, and subchapter I, Part D of the Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

EPA's disapproval of the State request under section 110 and subchapter I, part D of the Act does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA's disapproval of the submittal does not

impose any new Federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements and impose any new Federal requirements.

This action has been classified as a Table 2 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by an October 4, 1993 memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation. OMB has exempted this regulatory action from E.O. 12866 review.

The Administrator's decision to approve or disapprove the District of Columbia's oxygenated gasoline SIP revision will be based on whether it meets the requirements of section 110(a)(2)(A)–(K) and of the Clean Air Act, as amended, and EPA regulations in 40 CFR part 51.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: April 28, 1994.

Stanley L. Laskowski,

Acting, Regional Administrator, Region III.

[FR Doc. 94–16218 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 94–64, RM–8453]

Radio Broadcasting Services; Ider, AL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed on behalf of Deborah M. Thompson, requesting the allotment of FM Channel 254A to Ider, Alabama, as that community's first local aural transmission service. Coordinates used for this proposal are 34–48–43 and 85–36–07.

DATES: Comments must be filed on or before August 19, 1994, and reply comments on or before September 3, 1994.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner and her consultant, as follows: Deborah M. Thompson, Route 5, Box 88I, Scottsboro, AL 35768 (petitioner); and Kirk A. Tollett, Commsouth Media Associates, 4001 Highway 78 East, Jasper, AL 35501 (consultant).

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 94–64, adopted June 14, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–16133 Filed 7–1–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 94–62, RM–8444]

Radio Broadcasting Services; Kasilof, AK

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed on behalf of William Glynn, requesting the allotment of FM Channel 229A to Kasilof, Alaska, as that community's first local aural transmission service. Coordinates used for this proposal are 60–20–15 and 151–16–20.

DATES: Comments must be filed on or before August 19, 1994, and reply comments on or before September 3, 1994.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Benjamin Perez, Esq., Abacus Communications Company, 1801 Columbia Road, NW., suite 101, Washington, DC 20009–2031.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 94–62, adopted June 14, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street, NW., suite 1460, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–16134 Filed 7–1–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 94–60, RM–8455]

Radio Broadcasting Services; Duncan, AZ

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition for rule making filed on behalf of Duncan Community Radio proposing the allotment of FM Channel 264A to Duncan, Arizona, as that community's first local aural broadcast service. Coordinates for Channel 264A are 32–43–12 and 109–06–12. Duncan is located within 320 kilometers (199 miles) of the United States-Mexico border, and therefore, the Commission must obtain concurrence of the Mexican government to this proposal.

DATES: Comments must be filed on or before August 19, 1994, and reply comments on or before September 3, 1994.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: Jeffrey D. Southmayd, Esq., Southmayd & Miller, 1120–19th Street NW., Suite 400, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 94–60, adopted June 9, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857–3800, 2100 M Street NW., suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch Policy and Rules Division Mass Media Bureau.

[FR Doc. 94–16135 Filed 7–1–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 94–63, RM–8450]

Radio Broadcasting Services; Rocky Mount and Bassett, VA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition file by WNLB Radio, Inc., licensee of Station WZBB–FM, Channel 260A, Rocky Mount, Virginia, seeking the substitution of Channel 260C3 for Channel 260A, the reallotment of Channel 260C3 from Rocky Mount to Bassett, Virginia, and the modification of Station WZBB–FM's license to specify Bassett as the station's community of license. Channel 260C3 can be allotted to Bassett in compliance with the Commission's minimum distance separation requirements with a site restriction of 10.0 kilometers (6.2 miles) northwest to accommodate WNLB's desired site. The coordinates for Channel 260C3 at Bassett are 36–48–47 and 80–04–41. In accordance with Section 1.420(i) of the Commission's Rules, we will not accept competing expressions of interest in use of Channel 260C3 at Bassett or require the petitioner to demonstrate the availability of an additional equivalent class channel for use by such parties.

DATES: Comments must be filed on or before August 19, 1994, and reply comments on or before September 3, 1994.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Peter Gutmann, Pepper & Corazzini, 1776 S Street NW., Suite 200, Washington, DC 20006 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 94–63, adopted June 14, 1994, and released June 28, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–16136 Filed 7–1–94; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 94–53, Notice 01]

RIN No. 2127–AF19

Federal Motor Vehicle Safety Standards (FMVSS); New Pneumatic Tires

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document responds to a petition for rulemaking submitted by the Japan Automobile Tire Manufacturers' Association, Inc. (JATMA), and proposes to amend the labeling requirements of FMVSS No. 109, *New Pneumatic Tires*, to permit tires that

have a maximum inflation pressure of 60 pounds per square inch (psi) to be labeled "inflate to 420 kPa (60 psi)." Currently, the standard does not permit the metric unit to be on the label. The proposal would aid the international harmonization of standards. This notice also proposes to correct a typographical error in S4.3 of the standard.

DATES: *Comment closing date:* Comments on this notice must be received on or before September 6, 1994.

Proposed effective date: If adopted, the amendment proposed in this notice would become effective 30 days after publication of the final rule.

ADDRESSES: Comments should refer to the docket and notice numbers shown above and be submitted to: Docket Section, National Highway Traffic Safety Administration, 400 Seventh Street SW., Room 5109, Washington, DC 20590. Docket room hours are from 9:30 a.m. to 4:00 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Cook, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, 400 Seventh Street SW., Room 5307, Washington, DC 20590. Telephone: (202) 366–4803.

SUPPLEMENTARY INFORMATION: Standard 109 requires passenger car tires to be labeled with important safety information, including tire size, construction, and inflation pressure. Paragraph S4.3.5. of the standard provides that if the maximum inflation pressure of a tire is 60 psi, the words "Inflate to 60 psi" shall be molded into or onto both sidewalls of the tire in letters and numerals not less than ½ inch high.

JATMA submitted a petition to the agency suggesting an amendment to S4.3.5. The petition, submitted on behalf of Japanese tire manufacturers, suggested that S4.3.5 should require adding the words "or inflate to 420 kPa (60 psi)" after "Inflate to 60 psi." JATMA stated that the maximum inflation pressure of a "T"-type spare tire is listed as 420 kilopascals (kPa) in the Tire and Rim Association, Inc., Year Book, the JATMA Year Book, and in Japanese Industrial Standard (JIS) D4230. JATMA indicated that, if the suggested amendment were adopted by NHTSA, the amendment would simplify the manufacturing processes of Japanese tire manufacturers since they would be able to mark tires the same for both the Japanese and U.S. markets. NHTSA granted the petition by letter dated January 7, 1994.

This notice proposes to amend Standard No. 109 as requested by the petitioner. This NPRM is consistent with the requirement of § 5164 of the Omnibus Trade and Competitiveness Act (Pub. L. 100–418), which designated the metric system as the preferred system of weights and measures for U.S. trade and commerce. NHTSA believes that allowing metric units on tires would further the international harmonization of standards. Common sizing for all international markets would facilitate the manufacture of products, and could ultimately result in manufacturers selling their products at cheaper prices. NHTSA has tentatively determined that the petitioner's requested metric unit on tires would not confuse consumers or obscure the meaning of the inflation pressure information labeled on tires. Accordingly, NHTSA tentatively concludes there is no safety reason for precluding JATMA's requested metric labeling.

This notice also proposes to correct a typographical error in paragraph S4.3 of FMVSS 109. The first sentence of paragraph S4.3 provides that each tire shall have permanently molded into or onto both sidewalls the information "shown in paragraphs (a) and (g)" of S4.3. The word "and" in that phrase is incorrect. NHTSA intends that all the information specified in (a) *through* (g) be molded into or onto tires, not just (a) *and* (g). Accordingly, NHTSA proposes to substitute the word "through" for the word "and" at the end of the first sentence of paragraph S4.3. The agency notes that, notwithstanding the use of "and" in that sentence, tire manufacturers are labeling tires with the information of (a) through (g). Thus, this correction would not have any effect on how tires are currently labeled.

Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This notice has not been reviewed under E.O. 12866. NHTSA has considered the impact of this rulemaking action and has concluded that it is not significant under the DOT's regulatory policies and procedures. This action would not change any of the substantive requirements of Standard 109. The effect on labeling costs might be to decrease such costs slightly for tire manufacturers that now convert metric units on their tires to English units, or that now convert English units on tires to metric units for sale overseas. However, NHTSA believes the costs savings, if any, would be minimal. NHTSA has concluded, therefore, that the costs of complying with the changes proposed in this notice do not warrant preparation of a preliminary regulatory evaluation.

B. Regulatory Flexibility Act

NHTSA has considered the impacts of this rulemaking action under the Regulatory Flexibility Act. I hereby certify that the proposed amendments would not have a significant economic impact on a substantial number of small entities. Accordingly, the agency has not prepared a preliminary regulatory flexibility analysis.

The agency believes that few, if any, tire manufacturers qualify as small businesses. Small businesses, small organizations and small governmental units could be affected by the proposed amendments to the extent that they may purchase new tires affected by these proposed amendments. However, NHTSA does not believe the costs of tires would be affected by this rule. Thus, these entities would not be significantly affected.

C. National Environmental Policy Act

NHTSA has analyzed this rulemaking action for purposes of the National Environmental Policy Act and has determined that implementation of this action would have no significant impact on the quality of the human environment.

D. E.O. 12612 (Federalism)

NHTSA has analyzed this proposal in accordance with the principles and criteria contained in E.O. 12612 and has determined that this proposal does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

E. Civil Justice Reform

This proposed rule would not have any retroactive effect. Under § 103(d) of the National Traffic and Motor Vehicle Safety Act (Safety Act), 15 U.S.C. § 1392(d), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance that is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance applicable only to vehicles procured for the state's own use. Section 105 of the Safety Act (15 U.S.C. § 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Comments

Interested persons are invited to submit comments on these proposals. It is requested but not required that any comments be submitted in 10 copies each.

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

If a commenter wishes to submit certain information under a claim of confidentiality, 3 copies of the complete submission, including the purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address shown above, and 7 copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in 49 CFR Part 512, the agency's confidential business information regulation.

All comments received on or before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available to the public for examination in the docket at the above address both before and after the closing date. To the extent possible, comments received after the closing date will be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. Comments on the proposal will be available for public inspection in the docket. NHTSA will continue to file relevant information in the docket after the closing date, and it is recommended that interested persons continue to monitor the docket for new material.

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

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, and Tires.

In consideration of the foregoing, 49 CFR Part 571 would be amended as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

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

Authority: 15 U.S.C. 1392, 1397, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

2. Section 571.109 would be amended by revising the introductory paragraph of S4.3 and the entire paragraph of S4.3.5 to read as follows:

§ 571.109 Standard No. 109, New Pneumatic Tires.

* * * * *

S4.3 *Labeling Requirements.* Except as provided in S4.3.1 and S4.3.2, each tire shall have permanently molded into or onto both sidewalls, in letters and numerals not less than 0.078 inches high, the information shown in paragraphs S4.3 (a) through (g). On at least one sidewall, the information shall be positioned in an area between the maximum section width and bead of the tire, unless the maximum section width of the tire falls between the bead and one-fourth of the distance from the bead to the shoulder of the tire. For tires where the maximum section width falls in that area, locate all required labeling between the bead and a point one-half the distance from the bead to the shoulder of the tire. However, in no case shall the information be positioned on the tire so that it is obstructed by the flange or any rim designated for use with that tire in Standard Nos. 109 and 110 (§ 571.109 and § 571.110 of this part).

* * * * *

S4.3.5 If the maximum inflation pressure of a tire is 420 kPa (60 psi), the tire shall have permanently molded into or onto both sidewalls, in letters and numerals not less than ½ inch high, the words "Inflate to 60 psi" or "Inflate to 420 kPa (60 psi)." On both sidewalls, the words shall be positioned in an area between the tire shoulder and the bead of the tire. However, in no case shall the words be positioned on the tire so that they are obstructed by the flange of any rim designated for use with that tire in this standard or in Standard No. 110 (§ 571.110 of this part).

* * * * *

Issued on June 28, 1994.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 94–16112 Filed 7–1–94; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 59, No. 127
Tuesday, July 5, 1994

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

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Manufacturers' Shipments, Inventories, and Orders (M3).

Form Number(s): M–3(SD).

Agency Approval Number: 0607–0008.

Type of Request: Revision of a currently approved collection.

Burden: 24,000 hours.

Number of Respondents: 6,000.

Avg Hours Per Response: 20 minutes.

Needs and Uses: The Census Bureau conducts the M3 survey, one of the principal Federal economic indicators, to collect monthly manufacturing data from a sample of firms in the manufacturing sector of the economy. The data are used to analyze short– and long–term trends in the manufacturing sector and as related to other sectors of the economy. The shipments and inventory data are essential inputs into the gross domestic product accounts, while the orders data are direct inputs into the leading economic indicator series. The survey also provides valuable and timely data for economic planning and analysis to business firms, trade associations, research and consulting agencies, and academia on the domestic manufacturing sector.

Affected Public: Businesses or other for–profit organizations, Small businesses or organizations.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Maria Gonzalez, (202) 395–7313.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Taché, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: June 28, 1994.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 94–16211 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–07–F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Survey of Income and Program Participation – 1993 Panel Wave 7.

Form Number(s): SIPP–13700.

Agency Approval Number: 0607–0759.

Type of Request: Revision of a currently approved collection.

Burden: 63,000 hours.

Number of Respondents: 42,000.

Avg Hours Per Response: 30 minutes.

Needs and Uses: The Survey of Income and Program Participation (SIPP) is a longitudinal, demographic, survey in which the Census Bureau interviews sample households in waves occurring every 4 months over about a 3 year period. The survey is molded around a central "core" of labor force and income questions that remain fixed during each wave of a panel. The core is periodically supplemented with questions designed to answer specific needs. These supplemental questions are referred to as "topical modules." The topical modules for the 1993 Panel Wave 7 are the following: 1) Assets and liabilities, 2) Medical Expenses and Work Disability, and 3) Real Estate, Shelter Costs, Dependent Care, and Vehicles. Also, topical module items on Earnings and Employment, Stocks and Mutual Fund Shares, Rental Income, Mortgages, Royalties, and Other Financial Investments have been added in Sections 2 and 3 of the core. Wave 7 interviews will be conducted from February through May 1995. SIPP data on income distribution and changes over time in status and participation in welfare and transfer programs are used by economic policymakers, the Congress, state and local governments, and Federal agencies that administer these programs to support policy and program planning.

Affected Public: Individuals or households.

Frequency: Once during the panel.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Maria Gonzalez, (202) 395–7313.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Taché, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: June 28, 1994.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 94–16213 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–07–F

International Trade Administration

[A–549–813]

Initiation of Antidumping Duty Investigation: Canned Pineapple Fruit From Thailand

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: Stephen Alley or Lori Way, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482–5288 and 482–0656, respectively.

Initiation of Investigation

The Petition

On June 8, 1994, we received a petition filed in proper form from Maui Pineapple Company, Ltd. and the International Longshoremen's and Warehousemen's Union. Petitioners filed supplements to the petition on June 14 and 20, 1994. In accordance with 19 CFR 353.12, petitioners allege that imports of canned pineapple fruit from Thailand are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act), and that these imports are materially injuring, or threaten material injury to, a U.S. industry.

Petitioners have stated that they have standing to file the petition because they represent interested parties as defined under section 771(9)(C) and (D) of the Act, and because the petition was filed on behalf of the U.S. industry producing the product subject to this investigation. If any interested party, as described under paragraphs (C), (D), (E) or (F) of section 771(9) of the Act, wishes to register support for, or opposition to, this petition, such party should file a written notification with the Assistant Secretary for Import Administration.

Scope of Investigation

The product covered by this investigation is canned pineapple fruit (CPF). For the purposes of this investigation, CPF is defined as pineapple processed and/or prepared into various product forms, including rings, pieces, chunks, tidbits, and crushed pineapple, that is packed and cooked in metal cans with either pineapple juice or sugar syrup added. CPF is currently classifiable under subheadings 2008.20.0010 and 2008.20.0090 of the *Harmonized Tariff Schedule of the United States* (HTSUS). HTSUS 2008.20.0010 covers CPF packed in a sugar-based syrup; HTSUS 2008.20.0090 covers CPF packed without added sugar (*i.e.*, juice-packed). Although these HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope is dispositive.

United States Price and Foreign Market Value

Petitioners based U.S. price (USP) on average unit values derived from U.S. Customs IM–146 import statistics. To calculate U.S. price, petitioners made deductions for foreign inland freight.

Petitioners used Thai home market delivered price quotes provided by a market researcher to calculate foreign market value (FMV). According to petitioners, there is no difference in quality between the CPF sold in the Thai and U.S. markets. To calculate FMV, petitioners deducted an amount for home market inland freight expenses, and then converted the net price to dollars using contemporaneous exchange rates from the Federal Reserve.

The margin alleged by petitioners is 138.48 percent. If it becomes necessary at a later date to consider the petition as a source of best information available (BIA) in this investigation, we may review more thoroughly all of the bases for USP and FMV in determining BIA.

Initiation of Investigation

We have examined the petition on CPF from Thailand and have found that it meets the requirements of section 732(b) of the Act and 19 CFR 353.13(a). Therefore, we are initiating an antidumping duty investigation to determine whether imports of CPF from Thailand are being, or are likely to be, sold in the United States at less than fair value.

International Trade Commission Notification

Section 732(d) of the Act requires us to notify the International Trade Commission (ITC) of this action and we have done so.

Preliminary Determination by the ITC

The ITC will determine by July 25, 1994, pursuant to section 733(a)(1) of the Act, whether there is a reasonable indication that imports of CPF from Thailand are materially injuring, or threaten material injury to, a U.S. industry. Pursuant to section 733(a)(2) of the Act, a negative ITC determination will result in this investigation being terminated; otherwise, the investigation will proceed according to statutory and regulatory time limits.

This notice is published pursuant to section 732(c)(2) of the Act and 19 CFR 353.13(b).

Dated: June 27, 1994.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 94–16208 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–DS–P

International Trade Administration.

[A–301–801 and A–331–801]

Notice of Postponement of Preliminary Antidumping Duty Determinations: Fresh Cut Roses From Colombia and Ecuador

AGENCY: Import Administration, International Trade Administration, Commerce.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: James Maeder or James Terpstra, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230, at (202) 482–3330 or (202) 482–3965.

POSTPONEMENT: On June 24, 1994, we received a letter from petitioner in these investigations requesting that the Department of Commerce postpone the preliminary determinations in accordance with section 733(c)(1)(A) of the Tariff Act of 1930, as amended (the Act) (19 U.S.C. 1673b(c)(1)(A)). We find no compelling reasons to deny the request and are, accordingly, postponing the date of the preliminary determinations until September 12, 1994. The U.S. International Trade Commission is being advised of these postponements in accordance with section 733(f) of the Act.

This notice is published pursuant to section 733(c)(2) of the Act and 19 CFR 353.15 (b) and (d).

Dated: June 28, 1994.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 94–16206 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–DS–M

[A–122–506]

Oil Country Tubular Goods From Canada, Final Results of Antidumping Duty Administrative Review

AGENCY: International Trade Administration/Import Administration/ Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On April 20, 1994, the Department of Commerce (the Department) published the preliminary results of review of the antidumping duty order on oil country tubular goods from Canada (51 FR 21782; June 16, 1986). The review covers one manufacturer/exporter, IPSCO Inc.

(IPSCO), and the period June 1, 1992, through May 31, 1993.

We gave interested parties an opportunity to comment on the preliminary results. Since the Department received no comments, the final results remain unchanged from the preliminary results.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: David Genovese or Michael Heaney, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone (202)482–5254.

SUPPLEMENTARY INFORMATION:

Background

On June 25, 1993, IPSCO requested that the Department conduct an administrative review of the antidumping duty order on oil country tubular goods (OCTG) from Canada. The Department initiated the review on July 21, 1993 (58 FR 39007), covering the period June 1, 1992, through May 31, 1993. On April 20, 1994, the Department published the preliminary results of review (59 FR 18798). The Department has now completed this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Review

The products covered by this review include shipments of OCTG from Canada. This includes American Petroleum Institute (API) specification OCTG and all other pipe with the following characteristics except entries which the Department determined through its end use certification procedure were not used in OCTG applications: Length of at least 16 feet; outside diameter of standard sizes published in the API or proprietary specifications for OCTG with tolerances of plus ⅛ inch for diameters less than or equal to 8⅝ inches and plus ¼ inch for diameters greater than 8⅝ inches, minimum wall thickness as identified for a given outer diameter as published in the API or proprietary specifications for OCTG; a minimum of 40,000 PSI yield strength and a minimum 60,000 PSI tensile strength; and if with seams, must be electric resistance welded. Furthermore, imports covered by this review include OCTG with non-standard size wall thickness greater than the minimum identified for a given outer diameter as published in the API or proprietary specifications for OCTG, with surface scabs or slivers, irregularly cut ends, ID or OD weld flash, or open seams; OCTG may be bent, flattened or oval, and may lack certification because the pipe has not been mechanically tested or has failed those tests.

This merchandise is currently classifiable under the Harmonized Tariff Schedules (HTS) item numbers 7304.20, 7305.20, and 7306.20. The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

Final Results of Review

We gave interested parties an opportunity to comment on the preliminary results. The Department received no comments. Accordingly, we have determined that a final margin of zero percent exists for IPSCO for the period June 1, 1992 through May 1, 1993.

The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective for all shipments of the subject merchandise, entered or withdrawn from warehouse, for consumption on or after the publication date of these final results of review, as provided by section 751(a)(1) of the Act: (1) the cash deposit rate for IPSCO will be zero percent; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a previous review or the original less-than-fair-value (LTFV) investigation, the cash deposit rate will continue to be the rate published in the most recent final results or determination for which the manufacturer or exporter received a company-specific rate; (3) if the exporter is not a firm covered in this review, earlier reviews, or the original investigation, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in these final results of review, earlier reviews, or the original investigation, whichever is the most recent; and (4) the "all others" rate will be 16.65 percent, as explained below.

On May 25, 1993, the Court of International Trade, in *Floral Trade Council* v. *United States*, Slip Op. 93–79, and *Federal-Mogul Corporation* v. *United States*, 822 F. Supp. 782 (1993), decided that once an "all others" rate is established for a company it can only be changed through an administrative review. The Department has determined that in order to implement these decisions, it is appropriate to reinstate the original "all others" rate from the LTFV investigation (or that rate as amended for correction of clerical errors or as a result of litigation) in proceedings governed by antidumping duty orders. Accordingly, the cash deposit rate for any future entries from all other manufacturers or exporters, who are not covered in this or prior administrative reviews and who are unrelated to the reviewed firms or any previously reviewed firm, will be the "all others" rate established in the original LTFV investigation, which is 16.65 percent.

These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: June 27, 1994.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 94–16207 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–DS–P

Intent To Revoke Countervailing Duty Orders

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of intent to revoke countervailing duty orders.

SUMMARY: The Department of Commerce is notifying the public of its intent to revoke the countervailing duty orders listed below. Domestic interested parties who object to these revocations must submit their comments in writing not later than the last day of July, 1994.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: Mercedes Fitchett or Brian Albright,

Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

The Department of Commerce (the Department) may revoke a countervailing duty order if the Secretary of Commerce concludes that it is no longer of interest to interested parties. Accordingly, as required by section 355.25(d)(4) (19 CFR 355.25(d)(4) (1993)) of the Department's regulations, we are notifying the public of our intent to revoke the following countervailing duty orders for which the Department has not received a request to conduct an administrative review for the most recent four consecutive annual anniversary months:

Countervailing duty orders	Effective date
EC: Sugar (C–408–046)	07/31/78 43 FR 33237
Uruguay: Leather Wearing Apparel (C–355–001).	07/17/82 47 FR 31032

In accordance with section 355.25(d)(4)(iii) of the Department's regulations, if domestic interested parties (defined in section 355.2(i)(3), (i)(4), (i)(5), and (i)(6) of the regulations) do not object to the Department's intent to revoke these orders pursuant to this notice, or interested parties (defined in section 355.2(i) of the regulations) do not request an administrative review in accordance with the Department's notice of opportunity to request administrative review, we shall conclude that the countervailing duty orders are no longer of interest to interested parties and proceed with the revocations.

Opportunity to Object

Not later than the last day of July, 1994, domestic interested parties may object to the Department's intent to revoke these countervailing duty orders. Any submission objecting to a revocation must contain the name and case number of the order and a statement that explains how the objecting party qualifies as a domestic interested party under sections 355.2(i)(3), (i)(4), (i)(5), or (i)(6) of the Department's regulations.

Seven copies of any such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room B–099, U.S. Department of Commerce, Washington, D.C. 20230.

This notice is in accordance with 19 CFR 355.25(d)(4)(i).

Dated: June 28, 1994.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 94–16204 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–DS–P

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended export trade certificate of review, application No. 85–5A018.

SUMMARY: The Department of Commerce has issued an amendment to the Export Trade Certificate of Review granted to the U.S. Shippers Association ("USSA") on June 3, 1986. Notice of issuance of the Certificate was published in the **Federal Register** on June 9, 1986 (51 FR 20873).

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR Part 325 (1993).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

DESCRIPTION OF AMENDED CERTIFICATE: Export Trade Certificate of Review No. 85–00018 was issued to the U.S. Shippers Association ("USSA") on June 3, 1986 (51 FR 20873, June 9, 1986), and previously amended on January 16, 1990 (55 FR 2543, January 25, 1990); November 13, 1990 (55 FR 48664, November 21, 1990); and on September 22, 1993 (58 FR 51061, September 30, 1993).

USSA's Export Trade Certificate of Review has been amended to add the following company as a "Member" within the meaning of Section 325.2(l) of the Regulations (15 CFR 325.2(l) (1993)): ANGUS Chemical Company, Buffalo Grove, Illinois (Controlling entity: Alberta Natural Gas Company Ltd., Calgary, Alberta, Canada).

A Copy of the amended certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, D.C. 20230.

Dated: June 28, 1994.
Effective Date: March 30, 1994.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 94–16210 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–DR–P

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with Subsections 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 94–075. *Applicant:* West Virginia University, Physics Department, G-30 Hodges Hall, Morgantown, WV 26505-6315. *Instrument:* Atom/Radical Source, Model CARS25. *Manufacturer:* Oxford Applied Research, United Kingdom. *Intended Use:* The instrument will be used in research concerning the formation of point defects during molecular beam epitaxy growth and doping of wide band gap semiconductors. *Application Accepted by Commissioner of Customs:* May 27, 1994.

Docket Number: 94–076. *Applicant:* The Georgia Institute of Technology, 225 North Avenue, NW, Atlanta, GA 30322. *Instrument:* High-Shear Mixing Bleach Reactor, Model CRS1015. *Manufacturer:* CRS Reactor Engineering, Sweden. *Intended Use:* The instrument will be used in a study to develop novel bleaching technologies, such as ECF and TCF processes, other than traditional chlorine processes. The instrument will be used for educational and research

purposes mostly by graduate students seeking advance degrees. *Application Accepted by Commissioner of Customs:* May 31, 1994.

Docket Number: 94–077. *Applicant:* The Ohio State University, Aeronautical & Astronautical Research Laboratory, 2300 West Case Road, Columbus, OH 43235. *Instrument:* High Power, High Pressure Arc Discharge Plasma Source System. *Manufacturer:* Institute of Problems of Electrophysics, CIS. *Intended Use:* The instrument will be used for research that involves the determination of arc discharge mode, energy and power transfer efficiencies, electrode and insulator damage and wear. The experiments will be conducted for various gases over a range of initial pressures and currents and will involve electrical, pressure transducer and optical measurements. In addition, the instrument will contribute to educational objectives by providing the basis for student thesis research and design projects, and by challenging students with problems related to their coursework. *Application Accepted by Commissioner of Customs:* June 3, 1994.

Docket Number: 94–078. *Applicant:* University of Pittsburgh, Chemistry Department, 350 Thackeray Hall, Pittsburgh, PA 15260. *Instrument:* Mass Spectrometer, Model VG AutoSpec. *Manufacturer:* Fisons Instruments, United Kingdom. *Intended Use:* The instrument will be used to produce mass spectra of a wide variety of unique synthetic products and intermediate compounds (natural products, organic substrates for enzyme interaction, vitamin derivatives, and novel synthetic products) in the support of various research programs. The instrument will also be used to investigate the mechanisms of bombardment induced gas-phase ion chemistry and will involve the designing of additives to a FAB matrix that will induce specific chemical reactions within the mass spectrometer. In addition, the instrument will be used for educational purposes in the course Chemistry 2700 Graduate Research. *Application Accepted by Commissioner of Customs:* June 3, 1994.

Docket Number: 94–079. *Applicant:* Argonne National Laboratory, 9700 South Cass Avenue, Argonne, IL 60439. *Instrument:* EPR Spectrometer, Model ESP300-E-10-12. *Manufacturer:* Bruker Instruments, Germany. *Intended Use:* The instrument will be used to study photo-induced charge separation in natural photosynthetic and model photosynthetic systems. The experiments to be conducted will be both conventional electron paramagnetic resonance experiments on stable radicals and time-resolved electron paramagnetic resonance. *Application Accepted by Commissioner of Customs:* June 3, 1994.

Docket Number: 94–080. *Applicant:* University of California, Los Alamos National Laboratory, P.O. Box 990, Los Alamos, NM 87545. *Instrument:* Electron Microscope, Model JEM 2010. *Manufacturer:* JEOL Ltd., Japan. *Intended Use:* The instrument will be used for the study of liquid crystal polymers and thermosets. Experiments will be performed on a variety of liquid crystalline materials to investigate the effect of different preparation schemes on the structure and the resulting properties. *Application Accepted by Commissioner of Customs:* June 7, 1994.

Pamela Woods,

Acting Director, Statutory Import Programs Staff.

[FR Doc. 94–16209 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–DS–F

National Institute of Standards and Technology

[Docket No. 940680–4180]

RIN No. 0693–AB29

Proposed Federal Information Processing Standard (FIPS) for Application Profile for the Government Information Locator Service (GILS)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for comments.

SUMMARY: This proposed Federal Information Processing Standard describes an application profile for the Government Information Locator Service (GILS). This application profile is based primarily on the American National Standard for Information Retrieval Application Service Definition and Protocol Specification for Open Systems Interconnection (ANSI/NISO Z39.50–1992), developed by the National Information Standards Organization. The Government Information Locator Service (GILS) is a decentralized collection of servers and associated information services that will be used by the public either directly or through intermediaries to find public information throughout the Federal government.

Prior to the submission of this proposed FIPS to the Secretary of Commerce for review and approval, it is essential to assure that consideration is given to the needs and views of federal organizations, vendors, the public, and State and local governments. The purpose of this notice is to solicit such views.

The proposed FIPS contains two sections: (1) an announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section which deals with the technical requirements of the standard.

Only the announcement section of the standard is provided in this notice. Interested parties may obtain copies of the technical specifications for this proposed FIPS for Application Profile for the Government Information Locator Service (GILS) from Standards Processing Coordinator (ADP), Computer Systems Laboratory, National Institute of Standards and Technology, Technology Building, Room B–64, Gaithersburg, MD 20899, telephone (301) 975–2816.

DATES: Comments on this proposed FIPS must be received on or before October 3, 1994.

ADDRESSES: Written comments concerning the proposed FIPS should be sent to: Director, Computer Systems Laboratory, ATTN: Proposed FIPS for GILS, Technology Building, Room B154, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Written comments received in response to this notice will be made part of the public record and will be made available for inspection and copying in the Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Eliot Christian, U.S. Geological Survey, 802 National Center, Reston, VA 22092, telephone (703) 648–7245, fax (703) 648–7069, E–mail: echristi@usgs.gov.

Dated: June 28, 1994.

Samuel Kramer,

Associate Director.

Proposed Federal Information Processing Standards Publication_____

(date)

Announcing the Standard for Application Profile for the Government Information Locator Service (GILS)

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology (NIST) after approval by the Secretary of Commerce pursuant to Section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the

Computer Security Act of 1987, Public Law 100–235.

1. Name of Standard. Application Profile for the Government Information Locator Service (GILS).

2. Category of Standard. Software Standard, Information Interchange.

3. Explanation. This standard describes an application profile for the Government Information Locator Service (GILS). This application profile is based primarily on the American National Standard for Information Retrieval Application Service Definition and Protocol Specification for Open Systems Interconnection (ANSI/NISO Z39.50–1992), developed by the National Information Standards Organization (NISO). The Government Information Locator Service (GILS) is a decentralized collection of servers and associated information services that will be used by the public either directly or through intermediaries to find public information throughout the Federal government.

This GILS Profile specifies the use of ANSI/NISO Z39.50–1992 in information service applications and provides specifications for the overall GILS application, including the GILS Core and other aspect of a GILS server operating in the Internet environment. This GILS profile will enable GILS client systems to interconnect and to interoperate with any GILS server. This profile addresses intersystem interactions and information interchange for the GILS, but does not specify user interface requirements, the internal structure of databases that contain GILS Locator Records, or search engine functionality.

GILS servers will support search and retrieval by accepting a search query and returning a result set or diagnostic messages. GILS servers may also support browsing by accepting a well-known search query and returning a list of Locator Records in brief display format.

Some of the information resources pointed to by GILS Locator Records, as well as the GILS server itself, may be available electronically through other communications protocols including the common Internet protocols that facilitate electronic information transfer such as remote login (Telnet), File Transfer Protocol (FTP), and electronic mail. The use of SMTP and MIME protocols or other communications paths is outside the scope of the GILS Profile.

The GILS Profile was developed by a group of industry and government experts in ANSI/NISO Z39.50–1992 implementations, system implementations, and the organization of information. The specifications included in the GILS Profile reflect the consensus of this group based on its work and input from a range of stakeholders.

4. Approving Authority. Secretary of Commerce.

5. Maintenance Agency. U.S. Department of the Interior, United States Geological Survey (USGS).

Questions concerning this standard are to be addressed to the Maintenance Agency: GILS Program, United States Geological Survey (USGS), 802 National Center, Reston, VA 22092. Users of this standard who need to be notified or changes that occur prior to the next publication of the standard should complete the Change Request Form provided in this publication and send it to: Standards Processing Coordinator (ADP), Computer Systems Laboratory, National Institute of Standards and Technology, Gaithersburg, MD 20899. The NIST will issue Change Notices on an as-needed basis.

6. Related Documents.

a. Federal Information Resources Management Regulations (FIRMR) subpart 201–20.303, Standards and subpart 201–39–1002, Federal Standards.

b. Office of Management and Budget Bulletin 94–_____, Establishment of Government Information Locator Service.

c. American National Standard for Information Retrieval Application Service Definition and Protocol Specification for Open Systems Interconnection (ANSI/NISO Z39.50–1992).

d. A list of additional references for the Application Profile is contained in section 5, References, of the specifications.

7. Objectives. The objectives of the Application Profile for the GILS are to:

—Enable users to identify, locate, and access or acquire publicly available Federal information resources, including electronic information resources.

—Provide a uniform approach to providing information locator services to the public.

—Enable every agency to establish standards-based network-accessible locator records.

8. Applicability.

a. This standard is recommended for use by Federal agencies in the development and establishment of information locators, i.e., information resources that identify other information resources, describe the information available in those resources, and provide assistance in how to obtain the information.

b. This standard is required for use by Federal agencies in those information locators that are established and maintained as part of the Government Information Locator System (GILS) pursuant to the requirements of OMB Bulletin 94–_____ and other applicable, law, regulation, and policy.

c. The GILS Core requirements of this standard apply to those GILS locator records which:

—Describe information resources maintained by the Federal government;

—Comply with the defined GILS Core Elements;

—Are mutually accessible through interconnected electronic network facilities without charge to the direct user; and

—Are designated by the agency to be part of the Federal government GILS Core, pursuant to OMB Bulletin 94–_____.

9. Specifications. The Application Profile for the Government Information Locator System, (affixed).

10. Implementation. The implementation of this standard involves three areas of consideration: development and acquisition of GILS implementations, validation, and interpretations of the standard.

10.1 Development and Acquisition of GILS Implementations. This standard is effective _____ (6 months after approval by the Secretary of Commerce).

10.2 Validation. Validation of GILS implementations is not required at this time. Testing for conformance to this standard is at the discretion of the agency. Agencies may select the tests to be administered and the testing organizations that administer the tests.

10.3 Interpretation of this standard. Resolution of questions regarding this standard will be provided by NIST. Questions concerning the content and specifications should be addressed to: Director, Computer Systems Laboratory, Attn: FIPS for GILS Interpretation, National Institute of Standards and Technology, Gaithersburg, MD 20899, Telephone: (301) 975–2833.

11. Waivers. Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may redelegate such authority only to a senior official designated pursuant to Section 3506(b) of Title 44, U.S. Code. Waivers shall be granted only when:

a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal computer system, or

b. Cause a major adverse financial impact on the operator which is not offset by governmentwide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written decision which explains the basis on which the agency head made the required finding(s). A copy of each such decision, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; Attn: FIPS Waiver Decisions, Technology Building, room B–154; Gaithersburg, MD 20899.

In addition, notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Governmental Affairs of the Senate and shall be published promptly in the **Federal Register**.

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the Commerce Business Daily as part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment to such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any supporting and accompanying documents, with such deletions as the agency is authorized and decides to make under 5 U.S.C. 552(b), shall be part of the procurement documentation and retained by the agency.

12. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. (Sale of the included specifications document is by arrangement with the United States Geological Survey (USGS).) When ordering, refer to Federal Information Processing Standards Publication _____ (FIPSPUB _____), and title. Payment may be made by check, money order, or deposit account.

[FR Doc. 94–16205 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–LN–M

[Docket No. 940670–4170]

RIN 0693–AB26

Proposed Revision of Federal Information Processing Standard (FIPS) 125–1, MUMPS (Massachusetts General Hospital Utility Multi-Programming System)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; Request for comments.

SUMMARY: This proposed revision of Federal Information Processing Standard (FIPS) 125–1, MUMPS (Massachusetts General Hospital Utility Multi-Programming System), will adopt the revised voluntary industry specifications, ANSI/MDC X11.1–199X. The American National Standard for M (also known as MUMPS, [MASSACHUSETTS GENERAL HOSPITAL UTILITY MULTI-PROGRAMMING SYSTEM]) specifies the form and establishes the interpretation of programs written in the M programming language.

Prior to the submission of this proposed revision to the Secretary of Commerce for review and approval, it is essential to assure that consideration is given to the needs and views of manufacturers, the public, and state and local governments. The purpose of this notice is to solicit such views.

This proposed FIPS contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section which deals with the technical requirements of the standard. Only the announcement section of the standard is provided in this notice. Interested parties may obtain copies of the technical specifications (ANSI/MDC X11.1–199X) from the MUMPS Development Committee (MDC) Secretariat, 1738 Elton Road, Suite 205, Silver Spring, MD 20903, (301) 431–4070, FAX (301) 431–0017.

DATES: Comments on this proposed revision must be received on or before October 3, 1994.

ADDRESSES: Written comments concerning the proposed revision should be sent to: Director, Computer Systems Laboratory, ATTN: Proposed FIPS 125–2, M, Technology Building, Room B–154, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Written comments received in response to this notice will be made part of the public record and will be made available for inspection and copying in the Central Reference and Records Inspection Facility, Room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Dr. William H. Dashiell, National Institute of Standards and Technology, Gaithersburg, MD 20899, (301) 975–2490.

Dated: June 27, 1994.

Samuel Kramer,

Associate Director.

Proposed Federal Information Processing Standards Publication 125–2 (Supersedes FIPS PUB 125–1—1993 June 10)

(date)

Announcing the Standard for M (Also Known as MUMPS [MASSACHUSETTS GENERAL HOSPITAL UTILITY MULTI-PROGRAMMING SYSTEM])

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology (NIST) after approval by the Secretary of Commerce pursuant to Section 111(d) of the Federal Property and Administrative Services Act of 1949, as amended by the Computer Security Act of 1987, Public Law 100–235.

1. Name of Standard. M (also known as MUMPS [MASSACHUSETTS GENERAL HOSPITAL UTILITY MULTI-PROGRAMMING SYSTEM]) (FIPS PUB 125–2).

2. Category of Standard. Software Standard, Programming Language.

3. Explanation. This publication announces the adoption of American National Standard for M, ANSI/MDC X11.1–199X, as a Federal Information Processing Standard (FIPS). The American National Standard for M, ANSI/MDC X11.1–199X, specifies the form and establishes the interpretation of programs written in the M programming language. The purpose of the standard is to promote portability of M programs for use on a variety of data processing systems. The standard is for use by implementors as the reference authority in developing compilers, interpreters, or other forms of high level language processors; and by other computer professionals who need to know the precise syntactic and semantic rules adopted by ANSI. This publication is a revision of FIPS PUB 125–1 and supersedes that document in its entirety.

4. Approving Authority. Secretary of Commerce.

5. Maintenance Agency. U.S. Department of Commerce, National

Institute of Standards and Technology (NIST), Computer Systems Laboratory (CSL).

6. Cross Index. American National Standard for Information System—Programming Language—M (also known as MUMPS [MASSACHUSETTS GENERAL HOSPITAL UTILITY MULTI-PROGRAMMING SYSTEM]), ANSI/MDC X11.1–199X.

7. Related Documents.*

a. Federal Information Resources Management Regulations subpart 201–20.303, Standards, and subpart 201–39.1002, Federal Standards.

b. FIPS PUB 29–3, Interpretation Procedures for Federal Information Processing Standards for Software.

c. NBS Special Publication 500–117, Selection and Use of General-Purpose Programming Languages.

d. NIST, Validated Products List, (republished quarterly). Available by subscription from the National Technical Information Service (NTIS).

8. Objectives. Federal standards for high level programming languages permit Federal departments and agencies to exercise more effective control over the production, management, and use of the Government's information resources. The primary objectives of Federal programming language standards are:

—To encourage more effective utlilization and management of programmers by ensuring that programming skills acquired on one job are transportable to other jobs, thereby reducing the cost of programmer retraining.

—To reduce the cost of program development by achieving the increased programmer productivity that is inherent in the use of high level programming languages;

—To reduce the overall software costs by making it easier and less expensive to maintain programs and to transfer programs among different computer systems, including replacement systems; and

—To protect the existing software assets of the Federal Government by ensuring to the maximal feasible extent that Federal programming language standards are technically sound and that subsequent revisions are compatible with the installed base.

Government wide attainment of the above objectives depends upon the widespread availability and use of comprehensive and precise standard language specifications.

9. Applicability.

a. Federal standards for high level programming languages are applicable for computer applications and programs that are either developed or acquired for government use. FIPS M is one of the high level programming language standards provided for use by all Federal departments and agencies. FIPS M is suitable for the data processing applications which include but are not limited to:

—Those involving the creation and manipulation of string-oriented or text-oriented collections of data;

—Those requiring interactive data management.

b. The use of FIPS high level programming languages applies when one or more of the following situations exist:

—It is anticipated that the life of the program will be longer than the life of the presently utilized equipment.

—The application or program is under constant review for updating of the specifications, and changes may result frequently.

—The program is to be understood and maintained by programmers other than the original ones.

—The advantages of improved program design, debugging, documentation and intelligibility can be obtained through the use of this high level language regardless of interchange potential.

—The program is or is likely to be used by organizations outside the Federal Government (*i.e.*, State and local governments, and others).

—The program is being used for "cooperative" processing across multiple processing platforms (e.g., desktops, servers, and mainframes).

c. Nonstandard language features should be used only when the needed operation or function cannot reasonably be implemented with the portable features alone. Although nonstandard language features can be very useful, it should be recognized that their use may make the interchange of programs and future conversion to a revised standard or replacement processor more difficult and costly.

d. Programmatic requirements also may be more economically and efficiently satisfied by the use of automatic program generators. However, if the final output of a program generator is a M source program, then the resulting program should conform to the conditions and specifications of FIPS M.

10. Specifications. FIPS M (also known as MUMPS [MASSACHUSETTS GENERAL HOSPITAL UTILITY MULTI-PROGRAMMING SYSTEM]) specifications are the language specifications continued in American National Standard for Information System—Programming Language—M (also known as MUMPS, [MASSACHUSETTS GENERAL HOSPITAL UTILITY MULTI-PROGRAMMING SYSTEM]), ANSI/MDC X11.1–199X.

a. The ANSI/MDC X11.1–199X document specifies the representation, syntax, and semantics for M programs; the representation of input and output data processed by M programs; and the restrictions and limitations imposed by an implementation of M conforming to the ANSI/MDC X11.1–199X standard.

b. The standard does not specify:

—The mechanisms by which M programs are transformed or invoked for use by a data processing system;

—The mechanisms by which input data are transformed for use by a M program or output data are transformed after being produced by a M program;

—The limits on program size or complexity except when and where applicable to an application as specified in Part 2: M Portability Requirements of ANSI/MDC X11.1–199X;

—The results when the rules of the standard fail to establish an interpretation;

—The minimal requirements of a data processing system that is capable of supporting a conforming implementation.

11. Implementation. The implementation of FIPS M involves four areas of consideration: the effective date, acquisition of M processors, interpretation of FIPS M, and validation of processors.

1.1 Effective Date. This revised standard becomes effective six (6) months after the publication in the **Federal Register** announcing approval by the Secretary of Commerce. M Processors acquired for Federal use after this date should conform to FIPS PUB 125–2.

A transition period provides time for industry to produce M language processors conforming to the standard. The transition period begins on the effective date and continues for 90 days thereafter. The provisions of FIPS PUB 125–2 apply to orders placed after the effective date of this publication. If, during the transition period, a processor conforming to FIPS PUB 125–2 is not available, a processor conforming to FIPS PUB 125–1 may be acquired for interim use during the transition period.

This transition period is intended to give implementations time to make the

*Refers to most recent revision of FIPS PUBS.

enhancements necessary to enable conformance to FIPS PUB 125–2. No further transitional period is necessary.

11.2 Acquisition of M Processors. Conformance of FIPS M should be considered whether M processors are developed internally, acquired as part of an ADP system procurement, acquired by separate procurement, used under an ADP leasing arrangement, or specified for use in contracts for programming services. Recommended terminology for procurement of FIPS M is contained in the U.S. General Services Administration publication Federal ADP & Telecommunications Standards Index, Chapter 4 Part 1.

11.3 Interpretation of FIPS M. The National Institute of Standards and Technology provides for the resolution of questions (see FIPS PUB 29–3, Interpretation Procedures for FIPS Software, 29 October 1992) regarding the specifications and requirements, and issues official interpretations as needed. All questions about the interpretation of this standard should be addressed to: Director, Computer Systems Laboratory, Attn: FIPS M Interpretation, National Institute of Standards and Technology, Gaithersburg, MD 20899, Voice: 301–975–2490, Fax: 301–948–6213, E-mail: dashiell@ecf.ncsl.nist.gov.

11.4 Validation of M Processors. Implementations of FIPS M shall be validated in accordance with the NIST Computer Systems Laboratory (CSL) validation procedures for FIPS M. Recommended procurement terminology for validation of FIPS M is contained in the U.S. General Service Administration (GSA) publication *Federal ADP & Telecommunications Standards Index*, Chapter 4 Part 2. This GSA publication provides terminology for three validation options: Delayed Validation, Prior Validation Testing, and Prior Validation. The agency shall select the appropriate validation option and shall specify whether a Validation Summary Report or Certificate of Validation is required. The agency shall specify appropriate time frames for validation and correction of nonconformities. The agency is advised to refer to the NIST publication *Validated Product List* for information about the validation status of M products. This information may be used to specify validation time frames that are not unduly restrictive of competition.

The agency shall specify the criteria used to determine whether a Validation Summary Report (VSR) or Certificate is applicable to the hardware/software environment of the M implementation offered. The criteria for applicability of a VSR or Certificate should be appropriate to the size and timing of the procurement. A large procurement may require that the offered version/release of the M implementation shall be validated in a specified hardware/software environment and that the validation shall be conducted with specified hardware/software features or parameter settings; e.g. the same parameter settings to be used in a performance benchmark. An agency with a single/license procurement may review the *Validated Products List* to determine the applicability of existing VSRs or Certificates to the agency's hardware/software environment.

M implementations shall be evaluated using a NIST approved test suite.

For further information contact: Director, Computer Systems Laboratory, Attn: FIPS M Validation, National Institute of Standards and Technology, Gaithersburg, MD 20899, Voice: 301–975–2490, Fax: 301–948–6213, E-mail: dashiell@ecf.ncsl.nist.gov.

12. Waivers. Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may redelegate such authority only to a senior official designated pursuant to section 3506(b) of title 44, U.S. Code. Waivers shall be granted only when:

a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal computer system, or

b. Cause a major adverse financial impact on the operator which is not offset by Government wide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written decision which explains the basis on which the agency head made the required finding(s). A copy of each such decision, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; Attn: FIPS Waiver Decisions, Technology Building, Room B–154; Gaithersburg, MD 20899.

In addition, notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Governmental Affairs of the Senate and shall be published promptly in the **Federal Register**.

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the Commerce Business Daily as a part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment to such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any supporting and accompanying documents, with such deletions as the agency is authorized and decides to make under 5 U.S.C. 552(b), shall be part of the procurement documentation and retained by the agency.

13. Special Information. Agencies should consider adopting programming guidelines on the use of standard language features where determined appropriate.

It is recommended that agencies assess changes that may be forthcoming in future revisions of the ANSI/MDC X11.1–199X standard. For information on revisions to this standard, contact the M Development Committee at: M Development Committee Secretariat, 1738 Elton Road, Suite 205, Silver Spring, Maryland 20903 U.S.A., Telephone: (301) 779–6555, Fax: (301) 779–7674.

14. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. (Sale of the included specifications document is by arrangement with the American National Standards Institute.) When ordering, refer to Federal Information Processing Standards Publication 125–2 (FIPSPUB125–2), and title. Payment may be made by check, money order, or deposit account.

[FR Doc. 94–16113 Filed 7–1–94; 8:45 am]
BILLING CODE 3510–CN–M

National Oceanic and Atmospheric Administration

South Slough National Estuarine Research Reserve Public Meeting

AGENCY: Sanctuaries and Reserves Division (SRD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

SUMMARY: The South Slough National Estuarine Research Reserve is hosting a public meeting concerning the Reserve's 1994 revised management plan. The

revised plan updates the Reserve's 1984 plan and describes goals, objectives, and tasks for Reserve operations. The public meeting is an opportunity for Reserve Commissioners and staff to meet with the public, exchanges, ideas, and discuss the Reserve's role in the local and regional community. Copies of the plan may be reviewed at NOAA Sanctuaries and Reserves Division, 1305 East West Highway, Silver Spring, Maryland, 20910; at the Reserve Interpretive Center in Charleston, Oregon; and at the North Bend, Coos Bay, Coquille, and Southwest Oregon Community College libraries in Oregon.

TIME AND PLACE: July 21, 1994 at 7:30 p.m. at the Tioga Room, Southwest Oregon Community College, 1988 Newmark, Coos Bay, Oregon.

FOR FURTHER INFORMATION CONTACT: Sue Lowry at (619) 888–5558 or Nine Garfield at (301) 713–3141.

(Federal Domestic Assistance Catalog Number 11.429, Marine Sanctuary Program)

Dated: June 28, 1994.

W. Stanley Wilson,

Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 94–16175 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–08–M

[I.D. 062794A]

Marine Mammals

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

ACTION: Issuance of public display permit no. 931.

SUMMARY: Notice is hereby given that World Safari Company, Limited, 2399–1 Kushigamine, Katata, Shirahama-cho, Nishimuro-gun, Wakayama, Japan, has been issued a permit for public display purposes.

ADDRESSES: The permit is available for review by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, NOAA, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289); and

Director, Southwest Region, NMFS, NOAA, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213 (310/980–4016);

SUPPLEMENTARY INFORMATION: On Friday, April 29, 1994, notice was published in the **Federal Register** (59 FR 22151) that an application (P565) has been filed by World Safari Company, Limited. A public display permit was requested to obtain the care and custody five California sea lions (*Zalophus californianus*) and two elephant seals (*Mirounga leonina*), from unreleasable beached and stranded stock. On May 17, 1994, the permit application was modified to eliminate the request for the elephant seals. The requested permit has been issued subject to the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), and the conditions hereinafter set out.

Dated: June 24, 1994.

Ann D. Terbush,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 94–16155 Filed 7–1–94; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 062994B]

Marine Mammals

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

ACTION: Receipt of application to modify permit no. 765 (P70E).

SUMMARY: Notice is hereby given that Dr. William Watkins, has requested a modification to permit No. 765.

ADDRESSES: The modification request and related documents are available for review upon written request or by appointment in the following office(s):

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289); and

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930 (508/281–9328).

Written data or views, or requests for a public hearing on this request should be submitted to the Director, Office of Protected Resources, NMFS, NOAA, U.S. Department of Commerce, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular modification request would be appropriate.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

SUPPLEMENTARY INFORMATION: The subject modification to permit No. 765, issued on February 25, 1992 (57 FR 7735) is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered fish and wildlife (50 CFR parts 217–222)

Permit No. 765, as amended on March 17, 1994, authorizes the permit holder to: Tag up to five sperm whales (*Physeter macrocephalus*) with HF sonic and/or satellite tags (some may be double tagged); inadvertently harass up to 20 during tagging operations; and during various levels of sound playback experiments on tagged whales, inadvertently harass up to 60 additional sperm whales up to 10 times per day.

The permit holder requests authorization to: Add fin whales (*Balaenoptera physalus*) and sei whales (*B. borealis*) to the take authority for tagging. The same tag type and technique will be used to tag fin and sei whales that is authorized for tagging sperm whales. No additional numbers are requested, i.e., no more than five whales total will be tagged each year. Activities this field season will occur in international waters within 300 miles of the west coast of Iceland.

Dated: June 29, 1994.

Herbert W. Kaufman,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 94–16264 Filed 6–30–94; 12:10 pm]

BILLING CODE 3510–22–F

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities Under OMB Review

AGENCY: The Corporation for National and Community Service (CNCS).

ACTION: Information Collection Request Submitted to the Federal Office of Management and Budget (FOMB) for Review.

SUMMARY: This notice provides information about an information proposal by CNCS, currently under review by the Office of Management and Budget (OMB).

DATES: OMB and CNCS will consider comments on the proposed collection of information and record keeping requirements received within 30 days from the date of publication. Copies of the proposed forms and supporting documents may be obtained by contacting CNCS.

ADDRESSES: Send comments to both:
David Rymph, Study Coordinator, 1100 Vermont Ave., NW., Washington, DC 20525
Steve Semenuk, Desk Officer for CNCS, Office of Management and Budget, 3002 New Executive Office Building, Washington, DC 20503

FOR FURTHER INFORMATION CONTACT: Charles Helfer (202) 606–5000 ext. 248.

SUPPLEMENTARY INFORMATION:

Office of the Corporation for National and Community Service

Issuing Proposal: The Evaluation and Policy Coordination Unit.
Title of Forms: Project Director and Supervisor Evaluation Questionnaire.
Need and Use: The National and Community Service Trust Act of 1993 (PL 103–82) requires the Corporation for National and Community Service to evaluate its programs on a regular basis. This information is required for program management, planning, and required record keeping.
Type of Request: Submission of a new collection.
Respondent's Obligation to Reply: Voluntary.
Frequency of Collection: One time only.
Estimated Number of Responses: 455.
Average Burden Hours per Response: 0.35 Hours.
Estimated Annual Reporting or Disclosure Burden: 266 Hours.
Regulatory Authority: 42 U.S.C. 5056(a).

Dated: June 29, 1994.

David Rymph,

Director, Evaluation and Policy Coordination Unit.

[FR Doc. 94–16138 Filed 7–1–94; 8:45 am]

BILLING CODE 6050–28–M

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title and Applicable Form: Indebtedness of Military Personnel—Involuntary Allotments; DD Form 2653.
Type Of Request: Expedited Processing—Approval date requested: 60 days following publication in the **Federal Register**.
Number of Respondents: 91,680.
Responses per respondent: 1.
Annual Responses: 91,680.
Average Burden per Response: 15 minutes.
Annual Burden Hours: 22,920.
Needs and Uses: Public Law 103–94, "The Hatch Act Reform Amendments of 1993," directs the establishment of provisions for the involuntary allotment of the pay of a member of the uniformed services for indebtedness owed a third party as determined by the final judgment of a court, and as further determine by competent military or executive authority to be a compliance with the Soldiers' and Sailors' Civil Relief Act of 1940. These provisions must also take into consideration the absence of a member of the uniformed services from appearance in a judicial proceeding if the absence results from the exigencies of military duty. The information collected hereby, provides the DoD reviewing authority with the data necessary to act on requests from the public for assistance in the collection of debts.
Affected Public: Individuals or households; Businesses or other for profit; and Small businesses or organizations.
Frequency: On occasion.
Respondent's Obligation: Required to obtain or retain a benefit.
OMB Desk Office: Mr. Edward C. Springer.
Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 3235, New Executive Office Building, Washington, DC 20503.
DOD Clearance Officer: Mr. William P. Pearce. Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: June 28, 1994.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–16118 Filed 7–1–94; 8:45 am]

BILLING CODE 5000–04–M

Public Information Collection Requirement Submitted to the Office of Management and Budget (OMB) for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title and Applicable Form: Medical Treatment Facility Incident Statement; Air Force Form 765.
Type of Request: New collection.
Number of Respondents: 13,200.
Responses per Respondent: 1.
Annual Responses: 13,200.
Average Burden per Response: 5 minutes.
Annual Burden Hours: 1,056.
Needs and Uses: The Air Force Form 765, "Medical Treatment Facility Incident Statement," is completed by hospital personnel on behalf of patients, who may be non-governmental personnel, to document adverse events or specific incidents inconsistent with routine medical treatment facility operations or patient care.
Affected Public: Individuals or households; Federal agencies or employees.
Frequency: On occasion.
Respondent's Obligation: Voluntary.
OMB Desk Officer: Mr. Edward C. Springer.
Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 3235, New Executive Office Building, Washington, DC 20503.
DOD Clearance Officer: Mr. William P. Pearce.
Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: June 29, 1994.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–16191 Filed 7–1–94; 8:45 am]

BILLING CODE 5000–04–M

Department of the Navy

Notice of Intent to Prepare an Environmental Impact Statement/ Environmental Impact Report For Disposal and Reuse of Marine Corps Air Station, Tustin, CA

Pursuant to the National Environmental Policy Act as implemented by the Council on Environmental Quality regulations (40 CFR Parts 1500–08), and pursuant to the California Environmental Quality Act (CA Public Resources Code Sections 21000 et seq.), the U.S. Marine Corps and the City of Tustin intend to prepare a joint Environmental Impact Statement/Environmental Impact Report

(EIS/EIR) to evaluate the environmental effects of the disposal and reuse of Marine Corps Air Station (MCAS) Tustin. This action is being conducted in accordance with the Defense Base Closure and Realignment Act of 1990, and the specific 1993 base closure and realignment decisions approved by the Congress in September 1993.

The proposed action to be evaluated in the EIS/EIR is the disposal of land, buildings, and infrastructure of MCAS Tustin for subsequent reuse. The Marine Corps and City of Tustin intend to analyze the environmental effects of the disposal of MCAS Tustin based on the reasonable foreseeable reuse of the property, taking into account uses to be identified by the City of Tustin Base Closure Task Force.

The Task Force has developed a Specific Plan/Reuse Plan to guide the reuse of MCAS Tustin in a variety of uses, including public and private housing, commercial, light industrial, and recreation uses. Some of the existing structures and facilities, including housing, are anticipated to be reused. A number of facilities, including the airfield operation facilities, are proposed for removal. Agricultural and vacant areas on MCAS Tustin are proposed to be developed with urban uses.

Full buildout of the proposed land uses will result in a maximum of 4,601 dwelling units and about 12.3 million square feet of non-residential uses such as commercial business, light industrial, and recreational uses (about 2.1 million square feet is existing floor area on the base, and 10.2 million square feet is potential new floor area). It is also currently estimated that about 25 percent of the site would be used for public uses.

The project also will include the extension of major arterials through the base including Tustin Ranch Road to Von Karman, Warner Avenue from Red Hill to west of Jamboree Road, and creation of a secondary interior loop roadway and local roadways to facilitate local circulation. The Specific/Reuse Plan will also address possible variations to the Tustin Ranch Road and Warner Avenue extensions in the event the southerly blimp hangar is removed.

Alternatives to be addressed in the EIS/EIR can be characterized as follows:

1. Arterial Grid Pattern/High Residential—land uses are driven by a grid pattern of major arterial extensions. This alternative has the greatest number of residential units. This alternative also has no community core land use flexibility. The alternative could pose limitations in responding to market absorption and soil clean-up phasing.

2. Ideal Interior Loop Pattern/Low Residential—the alignment of arterial highways and the proposed looped system would be modified to show its optimum alignment if the southeast blimp hangar could not be reused, and would include possible variations to the Tustin Ranch Road and Warner Avenue extensions. This alternative would have the fewest number of residential units and would result in the highest commercial retail and office square footage, particularly at the southerly portion of the site.

3. No action—retention of the property by the Marine Corps in a caretaker status. However, because of the process mandated by the Base Closure and Realignment Act, selection of the no action alternative would be considered impracticable for the Marine Corps to implement.

Major environmental issues that will be addressed in the EIS/EIR include land use, housing, utilities, noise, transportation/circulation, public services, airfield operations, hazardous materials, water resources, air quality, biological resources, and cultural resources.

The Marine Corps and City of Tustin will initiate a scoping process to determine the extent of issues to be addressed and identifying the significant issues related to this action. The Marine Corps and City of Tustin will hold a public scoping meeting on July 20, 1994, beginning at 7:00 p.m., at the City of Tustin Community Center located in the Tustin Civic Center, 300 Centennial Way. This meeting will be advertised in area newspapers.

A brief presentation will precede the request for public comment. Marine Corps and City of Tustin representatives will be available at this meeting to receive comments from the public regarding issues of concern to the public. It is important that federal, state, and local agencies and interested individuals take this opportunity to identify environmental concerns that should be addressed during the preparation of the EIS/EIR. In the interest of available time, each speaker will be asked to limit oral comments to 5 minutes.

Agencies and the public are also invited and encouraged to provide written comment on scoping issues in addition to, or in lieu of, oral comments at the public meeting. To be most helpful, scoping comments should clearly describe specific issues or topics which the author/speaker believes the EIS/EIR should address. Written statements and questions regarding the scoping process should be mailed to: Christine Shingleton, Assistant City Manager, City of Tustin, 300 Centennial Way, Tustin, CA 92680, telephone number (714) 573–3116. All comments must be received no later than August 5, 1994.

Dated: June 28, 1994.

Lewis T. Booker, Jr.,

LCDR, JAGC, USN,

Federal Register Liaison Officer.

[FR Doc. 94–16114 Filed 7–1–94; 8:45 am]

BILLING CODE 3810–AE–P

Naval Research Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that the Naval Research Advisory Committee will meet on July 18 through 22, and July 25 through 29, 1994, at the Naval Command, Control and Ocean Surveillance Center, Research, Development, Test and Evaluation Division, San Diego, California. The sessions on July 18 through 22, and July 25 through 28, 1994, will commence at 8:00 a.m. and terminate at 5:00 p.m.; and the session on July 29, 1994, will commence at 8:30 a.m. and terminate at 11:30 a.m. All sessions of these meetings will be closed to the public.

The purpose of these meetings is to discuss basic and advanced research. All sessions of the meetings will be devoted to briefings, discussions, and technical examination of information related to Naval research and development, and modeling and simulation technology. Premature public disclosure of this information would be likely to significantly frustrate implementation of proposed policy actions by the Department of the Navy. The information involved is specifically authorized by Executive Order to be withheld from the public if the agency determines it to be in their best interest. It therefore is appropriate that all sessions of the meetings be closed to the general public. The agency-protected information to be discussed is so inextricably intertwined with unclassified matters as to preclude opening any portion of these meetings. Accordingly, the Secretary of the Navy has determined in writing that the public interest requires that all sessions of these meetings be closed to the public because they will be concerned with matters listed in section 552b(c)(9)(B) of title 5, United States Code.

For further information concerning these meetings contact: Captain M. J. Brinkac, U. S. Navy, Office of Naval Research, 800 North Quincy Street,

Arlington, VA 22217-5660, Telephone Number: (703) 696-4870.

Dated: June 29, 1994

Lewis T. Booker, Jr.

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 94-16260 Filed 7-1-94; 8:45 am]

BILLING CODE 3810-AE-F

DEPARTMENT OF EDUCATION

[CFDA No.: 84.133B]

Office of Special Education and Rehabilitative Services, National Institute on Disability and Rehabilitation Research, Applications for a New Award Under the Rehabilitation Research and Training Centers (RRTC) for Fiscal Year (FY) 1994

Purpose: On March 16, 1994 a notice was published in the Federal Register at 59 FR 12268 inviting applications for a new award under the RRTC program for fiscal year 1994 on Rehabilitation in the Pacific Basin. Satisfactory applications were not received for the RRTC, and there is a continuing need for the research. The purpose of this notice is to reinvite applications for an RRTC on Rehabilitation in the Pacific Basin for fiscal year 1994.

The Rehabilitation Act Amendments of 1992 require that each applicant for a grant demonstrate how its proposed activities address the needs of individuals from minority backgrounds who have disabilities.

Eligible Applicants: Institutions of higher education and public or private agencies and organizations collaborating with institutions of higher education, including Indian tribes and tribal organizations, are eligible to apply for awards under this program.

Deadline for Transmittal of Applications: August 19, 1994.

Applications Available: July 5, 1994.

Available Funds: $650,000.

Estimated Number of Awards: 1.

Note: The estimates of funding levels and awards in this notice do not bind the Department of Education to a specific level of funding or number of grants, unless the amount is otherwise specified by statute or regulation.

Project Period: Up to 60 months.

Priority: The priority published in the Federal Register on October 19, 1993 at 58 FR 54004 on Rehabilitation in the Pacific Basin applies to this competition.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, 86; (b) The regulations for this program in 34 CFR Parts 350 and 352; and (c) the notice of final priority published in the Federal Register on October 19, 1993 at 58 FR 54004.

FOR FURTHER INFORMATION CONTACT: In order to obtain further information and an application package, contact Dianne Villines, U.S. Department of Education, Room 3417 Switzer Building, 400 Maryland Avenue, S.W., Washington, D.C. 20202-2704. Telephone: (202) 205-9141. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205-8887.

Program Authority: 29 U.S.C. 760-762.

Dated: June 27, 1994.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 94-16160 Filed 7-1-94; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Availability of the Amendment of the Assured Delivery Provisions of Bonneville Power Administration's Long-Term Intertie Access Policy (LTIAP) and Increased Assured Delivery—Access for Non-Scheduling Utilities Record of Decision (ROD)

AGENCY: Bonneville Power Administration (BPA), DOE.

ACTION: Notice of ROD on Amendment of the Assured Delivery Provisions of BPA's LTIAP and Increased Assured Delivery—Access for Non-Scheduling Utilities.

SUMMARY: Today's notice announces the availability of the ROD for the Amendment of the Assured Delivery Provisions of BPA's LTIAP and Increased Assured Delivery—Access for Non-Scheduling Utilities.

BPA is proceeding with these decisions to facilitate expanded Pacific Northwest-Pacific Southwest Intertie access for non-Federal parties in a manner consistent with the Energy Policy Act of 1992.

ADDRESSES: If you would like a copy of the Amendment of the Assured Delivery Provisions of BPA's LTIAP and Increased Assured Delivery—Access for Non-Scheduling Utilities ROD, please call our document request line, toll-free 800-622-4520, and ask for the Amendment of the Assured Delivery Provisions of BPA's LTIAP and Increased Assured Delivery—Access for Non-Scheduling Utilities ROD.

FOR FURTHER INFORMATION CONTACT: Ms. Cathy Ehli, Public Utilities Specialist, Bonneville Power Administration—PMT, P.O. Box 3621, Portland, Oregon 97208-3621, Telephone 503-230-5173; or the Public Involvement office voice/TTY 503-230-3478 in Portland, toll-free 800-622-4519 for the rest of the United States. Fax number 503-230-3752.

Issued in Portland, Oregon, on June 13, 1994.

John S. Robertson,

Deputy Administrator.

[FR Doc. 94-16216 Filed 7-1-94; 8:45 am]

BILLING CODE 6450-01-P-M

Federal Energy Regulatory Commission

Notice of Cultural Resources Industry Outreach Training Course

June 27, 1994.

The Office of Pipeline Regulation (OPR) will convene a cultural resources compliance training course. This course is being held so that the regulated pipeline industry and interested individuals and/or organizations can gain an understanding of:

- How the Commission gives the industry and the public an opportunity to assist in meeting FERC's responsibilities under the National Historic Preservation Act (NHPA) and other historic preservation laws and regulations; and
- What cultural resources information the industry needs to file with the Commission pre- and post-issuance of a FERC certificate.

Interested organizations and the public are urged to take advantage of this course.

Course discussion will include the following topics:

- Objectives and requirements of the Commission regarding compliance with § 106 of the NHPA and related historic preservation laws;
- Guidance for reporting on cultural resources investigations;
- Definition of cultural resources terms used by FERC in the compliance process; and
- Efficient strategies for planning and conducting cultural resources investigations.

The one-day training course will be held on August 2, 1994 at the Georgetown University Conference Center, 3800 Reservoir Road NW., Washington, DC 20057. For hotel reservations, please contact the conference center at 1-800-446-9476 by

July 15, 1994 and identify yourself as a cultural resources seminar attendee. The staff of OPR and Enserch Environmental, the Commission's environmental support contractor, will conduct the training. There will be no fee for the course, but you must pre-register.

The same training course may be offered later in 1994 based on the level of interest. Western locations under consideration are Houston, Texas; San Francisco, California; or Denver, Colorado. Please comment on these or other course locations. If a second session is planned, information will be published in the **Federal Register** announcing the date and location.

If you would like to attend the Washington, DC, course or indicate your preference for another location, please call the telephone number listed below to obtain a form to complete.[1] Because space is limited, please submit the completed form within 15 days of publication of this notice by mail or fax to: Ms. Donna Connor, Enserch Environmental Corporation, 211 Congress Street, Boston, MA 02110, Phone: (617) 542–8805, FAX: (617) 695–1587.

You will receive confirmation of pre-registration and additional information before the training course.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16151 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER94–511–000, et al.]

Public Service Company of Colorado, et al.; Electric Rate and Corporate Regulation Filings

June 27, 1994.

Take notice that the following filings have been made with the Commission:

1. Public Service Company of Colorado

[Docket No. ER94–511–000]

Take notice that on June 23, 1994, Public Service Company of Colorado (Public Service) filed with the Commission a letter agreement dated March 17, 1992, between Public Service and Intermountain Rural Electric Association, Inc. This letter agreement was inadvertently omitted from the "Transmission Interconnection Agreement Between Public Service and Intermountain Rural Electric Association" which was filed by Public Service on December 29, 1993, in Docket No. ER94–511–000.

Public Service states that copies of this filing were served upon Intermountain Rural Electric Association, Inc., and state jurisdictional regulators which include the Public Utilities Commission of the State of Colorado and the State of Colorado Office of Consumer Counsel.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

2. LG&E Power Marketing Inc.

[Docket No. ER94–1188–000]

Take notice that on June 23, 1994, LG&E Power Marketing Inc, tendered for filing supplemental information to its April 26, 1994 filing in the above-referenced docket.

Comment date: July 8, 1994, in accordance with Standard Paragraph E at the end of this notice.

3. Oklahoma Gas and Electric Company

[Docket No. ER94–1199–000]

Take notice that on June 23, 1994, Oklahoma Gas and Electric Company (OG&E) tendered for filing additional supporting information relative to its proposed Letter Agreement with AES Power, Inc. (AESPI) for the sale of capacity and energy.

Copies of this filing have been sent to AESPI, the Oklahoma Corporation Commission, and the Arkansas Public Service Commission.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

4. Florida Power Corporation

[Docket No. ER94–1221–000]

Take notice that Florida Power Corporation (Florida Power) on June 21, 1994 tendered for filing a substitute Revised Sheet No. 6 for New Smyrna Beach, Florida (New Smyrna Beach). The filing corrects a misstated demand charge from $1.09 per kW per month to $1.14.

Florida Power requests that the change in the corrected sheet be made effective July 1, 1994.

Florida Power states that it has served copies of its filing on the New Smyrna Beach and the service list in this proceeding.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

5. PacifiCorp

[Docket No. ER94–1361–000]

Take notice that on June 15, 1994, PacifiCorp, tendered for filing, in accordance with § 35.13(a)(2) of the Commission's Rules and Regulations, First Revised Sheet No. 12 and Original Sheet No. 13 to PacifiCorp's FERC Electric Tariff, First Revised Volume No. 3 (Tariff) and Service Agreements with the following customers:

Lassen Municipal Utility District
City of Redding
AES Power Inc.
Ashton Energy Corporation
Catex Vitol Electric Inc.
Chicago Energy Exchange
Citizens Energy Corporation
Citizens Power & Light Corporation
CRSS Power Marketing, Inc.
Direct Electric Inc.
Eastern Power Distribution, Inc.
Eclipse Energy Inc.
Electric Clearinghouse, Inc.
Enron Power Marketing, Inc.
Equitable Resources Marketing Company
Heartland Energy Services, Inc.
Howell Power Systems, Inc.
InterCoast Power Marketing Company
LG&E Power Inc.
Louis Dreyfus Electric Power Inc.
MG Electric Power, Inc.
National Electric Associates (L.P.)
NorAm Energy Services, Inc.
North American Energy Conservation, Inc.
PowerNet G.P.
Rainbow Energy Marketing Corporation
Torco Energy Marketing, Inc.
Vesta Energy Company
Wholesale Power Services, Inc.

The Service Agreements provide for the sale of short-term firm power and energy and non-firm energy for resale in accordance with the Tariff. Only the Service Agreement with Lassen Municipal Utility District has been executed. All of the other Service Agreements are being filed unexecuted in anticipation of future requests for service under the Tariff. PacifiCorp's filing herein is provided to add the above customers to the Tariff.

PacifiCorp respectfully requests pursuant to § 35.11 of the Commission's Rules and Regulations, that a waiver of prior notice be granted and that these Service Agreements be accepted for filing effective on June 1, 1994.

Copies of this filing were supplied to the Public Utility Commission of Oregon.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

6. Texican Energy Ventures, Inc.

[Docket No. ER94–1362–000]

Take notice that Texican Energy Ventures, Inc. (Texican) on June 15, 1994, tendered for filing a petition for blanket approvals and waivers under various regulations of the Commission, and an order accepting its Rate

[1] The form referenced in this notice is not being printed in the **Federal Register**. Copies of the form were sent to those receiving this notice in the mail.

Schedule No. 1, to be made effective on August 15, 1994.

Rate Schedule No. 1 provides for the sale of energy and capacity at agreed prices. Rate Schedule No. 1 also provides that no sales may be made to affiliates.

According to Texican, it intends to engage in electric capacity and energy transactions as a marketer and a broker. In transactions in which Texican purchases power and resells such power to other purchasers, Texican will be functioning as a marketer. In Texican's marketing transactions, Texican proposes to charge rates mutually agreed upon by the parties. All sales will be at arms' length, and no sales will be made to affiliated entities. In transactions in which Texican does not take title to the electric power, Texican will be limited to the role of a broker and charge a fee for its services.

Texican further states it is not in the business of producing or transmitting electric power. Texican does not currently have or contemplate acquiring title to any electric power generation or transmission facilities.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

7. Pennsylvania Power & Light Company

[Docket No. ER94–1364–000]

Take notice that on June 15, 1994, Pennsylvania Power & Light Company (PP&L) tendered for filing an Electrical Output Sales Agreement (Agreement) between PP&L, and Enron Power Marketing, Inc. (EPMI) dated May 17, 1994. The Agreement provides for the sale by PP&L to EPMI of electrical output solely for EPMI's use in wholesale bulk power transactions.

PP&L has requested an effective date of August 14, 1994 for the Agreement. PP&L has not requested any notice period waivers.

PP&L states that a copy of its filing was provided to EPMI and to the Pennsylvania Public Utility Commission.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

8. Entergy Power, Inc.

[Docket No. ER94–1366–000]

Take notice that on June 15, 1994, Entergy Power, Inc. (Entergy Power), tendered for filing Amendment No. 3 to the Interchange Agreement between Entergy Power, Inc. and East Kentucky Power Cooperative, Inc. Entergy Power states that the purpose of the Third Amendment is to amend Service Schedule LP—Limited Firm Capacity of the Interchange Agreement to specify a rate cap for capacity and associated energy sold by Entergy Power under that schedule.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

9. Public Service Company of New Mexico

[Docket No. ER94–1367–000]

Take notice that on June 16, 1994, Public Service Company of New Mexico (PNM) submitted for filing a Capacity and Energy Services Agreement between PNM and Enron Power Marketing, Inc. (EPMI). Under the Agreement, PNM and EPMI will make capacity and energy services available to one another at rates reflecting current market conditions.

PNM requests a waiver of the Commission's notice requirements to permit the Agreement to become effective on July 1, 1994.

Copies of the filing have been served upon EPMI and the New Mexico Public Utility Commission.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

10. New York State Electric & Gas Corporation

[Docket No. ER94–1368–000]

Take notice that on June 16, 1994, New York State Electric & Gas Corporation (NYSEG), tendered for filing Supplement No. 12 to its Agreement with the New York Power Authority (NYPA), designated NYSEG Rate Schedule FERC No. 112. The proposed changes would increase revenues by $137,741 based on the twelve month period ending June 30, 1995.

This rate filing, Supplement No. 12 to Rate Schedule No. 112, is made pursuant to Article No. 2 of the September 28, 1993 Facilities Agreement. The annual charges associated with other taxes, operating expenses, maintenance expenses, administration and general expenses, working capital, and associated revenue taxes are revised based on data taken from NYSEG's Annual Report to the Federal Energy Regulatory Commission (FERC Form 1) for the twelve months ended December 31, 1993.

NYSEG requests an effective date of July 1, 1994, and, therefore, requests waiver of the Commission's notice requirements.

Copies of the filing were served upon the New York Power Authority and on the Public Service Commission of the State of New York.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

11. Alabama Power Company

[Docket No. ER94–1371–000]

Take notice that on June 17, 1994, Alabama Power Company, tendered for filing a Transmission Service Delivery Point Agreement dated May 11, 1994, reflecting the addition of a delivery point to Tallapoosa River Electric Cooperative. This delivery point will be served under the terms and conditions of the Agreement for Transmission Service to Distribution Cooperative Member of Alabama Electric Cooperative, Inc., dated August 28, 1980 (designed FERC Rate Schedule No. 147). The parties request an effective date of July 20, 1994, for the addition of the delivery point to Tallapoosa River Electric Cooperative.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

12. Alabama Power Company

[Docket No. ER94–1372–000]

Take notice that on June 15, 1994, Alabama Power Company tendered for filing, two (2) separate Transmission Service Delivery Point Agreements dated May 1, 1994 and June 1, 1994, which reflect the addition of delivery point to Central Alabama Electric Cooperative and upward revision of maximum capacity for certain deliveries to an existing delivery point to Dixie Electric Cooperative. These delivery points have been and will be served under the terms and conditions of the Agreement for Transmission Service to Distribution Cooperative Member of Alabama Electric Cooperative, Inc., dated August 28, 1980 (designed FERC Rate Schedule No. 147). The parties request an effective date of August 1, 1995, for the addition of a delivery point to Central Alabama Electric Cooperative, and of July 1, 1994, for the upward revision of maximum delivery point capacity power deliveries to Dixie Electric Cooperative.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

13. Southern California Edison Company

[Docket No. ER94–1373–000]

Take notice that on June 17, 1994, Southern California Edison Company tendered for filing the following amendment to Supplement No. 1 to the Power Purchase Agreement between

Nevada Power Company and Edison, Rate Schedule FERC No. 286:

Amendment No. 1 (Amendment) To Supplement No. 1 to the Power Purchase Agreement Between Nevada Power Company and Southern California Edison Company

The Amendment modifies paragraph 6 and adds paragraph 7 to Supplement No. 1 to the Power Purchase Agreement Between Nevada Power Company and Southern California Edison Company.

Copies of this filing were served upon the Public Utilities Commission of the State of California and all interested parties.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

14. New England Power Company

[Docket No. ER94–1375–000]

Take notice that on June 17, 1994, New England Power Company (NEP), tendered for filing a letter agreement with the Ashburnham (Mass.) Municipal Light Department. The agreement provides for voltage reduction and underfrequency interruption services to Ashburnham by NEP. NEP seeks an effective date of sixty days from its filing.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

15. Entergy Services, Inc.

[Docket No. ER94–1376–000]

Take notice that on June 17, 1994, Entergy Services, Inc. (Entergy Services), on behalf of Arkansas Power & Light Company, Gulf States Utilities Company, Louisiana Power & Light Company, Mississippi Power & Light Company, and New Orleans Public Service Inc. (collectively, the Entergy Operating Companies) tendered for filing the Fifth Transmission Service Agreement (Fifth TSA) between Entergy Services and Entergy Power, Inc. (EXPC). The Fifth TSA sets out the terms and conditions of non-firm transmission service under the Entergy Operating Companies' Transmission Service Tariff for sales by Entergy Power to East Kentucky Power Cooperative, Inc.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

16. Allegheny Power Service Corporation, on behalf of Monongahela Power Company, The Potomac Edison Company, West Penn Power Company (The APS Companies)

[Docket No. ER94–1378–000]

Take notice that on June 21, 1994, Allegheny Power Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (The APS Companies) filed an Emission Allowance Management Agreement. Allegheny Power Service Corporation requests waiver of notice requirements and asks the Commission to honor the proposed effective dates specified in the agreements.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

17. New England Power Company

[Docket No. ER94–1379–000]

Take notice that on June 21, 1994, New England Power Company (NEP), tendered for filing a service agreement for system sales service under NEP's FERC Electric Tariff, Original Volume No. 5 to New York State Electric & Gas Corporation.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

18. Delmarva Power & Light Company

[Docket No. ER94–1377–000]

Take notice that on June 20, 1994, Delmarva Power & Light Company (Delmarva) and Public Service Electric & Gas Company (PSE&G) tendered for filing a settlement agreement which resolves a contractual dispute between them regarding the conditions of PSE&G's use of the lower Delaware Valley Transmission System (LDV), including Delmarva's 500/236 kilovolt (kV) Keeney Substation, for delivery of 150 megawatts (MW) of PSE&G capacity and associated energy to Old Dominion Electric Cooperative (ODEC). Delmarva and PSE&G request that the Settlement Agreement be allowed to become effective on August 20, 1994, as a supplement to the LDV Agreement which is Delmarva Rate Schedule No. 43 and RSE&G's Rate Schedule No. 46.

Delmarva and PSE&G state that a copy of the filing has been posted as required by the Commission's regulations, and copies have been served upon each of the affected parties and upon the Public Service Commissions of the States of New Jersey, Delaware, Maryland and Virginia.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

19. Louisville Gas and Electric Company

[Docket No. ER94–1380–000]

Take notice that on June 20, 1994, Louisville Gas and Electric Company, tendered for filing proposed changes in its FERC Electric Service Tariffs, Volume Nos. 2 and 3. The proposed changes would provide access and service to LG&E's firm and non-firm transmission customers under Rate Schedules T and CT under the same or comparable terms and conditions as those enjoyed by LG&E.

The changes were filed in response to the findings of the Federal Energy Regulatory Commission in *American Electric Power Service Corp.*, 67 FERC ¶ 61,168 (1994), and *Kansas City Power & Light Company*, 67 FERC ¶ 61,183 (1994), that an open access transmission tariff that is not unduly discriminatory or anticompetitive should offer third parties access on the same or comparable basis, and under the same or comparable terms and conditions, as the transmission provider's uses of its system.

Copies of the filing were served upon the Kentucky Public Service Commission and upon LG&E's current customers under the affected rate schedules.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

20. Southwest Regional Transmission Association

[Docket No. ER94–1381–000]

Take notice that on June 17, 1994, Southwest Regional Transmission Association (SWRTA) tendered for filing copies of the Bylaws of SWRTA.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

21. Arizona Public Service Company

[Docket No. ER94–1382–000]

Take notice that on June 21, 1994, Arizona Public Service Company (APS) tendered for filing an Interruptible Transmission Service Agreement (Agreement) between APS and Yuma Cogeneration Associates (YCA). This Agreement provides for interruptible transmission service for output from YCA's generating facilities to the point of delivery.

Copies of this filing have been served upon YCA and the Arizona Corporation Commission.

Comment date: July 11, 1994, in accordance with Standard Paragraph E at the end of this notice.

22. West Texas Utilities Company

[Docket No. ER94–1386–000]

Take notice that on June 22, 1994, West Texas Utilities Company (WTU) tendered for filing an executed Service Agreement between WTU and Rio Grande Electric Cooperative, Inc. (Rio Grande) under WTU's FERC Electric Tariff TR–1.

WTU requests waiver of the notice requirements in order that the Service Agreement may become effective as of June 1, 1995.

Copies of the filing have been served on Rio Grande and the Public Utility Commission of Texas.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

23. Tampa Electric Company

[Docket No. ER94–1387–000]

Take notice that on June 22, 1994, Tampa Electric Company (Tampa Electric) tendered for filing a letter agreement between Tampa Electric and the City of Wauchula, Florida (Wauchula). The letter agreement amends an existing letter of commitment under Service Schedule D of the contract for interchange service between them, providing for the sale by Tampa Electric to Wauchula of capacity and energy from Tampa Electric's Big Bend Station.

Tampa Electric also tendered for filing an amendment to its existing partial requirements service agreement with Wauchula under Tampa Electric's FERC Electric Tariff, First Revised Volume No. 1.

Tampa Electric proposes an effective date of July 1, 1994, for the letter agreement and the amendment to the partial requirements service agreement, and therefore requests waiver of the Commission's notice requirement.

Copies of the filing have been served on Wauchula and the Florida Public Service Commission.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

24. Tampa Electric Company

[Docket No. ER94–1388–000]

Take notice that on June 22, 1994, Tampa Electric Company (Tampa Electric) tendered for filing a letter agreement between Tampa Electric and the City of Fort Meade, Florida (Fort Meade). The letter agreement amends an existing letter of commitment under Service Schedule D of the contract for interchange service between them, providing for the sale by Tampa Electric to Fort Meade of capacity and energy from Tampa Electric's Big Bend Station.

Tampa Electric also tendered for filing an amendment to its existing partial requirements service agreement with Fort Meade under Tampa Electric's FERC Electric Tariff, First Revised Volume No. 1.

Tampa Electric proposes an effective date of July 1, 1994, for the letter agreement and the amendment to the partial requirements service agreement, and therefore requests waiver of the Commission's notice requirement.

Copies of the filing have been served on Fort Meade and the Florida Public Service Commission.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

25. Northeast Utilities Service Company

[Docket No. ER94–1389–000]

Take notice that on June 22, 1994, Northeast Utilities Service Company (NUSCO) tendered for filing, on behalf of The Connecticut Light and Power Company, Western Massachusetts Electric Company, Holyoke Water Power Company (including Holyoke Power and Electric Company), and Public Service Company of New Hampshire (together, the NU System Companies), a First Amendment to System Power Sales Agreement (Amendment) with Hudson Light and Power Department (Hudson) and a Service Agreement between NUSCO and the NU System Companies for service under NUSCO's Short-Term Firm Transmission Service Tariff No. 5. The transaction provides Hudson with economic replacement power during the extended Seabrook refueling outage over the period June 12–July 6, 1994.

NUSCO requests that the rate schedule become effective on April 11, 1994. NUSCO states that copies of the rate schedule have been mailed or delivered to the parties to the Amendment and the affected state utility commissions.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

26. PacifiCorp

[Docket No. ER94–1390–000]

Take notice that PacifiCorp, on June 23, 1994, tendered for filing the AC Intertie Agreement, Contract No. DE–MS79–94BP94332; Midpoint-Meridian Transmission Agreement, Contract No. DE–MS79–94BP94285; and DC Intertie and Network Transmission Agreement, Contract No. DE–MS79–94BP94280, between PacifiCorp and Bonneville Power Administration.

PacifiCorp requests that a waiver of prior notice be granted and that an effective date of June 1, 1994 be assigned. This date being the effective date of the Agreements. Such waiver will have no effect on wholesale or wheeling customers under other rate schedules.

Copies of this filing were supplied to the Public Utility Commission of Oregon.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

27. Southwestern Public Service Company

[Docket No. ER94–1391–000]

Take notice that Southwestern Public Service Company (Southwestern) on June 23, 1994, tendered for filing a proposed amendment to the Agreement for Primary Electric Service and Golden Spread Electric Cooperative, Inc. for service to Midwest Electric Cooperative, Inc. (Midwest).

The amendment reflects an additional delivery point and increase in commitment to 18,000 KVA. These changes are necessary so that Midwest may transfer loads to Southwestern.

Comment date: July 12, 1994, in accordance with Standard Paragraph E at the end of this notice.

28. Indeck-Corinth Limited Partnership

[Docket No. QF87–422–005]

On June 23, 1994, Indeck-Corinth Limited Partnership tendered for filing an amendment to its initial filing in this docket.

The amendment pertains to the ownership structure and technical aspects of the cogeneration facility. No determination has been made that the submittal constitutes a complete filing.

Comment date: July 20, 1994, 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 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the

Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16224 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. CP94–161–000]

Avoca Natural Gas Storage; Facility Design Changes for the Proposed Avoca Gas Storage Field Project and Request for Comments on Environmental Issues

June 27, 1994.

On June 3 and 17, 1994, Avoca Natural Gas Storage (Avoca) filed an updated description of its proposed Avoca Gas Storage Field Project, in Docket No. CP94–161–000. Avoca's filing contained significant design changes in the proposed storage field project. This notice updates the Federal Energy Regulatory Commission's (FERC or Commission) "Notice of Intent To Prepare An Environmental Assessment for the Proposed Avoca Gas Storage Field Project and Request for Comments on Environmental Issues" (NOI) issued February 1, 1994.

Summary of the Proposed Changes in Facility Design

Avoca proposes the following changes in the Avoca Gas Storage Field Project:

- new locations for the brine disposal wells, brine disposal pipeline, water source pipeline, and the solution-mined cavern wells;
- a change in the design of the cavern system—instead of developing 10 individual caverns, Avoca would solution-mine 5 caverns using 10 wells (2 wells per cavern); and
- Avoca proposes to increase its solution-mining rate by withdrawing up to 3 million gallons of water per day (2,000 gallons per minute), rather than limiting its withdrawal to 2 million gallons of water per day. The total leaching period for all five caverns is approximately 3 years.

Avoca has moved several of its proposed facilities. The new proposed location of these facilities is shown in appendix 1.[1] Avoca states that the proposed changes in facility locations are a result of negotiations with local landowners.

Avoca proposes the change in cavern design and the increase in leaching rate to reduce the time required to solution-mine the proposed caverns. Avoca states that it has obligations to have certain facilities in service for the 1996 winter heating season. Avoca believes that reducing the time required to solution-mine its caverns will allow it to place some of the proposed facilities in service for the 1996 winter heating season.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us to discover and address concerns the public may have about proposals. We call this "scoping." The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission requests public comments on the scope of the issues it will address in the EA. All comments received are taken into account during the preparation of the EA.

The EA will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- geology and soils
- water resources, fisheries, and wetlands
- vegetation and wildlife
- endangered and threatened species
- land use
- cultural resources
- air quality and noise
- hazardous waste

We will also evaluate possible alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commission's official service list for this proceeding. A comment period will be allotted for review if the EA is published. We will consider all comments on the EA before we recommend that the Commission approve or not approve the project.

Additional Environmental Issues

We have already identified several environmental issues that we think deserve attention based on a preliminary review of the proposed facilities and the information provided by Avoca. These were listed in the Commission's February 1, 1994 NOI

As a result of Avoca's modified proposal, the following additional environmental issues will be addressed:

- Avoca proposes to use up to 3,000,000 gallons of water per day for the solution-mining process. This may have an impact on groundwater availability. Testing of wells in the local aquifers indicates that the water supply recharges up to 14,600,000 gallons of water per day.
- Avoca's brine disposal pipelines would cross five wetlands.
- Moving the facilities to the new locations may have an impact on cultural resources.

Public Participation

You can make a difference by sending a letter addressing your specific comments or concerns about the project. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be.

Please follow the instructions below to ensure that your comments are received and properly recorded:

- Address your letter to: Lois Cashell, Secretary, Federal Energy Regulatory Commission, 825 North Capitol St., NE., Washington, DC 20426;
- Reference Docket No. CP94–161–000;
- Send a copy of your letter to: Mr. Steven G. Grape, EA Project Manager, Federal Energy Regulatory Commission, 825 North Capitol St., NE. Room 7312, Washington, D.C. 20426; and
- Mail your comments so that they will be received in Washington, D.C. on or before July 14, 1994.

If you wish to receive a copy of the EA, you should request one from Mr. Grape at the above address.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding or become an "intervenor." Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide copies of its filings to all other parties. If you want to become an intervenor you must file a Motion to Intervene according to Rule 214 of the Commission's Rules of

[1] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies are available from the Commission's Public Reference Branch, Room 3104, 941 North Capitol Street, N.E., Washington, D.C. 20426, or call (202) 208–1371. Copies of the appendices were sent to all those receiving this notice in the mail.

Practice and Procedure (18 CFR 385.214) attached as appendix 2.

The date for filing timely motions to intervene in this proceeding has passed. Therefore, parties now seeking to file late interventions must show good cause, as required by section 385.214(b)(3), why this time limitation should be waived. Environmental issues have been viewed as good cause for late intervention. You do not need intervenor status to have your scoping comments considered.

Additional Questions?

Additional information about the proposed project is available from Mr. Steven G. Grape, EA Project Manager, at (202) 208–1046.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16147 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–P

[Project No. 1922–008 Alaska]

Ketchikan Public Utilities ; Availability of Final Environmental Assessment

June 27, 1994.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for a new major license for the existing Beaver Falls Hydroelectric Project, located on Beaver Falls Creek near the city of Ketchikan, in the First Judicial District of Alaska. The Federal Energy Regulatory Commission and the U.S. Forest Service, Ketchikan Ranger District, have prepared a Final Environmental Assessment (FEA) for the project that analyzes existing and potential future environmental impacts of the existing project and has concluded that approval of the project, with appropriate enhancement measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the FEA are available for review in the Public Reference Branch, Room 3104, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 94–S16142 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Project 2114–024 Washington]

Public Utility District No. 2 of Grant County; Intent to Prepare an Environmental Impact Statement and to Conduct a Scoping Meeting

June 27, 1994.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's regulations, 18 CFR part 380 (Order No. 486, 52 F.R. 47910), the Office of Hydropower Licensing has evaluated four downstream fish passage alternatives addressed in the Mid-Columbia Proceeding (Docket No. E–9569–003) for the Priest Rapids Project. Staff's initial evaluation of the proposed modifications was issued on May 25, 1994, in an environmental assessment (EA). The June 3, 1994 transmittal letter for the EA stated our intent to prepare an environmental impact statement (EIS).

A draft EIS will be issued and circulated for review by all interested parties. All comments filed on the draft EIS will be analyzed by staff and considered in the final EIS. Staff's conclusions and recommendations will then be presented for the consideration of the Commission in reaching its final decision.

Scoping Meetings

To obtain information from the public regarding relevant environmental issues that should be analyzed in the EIS, the Commission will conduct two public scoping meetings. The first scoping meeting will be held on Monday July 25, 1994 in Portland Oregon, at the Portland Building, 2nd Floor Auditorium, 1120 SW 5th Avenue, from 1 pm to 5 pm. The second scoping meeting will be held on Wednesday July 27, 1994 in Ephrata, Washington at the City of Ephrata Recreation Center, 112 Basin Street SW, from 7:00 pm to 11 pm. All interested individuals, organizations, and agencies are invited to attend.

The EA will be considered the initial coping document. Copies of the EA have been mailed to all entities who have expressed interest in this proceeding. The EA is also available in the Commission's Reference and Information Center, Room 3308, of the Commission's offices at 941 North Capitol Street, N.E. Washington, D.C. 20426 and will be available at the scoping meeting. We encourage all interested parties to read the EA prior to the scoping meeting.

Objectives

At the meeting the staff will: (1) describe the range of issues being considered in this post-licensing proceeding (2) review the conclusions and recommendations in the EA; (3) receive input from meeting participants on the alternatives considered in the EA; (4) identify any additional issues that should be included in the EIS; and (5) obtain any additional information that any entity feels should be considered during the preparation of the EIS.

Procedures

The scoping meeting will be recorded by a stenographer and all statements (oral and written) will become part of the Commission's public record for this proceeding. Interested persons who are unable to attend, or do not choose to speak at the scoping meeting, may submit written statements for inclusion in the public record. All written comments must be filed with the Secretary, Federal Energy Regulatory Commission, 825 North Capital Street N.E., Washington, DC 20426, on or before August 30, 1994.

All written correspondence should clearly show on the first page of each document the following caption: Priest Rapids Project, FERC Project No. 2114–024.

Further, please note the Commission's Rules of Practice and Procedure, requires all entities to file an original and eight copies of any filing with the Commission. Parties filing documents must also serve the documents on each person whose name is on the official service list.

For further information, please contact Timothy Welch at (202) 219–2666.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16144 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 2197–016 North Carolina]

Yadkin, Inc.; notice of availability of environmental assessment

Issued: June 28, 1994.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order 486, 52 FR 47897), the Commission's Office of Hydropower Licensing has reviewed a non-project use of project lands application for the Yadkin Hydropower Project, No. 2197–016. The Yadkin Project is located on the Yadkin/Pee Dee River in Stanly and Montgomery Counties, North Carolina. The application is for approval to build a

marina on the Narrows Reservoir. An Environmental Assessment (EA) was prepared for the application. The EA finds that approving the application would not constitute a major Federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, Room 3104, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426.

Please submit any comments within 20 days from the date of this notice. Any comments, conclusions, or recommendations that draw upon studies, reports, or other working papers of substance should be supported by appropriate documentation.

Comments should be addressed to Lois D. Cashell, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street. NE., Washington, DC 20426. Please affix Project No. 2197–016 to all comments. For further information, please contact Steve Hocking at (202) 219–2656.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16150 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Project Nos. 2543–037, et al.]

Hydroelectric Applications Montana Power Company, et al.]; Applications

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

1a. Type of Application: Amendment of License.

b. Project No.: 2543–037.

c. Date Filed: April 29, 1994.

d. Applicant: The Montana Power Company.

e. Name of Project: Milltown.

f. Location: On the Clark Fork River in Missoula County, Montana.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. Applicant Contact: Michael P. Manion, The Montana Power Company, 40 East Broadway, Butte, MT 59701, (406) 723–5421 (Ext. 72456).

Brian J. McManus, Reid & Priest, Market Square, 701 Pennsylvania Avenue, NW., Washington, DC 20004, (202) 508–4201.

i. FERC Contact: Regina Saizan, (202) 219–2673.

j. Comment Date: July 29, 1994.

k. Description of the Request: The licensee requests that its license be amended to extend the expiration date of the license five years, from December 31, 1999 to December 31, 2004.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

2a. Type of Application: Major License (Notice of Tendering).

b. Project No.: 11077–001.

c. Date filed: May 31, 1994.

d. Applicant: Alaska Power and Telephone Company.

e. Name of Project: Goat Lake.

f. Location: At the existing Goat Lake, near Skagway, Alaska. Sections 10, 11, 14, 15, and 16, Township 27 South, Range 60 West, CRM.

g. Filed Pursuant to: Federal Power Act, 16 USC §§ 791(a)–825(r)

h. Applicant Contact: Mr. Robert S. Grimm, President Alaska Power & Telephone Co. P.O. Box 222, Port Townsend, WA 98368 (206) 385–1733

i. FERC Contact: James Hunter (202) 219–2839

j. Brief Description of Project: The proposed project will consist of a siphon intake extending into Goat Lake, a penstock, and a powerhouse with an installed capacity of 4.0 megawatts, a tailrace discharging flows into the Skagway River, and a transmission line connecting to an existing distribution line at Clifton.

k. With this notice, we are initiating consultation with the State Historic Preservation Officer (SHPO), as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

l. In accordance with section (b)(7) of the Commission's regulations, if any resource agency, SHPO, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate, factual basis for a complete analysis of this application on its merits, they must file a request for the study with the Commission, together with justification for such request, not later than 60 days from the filing date and serve a copy of the request on the Applicant.

3a. Type of Application: Declaration of Intention.

b. Docket No.: D194–2–000.

c. Date Filed: June 2, 1994.

d. Applicant: Gary Kratzman.

e. Name of Project: Kratzman-Zebold Hydro.

f. Location: Unnamed Creek, tributary to Oyster Creek, T. 36, N., R. 3 E., sec. 4, SE¼SW¼ Skagit County, Washington.

g. Filed Pursuant to: Section 23(b) of the Federal Power Act, 16 U.S.C. § 817(b).

h. Applicant Contact: Gary Kratzman, Kratzman-Zebold Hydro, P.O. Box 52, Bow, WA 98232, (206) 428–9645.

i. FERC Contact: Hank Ecton, (202) 219–2678.

j. Comment Date: July 28, 1994.

k. Description of Project: The proposed project will consist of: (1) a 1,400-foot-long, 2-inch diameter pipeline from an unnamed creek; (2) a 7-kilowatt Pelton wheel, connected to the water supply for two residences; and (3) appurtenant facilities.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether the project: (1) would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

1. Purpose of Project: Applicant intends to use all energy produced on-site. No other power source is available for 3–5 miles.

m. This notice also consists of the following standard paragraphs: B, C1, and D2.

4a. Type of Application: Original License for Minor Project.

b. Project No.: 11285–001.

c. Date filed: February 25, 1993.

d. Applicant: Casitas Municipal Water District (Casitas District), Oak View, California.

e. Name of Project: Lake Casitas Power Recovery Facility.

f. Location: On Bureau of Reclamation's existing pipeline between its Casitas dam and its water treatment plant, near the City of San Buena Ventura, in Ventura County, California, on 0.38 acre of land owned by Reclamation.

g. Filed Pursuant to: Federal Power Act, 16 USC 791(a)–825(r).

h. Applicant Contact: Mr. John J. Johnson, General manager, Casitas Municipal Water District, 1055 Ventura Avenue, Oak View, CA 93022, (805) 649–2251.

i. FERC Contact: Mr. Surender M. Yepuri, P.E. (202) 219–2847.

j. Deadline Date: Deadline for filing Interventions, Protests, Comments, Recommendations, Terms and Conditions (see attached paragraph D4), and also for filing Written Scoping Comments [see item (1) below]—60 days from issuance.

k. Status of Environmental Analysis: The application is ready for environmental analysis at this time—paragraph D4 below.

l. Intent To Prepare An Environmental Assessment And Invitation For Written Scoping Comments: The Commission staff (staff) intends to prepare an Environmental Assessment (EA) on the hydroelectric project in accordance with the National Environmental Policy Act. The EA will objectively consider both site-specific and cumulative environmental impacts of the project and reasonable alternatives and will include economic, financial, and engineering analyses.

A draft EA will be issued and circulated for review by all interested parties. All timely filed comments on the draft EA will be analyzed by the staff and considered in the final EA. The staff's conclusions and recommendations will then be presented for consideration of the Commission in reaching its final licensing decision.

Scoping: Interested individuals, organizations, and agencies with environmental expertise are invited to assist the staff in identifying the scope of environmental issues that should be analyzed in the EA by submitting written scoping comments. To help focus those comments, a scoping document outlining subject areas to be addressed in the EA will be mailed to agencies and interested individuals on the Commission mailing list. Copies of the scoping document may also be requested from the staff.

Persons who have views on the issues or information relevant to the issues may submit written statements for inclusion in the public record. Those written comments should be filed with the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, by the deadline date shown in item (j) above. All written correspondence should clearly show the following caption on the first page: Lake Casitas Power Recovery Facility, FERC No. 11285.

Intervenors are reminded of the Commission's Rules of Practice and Procedure requiring parties filing documents with the Commission to serve a copy of the document on each person whose name appears on the official service list. Further, if a party or interceder files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

m. Description of Project: The project, on Reclamation's existing water distribution system originating from Lake Casitas, would consist of: (1) a 319-foot-long, 54-inch-diameter concrete penstock; (2) a 72-foot-long, 34-foot-wide concrete powerhouse, containing two turbine-generator units with a total installed capacity of 1,000 Kw; and (3) a 68-foot-long, 54-inch-diameter outlet pipe to carry the turbine discharge to the non-project water treatment plant.

n. Purpose of Project: Power generated at the project will be used by the applicant to off-set part of the power requirements at the treatment plant and the adjacent Rincon Pump Plant.

o. This notice also consists of the following standard paragraphs: A2, A9, B1 and D4.

p. Available Locations of Application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at the applicant's office (see item (h) above).

5a. Type of Application: Preliminary Permit.

b. Project No.: 11485–000.

c. Date Filed: June 1, 1994.

d. Applicant: North American Hydro, Inc.

e. Name of Project: Delhi Milldam Hydro Project.

f. Location: On the Maquoketa River near Delhi, in Delaware County, Iowa.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. Applicant Contact: Mr. Loyal Gake, North American Hydro, Inc., P.O. Box 167, Neshkoro, WI 54960, (414) 293–4628.

i. FERC Contact: Ed Lee (202) 219–2809.

j. Comment Date: August 15, 1994.

k. Description of Project: The proposed project would consist of: (1) an existing earth filled dam approximately 58.5 feet high and 700 feet long; (2) an existing 50-acre reservoir with a maximum storage of 880 acre-feet at pool elevation 896 feet MSL; (3) a powerhouse containing two generating units for a total installed capacity of 1425 kW; (4) a proposed 1.5-kV or equivalent transmission line; and (5) appurtenant facilities. The applicant estimates that the average annual generation would be 3,300 MWh. The cost of the work to be performed under the permit by the applicant would be $70,000. The existing dam and structures are owned by the Lake Delhi Recreation Association, R.R.2, Delhi, Iowa 52223.

l. Purpose of Project: The applicant anticipates that the power generated will be sold to a nearby utility company.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

6a. Type of Application: Preliminary Permit.

b. Project No.: 11483–000.

c. Date filed: May 27, 1994.

d. Applicant: James G. Ordway.

e. Name of Project: Glenwood Hydroelectric Project.

f. Location: At the Klickitat Salmon Hatchery, on Indian Ford Springs #1 and Wonder Springs, near the town of Glenwood, in Klickitat County, Washington.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. § 791(a)–825(r).

h. Applicant Contact: Albert Liou, P.E., Harza Engineering, Inc., 2353 130th Avenue N.E., Suite 200, P.O. Box C–96900, Bellevue, Washington 98005, (206) 882–2455.

i. FERC Contact: Mr. Michael Strzelecki, (202) 219–2827.

j. Comment Date: August 27, 1994.

k. Description of Project: The proposed project would include two developments. The first development would consist of: (1) a small existing diversion structure on Indian Ford Springs #1; (2) an existing 1,200-foot-long, 19-inch-diameter penstock; (3) a powerhouse with an installed capacity of 140 kW; (4) a 150-foot-long transmission line interconnecting with an existing Klickitat County PUD transmission line; and (5) appurtenant facilities.

The second development would consist of: (1) a small existing diversion structure on Wonder Springs; (2) an existing 1,100-foot-long, 24-inch-diameter penstock; (3) a powerhouse with an installed capacity of 50 kW; (4) a 900-foot-long transmission line interconnecting with an existing Klickitat County PUD transmission line; and (5) appurtenant facilities.

All existing facilities are owned by the Washington Department of Fish and Wildlife. No new access roads will be needed to conduct the studies.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

7a. Type of Application: Preliminary Permit.

b. Project No.: P–11487–000.

c. Date Filed: June 14, 1994.

d. Applicant: N.E.W. Hydro, Inc.

e. Name of Project: Vulcan Hydro Project.

f. Location: On the Fox River near Appleton, in Outagamie County, Wisconsin.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. Applicant Contact: Mr. Charles Alsberg, N.E.W. Hydro, Inc., P.O. Box 167, Neshkoro, WI 54960, (414) 293–4628.

i. FERC Contact: Ed Lee (202) 219–2809.

j. Comment Date: August 29, 1994.

k. Description of Project: The proposed project would utilize the existing U.S. Army Corps of Engineers' Upper Dam and Reservoir, and would consist of: (1) an existing 600-foot-long and 50-foot-wide power canal; (2) the Vulcan powerhouse housing two generating units for a total installed capacity of 900 kW; (3) a new 450-foot-long tailrace; (4) a short transmission line; and (5) appurtenant facilities. The applicant estimates that the average annual generation would be 3,300 MWh. The cost of the work to be performed under the permit by the applicant would be $70,000. The existing powerhouse is owned by Wisconsin Electric Power Company, 231 West Michigan, Milwaukee, WI 53201.

l. Purpose of Project: The applicant anticipates that the power generated will be sold to a nearby utility company.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

8a. Type of Application: Surrender of License.

b. Project No.: 2794–004.

c. Date filed: June 16, 1994.

d. Applicant: Silver King Limited.

e. Name of Project: Warren Hydro Project.

f. Location: Warren Creek, Idaho County, Idaho.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. Applicant Contact: David Hammerquist, Ringert Clark, Chartered Lawyers, 455 South Third Street, P.O. Box 2773, Boise, Idaho 83701, (208) 342–4591.

i. FERC Contact: Etta Foster, (202) 219–2679.

j. Comment Date: August 11, 1994.

k. Description of Proposed Action: Silver King Limited has decided to surrender the license for the Warren Hydro Project because of economic reasons.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

9a. Type of Application: Plan to Monitor Recreation Use and Demand.

b. Project No: 2916–015.

c. Date Filed: January 10, 1994.

d. Applicant: East Bay Municipal Utility District.

e. Name of Project: Lower Mokelumne Project.

f. Location: Mokelumne River, Amador, Calaveras, and San Joaquin Counties, California.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. Applicant Contact: Mr. John A. Myers, 375 Eleventh Street, Oakland, CA 94623, (510) 287–1121.

i. FERC Contact: Patti Pakkala, (202) 219–0025.

j. Comment Date: August 11, 1994.

k. Description of Project: East Bay Municipal Utility District, licensee for the Lower Mokelumne Project, requests approval of a plan to monitor recreation use and demand at the South Camanche Shore Recreation Area. The data obtained by monitoring use and demand would complement the recreational opportunities and facilities currently being offered at the South Camanche Shore location.

l. This notice also consists of the following standard paragraphs: B, C1, and D2.

Standard Paragraphs

A2. Development Application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A5. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30 (b)(1) and (9) and 4.36.

A7. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A9. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

A10. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit will be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file aa motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

B1. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

C. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT

TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Federal Energy Regulatory Commission, Room 1027, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's must also be sent to the Applicant's representatives.

D4. Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to section 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice (August 15, 1994 for Project No. 11285–001). All reply comments must be filed with the Commission within 105 days from the date of this notice (September 28, 1994 for Project No. 11285–001).

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) bear in all capital letters the title "PROTEST", "MOTION TO INTERVENE", "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commmission in this proceeding with 18 supervisors in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: June 28, 1994.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16222 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. CP94–619–000, et al.]

Transcontinental Gas Pipe Line Corporation, et al.; Natural Gas Certificate Filings

June 27, 1994.

Take notice that the following filings have been made with the Commission:

1. Transcontinental Gas Pipe Line Corporation

[Docket No. CP94–619–000]

Take notice that on June 21, 1994, Transcontinental Gas Pipe Line Corporation (TGPL), P.O. Box 1396, Houston, Texas 77251, filed in Docket No. CP94–619–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon a transportation service for Public Service Electric & Gas Company (PSE&G), which was authorized in Docket No. CP79–389, as amended, all as more fully set forth in the application on file with the Commission and open to public inspection.

TGPL proposes to abandon firm and interruptible transportation carried out under its Rate Schedule X–222 for PSE&G. TGPL is authorized to transport up to 75,000 dt equivalent of natural gas per day (or a greater amount if mutually agreed upon) on an interruptible basis for PSE&G and up to 6,600 dt equivalent of natural gas per day on a firm basis. Both firm and interruptible services were for transportation from offshore and onshore Louisiana to various delivery points in New Jersey. PSE&G has notified TGPL of its intent to terminate the service under Rate Schedule X–222 with an effective date of June 22, 1994. It is stated that the service proposed for abandonment would be replaced by TGPL's existing Part 284 transportation on an interruptible service under TGPL's Rate Schedule IT. It is asserted that PSE&G can receive equivalent service this way with the same quality and flexibility as other Rate Schedule IT shippers.

Comment date: July 18, 1994, in accordance with Standard Paragraph F at the end of this notice.

2. ANR Pipeline Company Columbia Gulf Transmission Company

Docket No. CP94–623–000

Take notice that on June 22, 1994, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, and Columbia Gulf Transmission Company (Columbia Gulf), P. O. Box 1273, Charleston, West Virginia 25325, filed in Docket No. CP94–623–000, a joint application pursuant to Section 7(b) of the Natural Gas Act and Part 157 of the Commission's Regulations for an

order permitting and approving the abandonment of a natural gas exchange service known as ANR's (formerly Michigan Wisconsin Pipe Line Company) Rate Schedule X–39 and as Columbia Gulf's Rate Schedule X–15, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

ANR and Columbia Gulf state that this exchange service, authorized by an October 26, 1973, order in Docket No. CP74–39, provides for an exchange to take place when a shortage of gas exists on either company's system, which could be alleviated by deliveries of gas from the system of the other company. ANR and Columbia Gulf state the points of exchange are at an interconnection in Eugene Island Block 250, off-shore Louisiana, and at an interconnection near Calumet, St. Mary Parish, Louisiana. ANR and Columbia Gulf maintain there is no abandonment of any facilities pursuant to the instant application.

ANR and Columbia Gulf relate that on August 17, 1993, Columbia Gulf gave ANR written notice of its intention to terminate the exchange service.

Comment date: July 18, 1994, in accordance with Standard Paragraph F at the end of this notice.

3. Texas Eastern Transmission Corporation

[Docket No. CP94–624–000]

Take notice that on June 23, 1994, Texas Eastern Transmission Corporation (Texas Eastern), 540 Westheimer Court, Houston, Texas 77056–5301, filed in Docket No. CP94–624 a request pursuant to §§ 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205, and 157.211) for authorization to construct a new delivery point to enable Texas Eastern to deliver natural gas to GATX Terminals Corporation (GATX), end user. It is stated that it would enable Texas to make natural gas deliveries to GATX under Texas Eastern's blanket certificate issued on November 5, 1982 in Docket No. CP82–535–000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Pursuant to Section 157.211 of the Commission's regulations, Texas Eastern requests authorization to install a new delivery point in order to deliver natural gas under the agreement covering service for GATX under Rate Schedule IT–1 of Texas Eastern's FERC Gas Tariff, Volume No. 1, and that Texas Eastern's existing tariff does not prohibit the additional volumes. Texas Eastern states that the peak and average day deliveries at the point would be 5,000 Dth per day.

Texas Eastern states that the installation of the delivery point will have no effect on Texas Eastern's peak day or annual deliveries. Texas Eastern submits that its proposal will be accomplished without detriment or disadvantage to Texas Eastern's other customers.

The delivery point to be installed by Texas Eastern includes the installation of two 2-inch taps on Texas Eastern's 12-inch Line Nos. 1–C and 1–R at M.P. 2.63 in Richmond County, New York. The approximate cost of such facilities is $551,500 and would be 100% reimbursable by GATX.

It is further stated that GATX would cause to be installed a dual 2-inch meter station, including 50 feet of 4-inch pipeline between the proposed Texas Eastern taps to GATX's proposed meter station and electronic gas measurement equipment.

Comment date: August 11, 1994, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or to make any protest with reference to said application should on or before the comment date, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and/or permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16223 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–P

Chance Pond Brook Associates; Surrender of Preliminary Permit

[Project No. 11378–001 New Hampshire]

June 27, 1994

Take notice that Chance Pond Brook Associates, permittee for the Lower Chance Pond Brook Project No. 11378, located on the Chance Pond Brook, Merrimack County, New Hampshire, has requested that its preliminary permit be terminated. The preliminary permit was issued on May 12, 1993, and would have expired on April 30, 1996. The permittee states that the project would be economically infeasible.

The permittee filed the request on June 17, 1994, and the preliminary permit for Project No. 11378 shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR

part 4, may be filed on the next business day.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16141 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 11204–001 Idaho]

Magic Irrigators, Inc.; Surrender Of Preliminary Permit

June 27, 1994.

Take notice that Magic Irrigators, Inc., Permittee for the Hertzinger Project No. 11204, has requested that its preliminary permit be terminated. The preliminary permit for Project No. 11204 was issued February 28, 1992, and would have expired January 31, 1995. The project would have been located on Salmon Falls Creek, In Twin Falls County, Idaho.

The Permittee filed the request on May 31, 1994, and the preliminary permit for Project No. 11204 shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR part 4, may be filed on the next business day.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16143 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–m

[Docket No. ER94–1099–000]

Eclipse Energy, Inc.; Issuance of Order

June 27, 1994.

On March 30, 1994 and April 28, 1994, Eclipse Energy, Inc. (Eclipse) submitted for filing a rate schedule under which Eclipse will engage in wholesale electric power and energy transactions as a marketer. Eclipse also requested waiver of various Commission regulations. In particular, Eclipse requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Eclipse.

On June 15, 1994, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under 18 CFR part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Eclipse 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).

Absent a request for hearing within this period, Eclipse is authorized to issue securities and assume obligations or liabilities as a guaranto, endorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public or private interests will be adversely affected by continued approval of Eclipse's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set for the above, is July 15, 1994.

Copies of the full text of the order are available from the Commission's Public Reference Branch, room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16145 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP93–187–000, *et al.*]

Equitrans, Inc.; Informal Settlement Conference

June 28, 1994.

Take notice that an informal conference will be convened in this proceeding on Tuesday, July 12, 1994, at 10 a.m., for the purpose of exploring the possible settlement of the above-referenced docket. The conference will be held at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC, 20426.

Any party, as defined by 18 CFR 385.102(c), or any participant, as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, please contact Hollis J. Alpert at (202) 208–0783 or Arnold H. Meltz at (202) 208–2161.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16148 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP94–260–001]

Natural Gas Pipeline Co. of America; Proposed Changes in FERC Gas Tariff

June 27, 1994.

Take notice that on June 23, 1994, Natural Gas Pipeline Company of America (Natural) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, Sixth Revised Sheet No. 14, to be effective July 1, 1994.

Natural states that it is filing to supplement its GSR filing of May 31, 1994, filed at Docket No. RP94–260–000, to be effective July 1, 1994. Natural states that contrary to what was stated in the May 31st filing, its Rate Schedule ITS rates should also have changed to reflect the increases that were indicated on Exhibit A of the May 31st filing.

Natural requested whatever waivers may be necessary to permit the tariff sheet as submitted herein to become effective July 1, 1994.

Natural states that copies of the filing are being mailed to Natural's jurisidictional customers and interested state regulatory agencies.

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 §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before July 5, 1994. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16140 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER94–1061–000]

Rainbow Energy Marketing Corp.; Issuance of Order

June 27, 1994.

On March 18, 1994 and April 19, 1994, Rainbow Energy Marketing Corporation (Rainbow) submitted for filing a rate schedule under which Rainbow will engage in wholesale electric power and energy transactions as a marketer. Rainbow also requested waiver of various Commission regulations. In particular, Rainbow requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Rainbow.

On June 10, 1994, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under 18 CFR part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Rainbow 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).

Absent a request for hearing within this period, Rainbow is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security or another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public or private interests will be adversely affected by continued approval of Rainbow's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set for the above, is July 11, 1994.

Copies of the full text of the order are available from the Commission's Public Reference Branch, room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16146 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP94–622–000]

Trunkline Gas Co.; Request Under Blanket Authorization

June 28, 1994.

Take notice that on June 22, 1994, Trunkline Gas Company (Trunkline), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP94–622–000 a request pursuant to §§ 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to abandon a delivery point located in Calcasieu Parish, Louisiana under Trunkline's blanket certificate issued in Docket No. CP83–84–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Trunkline proposes to abandon the facilities associated with its Amoco Delivery Point located at the interconnect with Florida Gas Transmission Company in Section 27, Township 8 South, Range 7 West, Calcasieu Parish, Louisiana. Trunkline states that the Amoco Delivery Point was originally constructed to serve Amoco Production Company (Amoco), and that Amoco removed its compressor units and abandoned the site in 1992. Trunkline further states that no firm or interruptible transportation agreements utilize the facilities proposed to be abandoned herein.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16149 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP94–296–000]

Williams Natural Gas Co.; Proposed Changes in FERC Gas Tariff

June 27, 1994.

Take notice that Williams Natural Gas Company (WNG) on June 20, 1994, tendered for filing the following tariff sheets to its FERC Gas Tariff, Second Revised Volume No. 1:

Second Revised Sheet Nos. 1 and 9
First Revised Sheet Nos. 10, 11 and 252

The proposed effective date of these tariff sheets is July 20, 1994.

WNG states that this filing is being made pursuant to Section 4 of the Natural Gas Act and Article 14 of the General Terms and Conditions of its FERC Gas Tariff, Second Revised Volume No. 1. WNG proposes to recover approximately $22.7 million in unrecovered purchased gas costs and approximately $13.7 million representing the unamortized portion of deferred gas storage costs. As provided in Article 14.1, WNG proposes to direct bill such amounts to parties who were customers under WNG's former Rate Schedules F, PR(A), PR(B) and P on May 18, 1992, based on each customer's purchases as a percentage of total purchases by all customers under the above rate schedules during the 12-month period ending September 30, 1993.

WNG states that a copy of its filing was served on all jurisdictional customers and interested state commissions.

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 §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before July 5, 1994. 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 on intervene. Copies of this filing are on the file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 94–16152 Filed 7–1–94; 8:45 am]

BILLING CODE 6717–01–M

Office of Fossil Energy

[FE Docket No. 94–47–NG]

Coastal Gas Marketing Company; Order Granting Blanket Authorization to Import and Export Natural Gas, Including Liquefied Natural Gas, From and to Canada and Mexico

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Coastal Gas Marketing Company authorization to import and export a combined total of up to 750 Bcf of natural gas, including liquefied natural gas (LNG), from and to Canada and Mexico. The term of the authorization is for a period of two years beginning on the date of the initial import or export after July 11, 1994.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on June 24, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–16231 Filed 7–1–94; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 94–46–NG]

Oxy USA Inc.; Order Granting Blanket Authorization to Import and Export Natural Gas From and to Canada and Mexico and Vacating Authorization

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting OXY USA Inc. (OXY) authorization to import and export a combined total of up to 29.2 Bcf of natural gas from and to Canada and Mexico. This import/export authorization shall extend for a period of two years beginning on the date of the initial import or export delivery, whichever occurs first. This order replaces DOE/FE Opinion and Order No. 666, issued to OXY on September 9, 1992 (1 FE ¶ 70,633).

OXY's order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, June 24, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–16230 Filed 7–1–94; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 94–38–NG]

Phibro Division of Salomon Inc.; Order Granting Blanket Authorization to Import Natural Gas, Including Liquefied Natural Gas from Canada, and to Export Natural Gas to Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of an order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Phibro Division of Salomon Inc. blanket authorization to import up to 200 billion cubic feet (Bcf) of natural gas, including liquefied natural gas (LNG), from Canada, and to export up to 200 Bcf of natural gas to Canada, over a two-year term beginning on the date of first import or export.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, June 21, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–16229 Filed 7–1–94; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 94–48–NG]

Talisman Marketing (U.S.) Inc.; Order Granting Blanket Authorization to Import and Export Natural Gas From and to Canada and Mexico and Vacating Authorizations

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Talisman Marketing (U.S.) Inc. (Talisman U.S.) authorization to import and export a combined total of up to 60 Bcf of natural gas from and to Canada and Mexico. This import/export authorization shall extend for a period of two years beginning on the date of the initial import or export delivery, whichever occurs first. In conjunction with this new authorization, two import authorizations previously issued to BP Resources Canada Limited and to Encor Energy (America) Inc. have been vacated.

Talisman U.S.'s order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, June 24, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–16232 Filed 7–1–94; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5006–5]

Prevention of Significant Deterioration of Air Quality (PSD) Final Determinations

AGENCY: United States Environmental Protection Agency.

ACTION: Notice of final actions.

SUMMARY: The purpose of this notice is to announce that between February 1, 1994 and April 30, 1994, the United States Environmental Protection Agency (EPA) Region II Office, issued 3 final determinations and the New Jersey Department of Environmental Protection and Energy issued 1 final determination pursuant to the Prevention of Significant Deterioration of Air Quality (PSD) regulations codified at 40 CFR 52.21. In addition, EPA Region II and the New York State Department of Environmental Conservation (NYSDEC) issued 2 final determinations between October 1, 1993 and January 31, 1994. These 2 determinations were inadvertently omitted from the last publication.

DATES: The effective dates for the above determinations are delineated in the following chart (See **SUPPLEMENTARY INFORMATION**).

FOR FURTHER INFORMATION CONTACT: Frank Jon of the Permitting and Toxics Support Section, Air Compliance Branch, Division of Air and Waste Management, U.S. Environmental

Protection Agency Region II Office, 26 Federal Plaza, Room 505, New York, New York 10278, (212) 264–6672.

SUPPLEMENTARY INFORMATION: Pursuant to the PSD regulations, the EPA Region II and the NYSDEC have made final PSD determinations relative to the sources listed below:

Name	Location	Project	Agency	Final Action	Date
Virgin Islands Water and Power Authority—Unit 19.	St. Croix, Virgin Islands.	Permit modification to allow Unit 19 to begin operating for a period of up to 180 days prior to the date of installation of the continuous emission monitors. This modification had no effect on any control or emission requirement contained in the PSD permit..	EPA	PSD Permit Modification.	Apr. 23, 1994.
American Ref-Fuel Company of Essex County (Resource Recovery Facility).	Newark, New Jersey.	PSD permit modification to install selective non-catalytic reduction and require yard waste separation to meet permitted levels of NO_x..	NJDEPE	PSD Permit Modification.	July 7, 1993.
				Environmental Appeals Board's Order Denying Review.	Apr. 18, 1994.
Halfmoon Cogeneration Project (Inter-Power).	Halfmoon, New York.	New 210 MW cogeneration project consisting of 3 coal-fired fluidized bed combustors.	EPA	PSD Permit	Oct. 26, 1992.
				Environmental Appeals Board's Order Granting Review.	Apr. 7, 1993
				Environmental Appeals Board's Final Order Affirming PSD Permit and Denying Administrative Review.	Mar. 16, 1994
Virgin Islands Water and Power Authority—Unit 20.	St. Croix, Virgin Islands.	New 24.5 MW oil-fired gas turbine (Unit 20) and the retirement of an existing 4.5 MW diesel engine (Unit 12)..	EPA	PSD Permit	Mar. 1, 1994
Caribbean Petroleum Corporation.	Bayamon, Puerto Rico.	Permit modification to increase the utilization of the crude heater, CH–6, and increase the utilization of the CO boiler during startups of the Fluid Catalytic Cracking Unit while maintaining annual emissions for the CO boiler to previously permitted levels. In addition, EPA allowed the use of 12-month rolling averages instead of the 365-day rolling averages..	EPA	PSD Permit Modification.	Jan. 14, 1994
Indeck Silver Springs Cogeneration.	Silver Springs, New York.	Modification at a 55 MW combined cycle gas turbine project firing natural gas with No. 2 fuel oil as backup..	NYSDEC	PSD Permit Modification.	Oct. 1, 1993

This notice lists only the sources that have received final PSD determinations. Anyone who wishes to review these determinations and related materials should contact the following offices:

EPA Actions

United States Environmental Protection Agency, Region II Office, Air Compliance Branch - Room 505, 26 Federal Plaza, New York, New York 10278.

NJDEPE Actions

New Jersey Department of Environmental Protection and Energy, Division of Environmental Quality, Bureau of Engineering and Technology, 401 East State Street, Trenton, New Jersey 08625.

NYSDEC ACTIONS

New York State Department of Environmental Conservation, Division of Air Resources, Source Review and Regional Support Section, 50 Wolf Road, Albany, New York 12233–0001.

If available pursuant to the Consolidated Permit Regulations (40 CFR 124), judicial review of these determinations under Section 307(b)(1) of the Clean Air Act (the Act) may be sought only by the filing of a petition for review in the United States Court of Appeals for the appropriate circuit within 60 days from the date on which these determinations are published in the **Federal Register**. Under Section 307(b) (2) of the Act, these determinations shall not be subject to later judicial review in civil or criminal proceedings for enforcement.

Dated: June 2, 1994

Jeanne M. Fox,

Regional Administrator.

[FR Doc. 94–16214 Filed 7–1–94, 8:45 am]

BILLING CODE 6560–50–P

[FRL–5006–6]

Transfer of Data to Contractors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Intended Transfer of Confidential Business Information to a Subcontractor.

SUMMARY: The Environmental Protection Agency (EPA) intends to transfer confidential business information (CBI) collected from the landfills and incinerators industry to Highland Data Services, a subcontractor of Science Applications International Corporation (SAIC). The information being transferred was collected or will be collected under the authority of Section 308 of the Clean Water Act. Interested persons may submit comments on this intended transfer of information to the address noted below.

DATES: Information will not be provided to Highland Data Services before July 12, 1994.

ADDRESSES: Comments may be sent to David Hoadley, Engineering and Analysis Division (4303), Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: David Hoadley, Document Control Officer, Engineering and Analysis Division (4303), U. S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 260–7765.

SUPPLEMENTARY INFORMATION: EPA intends to transfer information, including CBI, to Highland Data Services for data entry. In accordance with 40 CFR Part 2, Subpart B, SAIC was identified in letters to industry as one of a number of contractors and subcontractors receiving this information. In effect, this notice merely adds Highland Data Services to the list.

The information being transferred consists of information previously collected by EPA's Office of Science and Technology (OST), in connection with the Waste Treatment Industry Phase II Questionnaires, to support the development of effluent limitations guidelines and standards under the Clean Water Act for the landfills and incinerators industry.

EPA also intends to transfer to SAIC and Highland Data Services all information listed in this notice, of the type described above (including CBI) that may be collected in the future under the authority of CWA Section 308, as is necessary to enable SAIC and Highland Data Services to carry out the work required by their contracts to support EPA's development of effluent limitations guidelines and standards for the landfills and incinerators industry.

EPA office receiving support	Contract No.	Contractor (P=prime contractor S=subcontractor)	Type of support
OW/OST/EAD	68–C1–0006	SAIC(P) Hackensack, NJ Highland Data Services(S) Bluegrass, VA	Technical. Data Entry.

Dated: June 8, 1994.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 94–16110 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–50–P

National Air Pollution Control Techniques Advisory Committee; Open Meeting

ACTION: Notice of open meeting.

SUMMARY: A meeting of the National Air Pollution Control Techniques Advisory Committee (NAPCTAC) will be held at the Sheraton Inn University Center, 2800 Middleton Avenue, Durham, North Carolina 27705. The telephone number is (919) 383–8575.

DATES: July 18 and 19, 1994.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public. Anyone wishing to make a presentation must contact Ms. Teresa Clemons at the Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina by July 14, 1994. The telephone number is (919) 541–5571.

SUPPLEMENTARY INFORMATION: Section 183(e) of the Clean Air Act of 1990 requires the U.S. Environmental Protection Agency (EPA) to conduct a study of emissions of volatile organic compounds (VOC's) from consumer and commercial products and to report to Congress the findings of the study. Upon submittal of the report to the Congress, the EPA must list those categories of products which contribute at least 80 percent of the VOC emissions from all consumer and commercial products in ozone nonattainment areas. The EPA must at that time divide the list into 4 groups by priority. Beginning no later than 2 years after publishing the list, the EPA must regulate one group every 2 years until all 4 groups are regulated.

One objective of the study is to develop criteria for regulating consumer and commercial products under section 183(e). These criteria are to be used to select products for regulation. Section 183(e) lists 5 factors which must be taken into consideration when developing the criteria: (1) The uses, benefits, and commercial demand of consumer and commercial products; (2) any health or safety functions served by the products; (3) those consumer and commercial products which emit highly reactive VOC's into the ambient air; (4) those products which are subject to the most cost-effective controls; and (5) the availability of any alternatives to such consumer and commercial products that are of comparable costs, considering health, safety, and environmental impacts. The EPA has developed criteria based on the 5 factors listed in section 183(e).

The EPA has not yet exercised the criteria to develop a prioritized list of categories for regulation under section 183(e). In order to ensure consistency and fairness in developing the draft prioritized category list, a decision was made to convene an independent panel to exercise the criteria.

The National Air Pollution Control Techniques Advisory Committee (NAPCTAC), established in 1968 by the Surgeon General, is an ongoing advisory group which provides independent views based upon specialized knowledge and skills unavailable in the EPA. The NAPCTAC consists of the Director, Office of Air Quality Planning and Standards, or his designee, as chairperson and 11 members appointed by the EPA's Deputy Administrator. The members are selected from the chemical, engineering, biomedical, and socioeconomic disciplines resident in universities, State and local governments, research institutions, industry, and public interest groups.

Because of the balance afforded by such a diverse group, the NAPCTAC was considered a logical and convenient choice for the panel. The panel will consider each category of products subject to section 183(e) and will assign a score of 1 to 5 for each criterion. The output of the scoring exercise will be a draft prioritized category list, with the highest scored categories receiving the highest priority for regulation.

The draft list will be reviewed by the Administrator who reserves the right to make adjustments to the list. For example, certain health and safety products may be considered for exemption as provided for in section 183(e)(3)(a). Some product categories may be grouped in the interest of regulatory efficiency. The criteria and draft prioritized category list are not final and may be subject to change until regulatory action is taken.

The agenda for the meeting is as follows:

July 18 (Monday)—9 a.m. to 12 p.m.

—Overview of section 183(e) and expectations for the meeting.
—Presentations by interested parties (10 minutes each).

1 to 5 p.m.

—Criteria exercised by the NAPCTAC panel

7 to 10 p.m. Evening Session

—Continue criteria exercise

July 19 (Tuesday)—8 a.m. to 12 p.m.

—Continue criteria exercise

1 to 5 p.m.

—Continue and conclude criteria exercise
—Closing remarks

Dated: June 28, 1994.

John S. Seitz,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 94–16212 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–50–M

[FRL–5007–6]

Proposed Agreement and Covenant Not To Sue Under the Comprehensive Environmental Response, Compensation, and Liability Act; Peterson/Puritan, Inc. Superfund Site; Lincoln and Cumberland, RI

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed agreement and covenant not to sue and request for public comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing to enter into a prospective purchaser agreement and covenant not to sue (the "agreement") to resolve potential claims under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9601. Notice is being published to inform the public of the proposed agreement and of the opportunity to comment. The agreement is intended to resolve the potential liability under CERCLA of Alpha-Realty Corporation, N.F.A. Corporation and The Rhode Island Industrial Facilities Corporation ("the Settling Parties") regarding a portion of the Peterson/Puritan, Inc. Superfund Site in Lincoln and Cumberland, Rhode Island. The Settling Parties are acquiring the Health-Tex property portion of the Peterson/Puritan, Inc. Superfund Site.

DATES: Comments must be provided on or before July 26, 1994.

ADDRESSES: Comments should be addressed to the Docket Clerk, U.S. Environmental Protection Agency, Region I, JFK Federal Building—RCG, Boston, Massachusetts 02203, and should refer to: In the Matter of Alpha-Realty Corporation, N.F.A. Corporation, and The Rhode Island Industrial Facilities Corporation, U.S. EPA Docket No. I–94–1061.

FOR FURTHER INFORMATION CONTACT: Brian Rohan, U.S. Environmental Protection Agency, Office of Regional Counsel, RCU, J.F.K. Federal Building, Boston, Massachusetts 02203, (617) 565–3699.

SUPPLEMENTARY INFORMATION: Notice is hereby given of a proposed agreement concerning the Peterson/Puritan, Inc. Superfund Site in Lincoln and Cumberland, RI. The agreement was approved by EPA Region I on June 22, 1994 subject to review by the public pursuant to this Notice. The Settling Parties have executed signature pages committing them to participate in the agreement. Under the proposed agreement, the Settling Parties are required to pay $150,000 to the Hazardous Substances Superfund; grant access to the property to EPA, its authorized officers, employees, representatives, and all other persons performing response actions under EPA oversight; and record institutional controls for the property in the form of a deed restriction. EPA believes the settlement is fair and in the public interest.

EPA is entering into this agreement under the inherent settlement authority of CERCLA. CERCLA provides EPA with authority to consider, compromise, and settle a potential claim under section 107 of CERCLA if the claim has not been referred to the U.S. Department of Justice for further action. The U.S. Department of Justice approved this settlement in writing on June 20, 1994.

EPA will receive written comments relating to this settlement for twenty-one (21) days from the date of publication of this Notice.

A copy of the proposed administrative settlement may be obtained in person or by mail from Brian Rohan, U.S. Environmental Protection Agency, Office of Regional Counsel, JFK Federal Building—RCU, Boston, Massachusetts 02203, (617) 565–3699.

The Agency's response to any comments received will be available for public inspection with the Docket Clerk, U.S. Environmental Protection Agency, Region I, JFK Federal Building—RCG, Boston, Massachusetts (U.S. EPA Docket No. I–94–1061).

Dated: June 22, 1994.

John P. DeVillars,

Regional Administrator.

[FR Doc. 94–16221 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

June 27, 1994.

The Federal Communications Commission has submitted the following information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of these submissions may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800. For further information on these submissions contact Judy Boley, Federal Communications Commission, (202) 632–0276. Persons wishing to comment on these information collections should contact Timothy Fain, Office of Management and Budget, Room 3221 NEOB, Washington, DC 20503, (202) 395–3561.

OMB Number: 3060–0246
Title: Section 74.452, Equipment changes
Action: Extension of currently approved collection
Respondents: State or local governments, non-profit institutions, and businesses or other for-profit (including small businesses)
Frequency of Response: On occasion reporting requirement
Estimated Annual Burden: 25 responses; 0.5 hours average burden per response; 13 hours total annual burden
Needs and Uses: Section 74.452 requires that licensees of remote pickup stations notify the Commission of any equipment changes that are deemed desirable or necessary (without departing from its station authorization) upon completion of such changes. The data are used by FCC staff to assure that changes made

comply with the rules and regulations.

OMB Number: 3060–0254
Title: Section 74.433, Temporary authorizations
Action: Extension of a currently approved collection
Respondents: State or local governments, non-profit institutions, and businesses or other for-profit (including small businesses)
Frequency of Response: On occasion reporting requirement
Estimated Annual Burden: 30 responses; 1 hour average burden per response; 30 hours total annual burden
Needs and Uses: Section 74.433 requires that a licensee of a remote pickup station make an informal written request to the FCC when requesting temporary authorization for operations of a temporary nature that cannot be conducted in accordance with § 74.24. The data is used by FCC staff to insure that the temporary operation of a remote pickup station will not cause interference to existing stations.

OMB Number: 3060–0342
Title: Section 74.1284, Rebroadcasts
Action: Extension of a currently approved collection
Respondents: Businesses or other for-profit (including small businesses)
Frequency of Response: On occasion reporting requirement
Estimated Annual Burden: 25 responses; 1 hour average burden per response; 25 hours total annual burden
Needs and Uses: Section 74.1284 requires that the licensee of an FM Translator station obtain prior consent from the primary FM broadcast station or other FM translator before rebroadcasting their programs. In addition, the licensee must notify the Commission of the call letters of each station rebroadcast and must certify that written consent has been received from the licensee of that station. The data is used by FCC staff to update records and to assure compliance with FCC rules and regulations.

OMB Number: 3060–0483
Title: Section 73.687, Transmission system requirements
Action: Extension of a currently approved collection
Respondents: Businesses or other for-profit (including small businesses)
Frequency of Response: On occasion reporting requirement
Estimated Annual Burden: 6 responses; 1 hour average burden per response; 6 hours total annual burden
Needs and Uses: Section 73.687(e)(3) requires TV broadcast stations operating on Channels 14 and 69 to take special precautions to avoid interference to adjacent spectrum land mobile operations. This requirement applies to all new Channel 14 and 69 TV broadcast stations and those authorized to change channel, increase effective radiated power (ERP), change directional antenna characteristics such that ERP increases in any azimuth direction or change location, involving an existing or proposed channel 14 or 69 assignment. Section 73.687(e)(4) requires these stations to submit evidence to the FCC that no interference is being cause before they will be permitted to transmit programming on the new facilities. The data is used by FCC to ensure proper precautions have been taken to protect land mobile stations from interference. It will also increase and improve service to the public by broadcasters and land mobile services operating in certain parts of the spectrum.

Federal Communications Commission.
William F. Caton,
Acting Secretary.
[FR Doc. 94–16137 Filed 7–1–94; 8:45 am]
BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Revocations

Notice is hereby given that the following ocean freight forwarder licenses have been revoked by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR 510.

License Number: 3333
Name: Integrated Traffic Systems, Inc.
Address: 122 W. 22nd, #301, Oak Brook, IL 60521
Date Revoked: March 18, 1994
Reason: Failed to maintain a valid surety bond.

License Number: 3353
Name: Zuazu International, Inc.
Address: 310 Madison Ave., Ste. 1010, New York, NY 10017
Date Revoked: April 4, 1994
Reason: Failed to maintain a valid surety bond.

License Number: 2610
Name: Tar-Mac International, Inc.
Address: 2700 Greens Rd., Bldg. K, Ste. 300, Houston, TX 77032
Date Revoked: May 23, 1994
Reason: Failed to maintain a valid surety bond.

License Number: 1812
Name: Byrd Freight Services International, Inc. dba U-Freight/BFS International
Address: 14720 Lee Road, Humble, TX 77396
Date Revoked: May 25, 1994
Reason: Failed to maintain a valid surety bond.

License Number: 83
Name: Alro Forwarding Co., Ltd.
Address: One World Trade Center, Ste. 4623, NY, NY 10048
Date Revoked: June 1, 1994
Reason: Surrendered license voluntarily.

License Number: 1462
Name: Commodity Forwarders, Inc.
Address: 210 Baronne Street, Ste 1242, New Orleans, LA 70112
Date Revoked: June 5, 1994
Reason: Failed to maintain a valid surety bond.

Bryant L. VanBrakle,
Director, Bureau of Tariffs, Certification and Licensing.
[FR Doc. 94–16164 Filed 7–1–94; 8:45 am]
BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

NationsBank Corporation; Notice of Application to Engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The 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 on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing.

identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 25, 1994

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. NationsBank Corporation, Charlotte, North Carolina, to engage *de novo* through its subsidiary NationsBanc-CRT Services, Inc., Chicago, Illinois, and NationsBanc-CRT Energy (U.K. Ltd., London, England, in acting as a futures commission merchant for unaffiliated customers in executing and clearing (including clearing without executing) and providing investment advice on futures and options on financial instruments and non-financial commodities; and also providing securities brokerage services pursuant to § 225.25(b)((15), (b)(18), and (b)(19) of the Board's Regulation Y and *J.P. Morgan & Co., Inc.*, 80 Federal Reserve Bulletin 151 (1994).

Board of Governors of the Federal Reserve System, June 28, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16165 Filed 7–1–94; 8:45 am]

BILLING CODE 6210–01–F

Howard R. Ross, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 94-15270) published on page 32432 of the issue for Thursday, June 23, 1994.

Under the Federal Reserve Bank of Kansas City heading, the entry for Howard R. Ross is revised to read as follows:

1. Howard R. Ross, Chicago, Illinois; to acquire 23.05 percent; Steve Bangert, Denver, Colorado, to acquire 23.05 percent; Noel Rothman, Chicago, Illinois, to acqiure 11.53 percent; Elizabeth W. Parker Trust, created under the George S. Parker Trust; co-trustees & Elizabeth W. Parker, San Juan, Puerto Rico, and Robert Fiddes, Naples, Florida, to acquire 8.65 percent; Scott C. Wylie, Denver, Colorado, to acquire 5.76 percent; John Rose, Chicago, Illinois, to acquire 1.73 percent; Edward Ross, Chicago, Illinois, to acquire 8.65 percent; Howard Gilbert, Chicago, Illinois, to acquire 4.61 percent; Walter Schaub, Schaumburg, Illinois, to acquire 2.59 percent; John M. Eggemeyer, Chicago, Illinois, to acquire 2.31 percent; Mark Kipnis, Chicago, Illinois, to acquire 1.73 percent; Memorial Capital Corporation, Hato Rey, Puerto Rico, to acquire 1.44 percent; and American Investment Corporation, Hato Rey, Puerto Rico, to acquire 1.44 percent of the voting shares of Equitable Bankshares of Colorado, Inc., Denver, Colorado, and thereby indirectly acquire Women's Bank, N.A., Denver, Colorado, and Equitable Bank of Littleton, N.A., Littleton, Colorado.

Comments on this application must be received by July 13, 1994.

Board of Governors of the Federal Reserve System, June 28, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16166 Filed 7–1–94; 8:45 am]

BILLING CODE 6210–01–F

Wiley W. Smith; Change in Bank Control Notice

Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than July 25, 1994.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Wiley W. Smith, individually and as trustee, and Edward A. Carson, considered to be a group acting in concert, both of Sapulpa, Oklahoma, to acquire an additional 22.29 percent for a total of 27.16 percent of the voting shares of Security National Bank of Sapulpa, Sapulpa, Oklahoma.

Board of Governors of the Federal Reserve System, June 28, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16167 Filed 7–1–94; 8:45 am]

BILLING CODE 6210–01–F

SouthTrust Corporation, 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 July 29, 1994.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. SouthTrust Corporation, Birmingham, Alabama and SouthTrust of Florida, Inc., Jacksonville, Florida to acquire 100 percent of the voting shares of Island Bank of Collier County, Marco Island, Florida.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Western State Agency, Inc., Devils Lake, North Dakota, to merge with Towner Bancorporation, Ltd., Towner, North Dakota, and thereby indirectly acquire State Bank of Towner, Towner, North Dakota.

C. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Rockwell Bancorp, Inc., to become a bank holding company by acquiring 81 percent of the voting shares of Rockwell, Bank, N.A., Oklahoma City, Oklahoma.

Board of Governors of the Federal Reserve System, June 28, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16168 Filed 7–1–94; 8:45 am]

BILLING CODE 6210–01–F

Western State Agency, Inc.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The 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 on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 29, 1994.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Western State Agency, Inc., Devils Lake, North Dakota, to acquire McHenry Insurance, Inc., Towner, North Dakota, and thereby engage in general insurance activities in a town with a population of less than 5,000 people, pursuant to § 225.25(b)(8)(iii) of the Board's Regulation Y. The geographic area to be served is Towner, North Dakota.

Board of Governors of the Federal Reserve System, June 28, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16169 Filed 7–1–94; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL TRADE COMMISSION

Policy Statement Concerning Errors and Omissions Clauses in Consent Decrees

AGENCY: Federal Trade Commission.

ACTION: Statement of policy.

SUMMARY: The Commission has determined that it is unnecessary and inappropriate to include in any of its consent decrees any provision establishing as a defense to an action brought to enforce the consent decree that the defendant's errors and omissions were inadvertent and unintentional and that the causes and consequences of these errors and omissions were quickly remedied.

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: Joel N. Brewer, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580, (202) 326–2967.

SUPPLEMENTARY INFORMATION: In each of two previous Consent Decrees, *Damark International, Inc.*, Civ. No. 4–91–275 (D. Minn. 1991), and *Lillian Vernon Co.*, 92 Civ. 7537 (CLB) (S.D.N.Y. 1992), the Commission included a provision that provided a defense against an enforcement action if the defendant could establish that (1) any order violations arose from inadvertent and unintentional errors that may have occurred despite the defendant's good faith maintenance of records and procedures to prevent such errors, and (2) the defendant took prompt action to remedy any cause of, or injury resulting from, those errors. The Commission now has decided that such provisions are unnecessary in light of the Commission's inherent prosecutorial discretion.

The Commission initiates law enforcement actions under Section 5 of the FTC Act, 15 U.S.C. 45, only when it has reason to believe both that the law has been violated and that an action is in the public interest. In deciding whether an action is in the public interest, the Commission considers, among other things, the scope of the alleged violation, the circumstances in which it occurred and the extent of any resulting injury. Accordingly, the Commission believes that the inclusion of the language referred to above from the decisions and orders in *Damark* and *Lillian Vernon* is redundant to its public interest considerations and could cause confusion concerning the Commission's exercise of prosecutorial discretion within the terms of Section 5. Therefore, the Commission's policy will be to refuse to approve proposed consent decrees containing provisions designed to circumscribe liability for inadvertent and promptly remedied errors, or otherwise to delineate the Commission's discretion in initiating law enforcement proceedings.

Authority: 15 U.S.C. 41–58.

List of Subjects

Trade practices.

By direction of the Commission.

Donald S. Clark,

Secretary.

Dissenting statement of Commissioner Deborah K. Owen, regarding the Commission's policy statement concerning errors and omissions clauses in consent decrees.

I have voted against the proposed change in Commission policy, which would preclude a defense in consent decrees relating to inadvertent and unintentional errors by defendants. In my view, such language is harmless with respect to any legitimate Commission interest, and may serve to reassure parties as to the judicious exercise of our prosecutorial discretion.

[FR Doc. 94–16181 Filed 7–1–94; 8:45 am]

BILLING CODE 6750–01–M

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration

and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 061394 AND 062494

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Michaels Stores, Inc., Frontenac Company, An Illinois Partnership, Leewards Creative Crafts, Inc	94-1383	06/13/94
The 1818 Fund, L.P., Columbia/HCA Healthcare Corporation, Columbia/HCA Healthcare Corporation	94-1412	06/14/94
AGCO Corporation, Varity Corporation, Massey Ferguson Group Limited	94-1484	06/14/94
Ceridian Corporation, Tesseract Investors, L.P., Tesseract Corporation	94-1515	06/14/94
American Gas & Oil Investors, Enterra Corporation, Enterra Corporation	94-1372	06/15/94
AmGO II, Enterra Corporation, Enterra Corporation	94-1373	06/15/94
AmGO III, Enterra Corporation, Enterra Corporation	94-1374	06/15/94
First Reserve Secured Energy Assets Fund, L.P., Enterra Corporation, Enterra Corporation	94-1375	06/15/94
First Reserve Fund V, Limited Partnership, Enterra Corporation, Enterra Corporation	94-1376	06/15/94
First Reserve Fund V-2, Limited Partnership, Enterra Corporation, Enterra Corporation	94-1377	06/15/94
First Reserve Fund VI, Limited Partnership, Enterra Corporation, Enterra Corporation	94-1378	06/15/94
Enterra Corporation, Total Energy Services Company, Total Energy Services Company	94-1379	06/15/94
Specialty Paperboard, Inc., W.R. Grace & Co., W.R. Grace & Co.—Conn.'s Endura Products Division	94-1411	06/15/94
Apollo Real Estate Investment Fund, L.P., Aetna Life and Casualty Company, Kanawah Mall, Charleston, West Virginia	94-1434	06/15/94
The Mutual Life Assurance Company of Canada, Milwaukee Insurance Group, Inc., Milwaukee Life Insurance Company	94-1441	06/15/94
Helmerich & Payne, Inc., Energy Service Company, Inc., ENSCO Drilling Company	94-1455	06/15/94
GATX Corporation, Royal Dutch Petroleum Company (a Netherlands Corp.), Shell Oil Company	94-1457	06/15/94
General Electric Company, Quaker State Corporation, Heritage Insurance Group, Inc	94-1468	06/15/94
New York Life Insurance Company, Bruce A. Flashner, M.C., Flashner Medical Partnership	94-1494	06/15/94
Illinois Power Company, The Montana Power Company, North American Energy Services Company	94-1496	06/15/94
Johnson Controls, Inc., Chrysler Corporation, Ensamble de Interiores Automotrices, S.A. de C.V	94-1424	06/16/94
General Electric Company, Steel Dynamics, Inc., Steel Dynamics, Inc	94-1476	06/16/94
Tyler Capital Fund, L.P., Smith Corona Corporation, SCM Office Supplies, Inc	94-1497	06/16/94
Mr. John N. Ehrman, S.A. Louis Dreyfus et Cie, Louis Dreyfus Natural Gas Corp	94-1354	06/20/94
Bob Magness, TCI/Liberty Holding Company, TCI/Liberty Holding Company	94-1409	06/20/94
The May Department Stores Company, J.C. Penney Company, Inc., J.C. Penney Properties, Inc	94-1414	06/20/94
Dover Corporation, Equity Holding Limited, Hill Refrigeration, Inc	94-1415	06/20/94
Motorola, Inc., Harris Corporation, Harris Corporation	94-1432	06/20/94
TCI/Liberty Holding Company, Cablevision of Baton Rouge, Ltd., Cablevision of Baton Rouge, Ltd	94-1438	06/20/94
Golder, Thoma, Cressey Fund III Limited Partnership, New Polymer, New Polymer	94-1452	06/20/94
Jerry Zucker, New Polymer, New Polymer	94-1453	06/20/94
CSM nv, Henry & Henry, Inc., Henry & Henry, Inc	94-1466	06/20/94
The Lakeland Health Care Corporation, Congregation of the Sisters of the Humility of Mary, St. Joseph Hospital and Health Center	94-1491	06/20/94
MobileMedia Corporation, Local Area Telecommunications, Inc., Local Area Telecommunications, Inc	94-1500	06/20/94
The Allen T. Gilliland Trust dated August 4, 1982, MobileMedia Corporation, MobileMedia Corporation	94-1501	06/20/94
John C. Malone, TCI/Liberty Holding Company, TCI/Liberty Holding Company	94-1502	06/20/94
A. Jerrold Perenchio, Combined Broadcasting, Inc., Combined Broadcasting of Chicago, Inc	94-1508	06/20/94
Integrated Health Services, Inc., Chemical Banking Corporation, Cooper Holding Corporation	94-1519	06/20/94
Welsch, Carson, Anderson & Stowe VI, L.P., Housecall, Inc., Housecall, Inc	94-1522	06/20/94
TCW Special Credits Fund V—The Principal Fund, General Electric Company, Chief Auto Parts	94-1527	06/20/94
Pratt Family Holdings Trust, Mr. Carl Cheek, Georgia Box, Inc	94-1529	06/20/94
Whitehall Street Real Estate Limited Partnership III, The Prudential Insurance Company of America, The Prudential Insurance Company of America	94-1535	06/20/94
Banta Corporation, United Graphics Inc., United Graphics Inc	94-1541	06/20/94
The Promus Companies Incorporated, Pittsburgh History & Landmarks Foundation, The Landmarks Development Corporation	94-1545	06/20/94
Time Warner Inc., NVC International Inc., NVC International Inc	94-1547	06/20/94
Lagardere Groupe S.C.A., The Walt Disney Company, Disney Direct Response Publishing, Inc	94-1548	06/20/94
BellSouth Corporation, BellSouth Corporation, RAM/BSE, L.P	94-1550	06/20/94
PennCorp Financial Group, Inc., American General Corporation, Pioneer Security Life Insurance Company et al	94-1551	06/20/94
Health Management Associates, Inc., Adventist Health System/Sunbelt Health Care Corporation, Newco	94-1430	06/21/94
CMS Energy Corporation, Sun Company, Inc., Sun Colombia Oil Company	94-1431	06/21/94
The Standard Register Company, Settsu Corporation, Uarco, Inc	94-1443	06/21/94
Harcourt General, Inc., The Times Mirror Company, the Brown-ROA division of Wm. C. Brown Communications	94-1499	06/21/94
Pioneer Telephone Cooperative, Inc., GTE Corporation, GTE Southwest Incorporated	94-1503	06/21/94
Anderson News Corporation, Wal-Mart Stores, Inc., Western Merchandisers, Inc	94-1504	06/21/94
Atlas Corporation, M.I.M. Holdings Limited (an Australian company), Granges Inc	94-1521	06/21/94
American National Insurance Company, Temple-Inland Inc., Guaranty Federal Bank, F.S.B	94-1532	06/21/94
The Mayer Electric Supply Company, Inc., Donald F. McMullan, Mack Electric Supply Co., Inc	94-1553	06/21/94
Ronald W. Burkle, Fiducie M.H.G. (a Canadian Trust), Smitty's Super Valu, Inc	94-1554	06/21/94

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 061394 AND 062494—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Daughters of Charity National Health System, Inc., Sisters of St. Joseph of Tipton, Indiana, St. Joseph Hospital & Health Center of Kokomo, IN, Inc	94-1423	06/22/94
Enron Corporation, Bridge Oil Limited, Bridge Oil Limited	94-1610	06/22/94
Kelso Investment Associates IV, L.P., F. DeWight Titus, F.D. Titus and Son Inc	94-1530	06/23/94
Swift Energy Company, Parker & Parsley Petroleum Company, P&P Producing, Inc	94-1538	06/23/94
United States Filter Corporation, Warburg, Pincus Capital Company, L.P., Liquipure Technologies, Inc	94-1384	06/24/94
United States Filter Corporation, John S. Swartley, Liquipure Technologies, Inc	94-1385	06/24/94
Warburg, Pincus Capital Company, L.P., United States Filter Corporation, United States Filter Corporation	94-1387	06/24/94
Thomas H. Lee Equity Partners, L.P., Mid-State Plastics, Inc., Mid-State Plastics, Inc	94-1469	06/24/94
Atlantic Equity Partners, L.P., MagneTek, Inc., MagneTek Controls, Inc	94-1473	06/24/94
Main Street Partners, L.P., CommNet Cellular, Inc., CommNet Cellular, Inc	94-1475	06/24/94
Gerhard R. Andlinger, Robert R. Dyson, Cissell Manufacturing Company	94-1516	06/24/94
Cardinal Health, Inc., Behrens Inc., Behrens Inc	94-1525	06/24/94
The Vigoro Corporation, Peter Lederer, Koos, Inc. and Lederer of Florida, Inc	94-1536	06/24/94
AT&T Corp., CP Institutional Partners I, Inc., CP Institutional Partners I, Inc	94-1540	06/24/94
Mariner Health Group, Inc., M&F Legend Holdings, L.P., Legend/Byrnebrook Corporation	94-1542	06/24/94
General Electric Company, Cavco Industries, Inc., C.V.C. Leasing Division	94-1544	06/24/94
I.C.H. Corporation, Robert T. Shaw, Consolidated Fidelity Life Insurance Company	94-1557	06/24/94
N.V. Verenigd Bezit VNU, Citicorp, I/B/E/S	94-1568	06/24/94
Pfizer Inc., Neurogen Corporation, Neurogen Corporation	94-1569	06/24/94
Charter Medical Corporation, National Medical Enterprises, Inc., NME Psychiatric Properties, Inc	94-1577	06/24/94
Canadian Pacific Limited, Doubletree Corporation, Joint Venture, Doubletree Corporation, Joint Venture	94-1594	06/24/94
General Electric Company, Doubletree Corporation, Joint Venture, Doubletree Corporation, Joint Venture	94-1608	06/24/94
Kidd, Kamm Equity Partners, L.P., Luigi Massironi, Houbigant, Inc	94-1613	06/24/94

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Renee A. Horton, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, room 303, Washington, DC 20580, (202) 326-3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 94-16182 Filed 7-1-94; 8:45 am]

BILLING CODE 6750-01-M

[Dkt. C-3497]

Arizona Automobile Dealers Association; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, an Arizona association consisting of approximately 199 dealers from restricting, regulating, or interfering with truthful, non-deceptive comparative or price advertising or advertising concerning financing by its members in the future. In addition, the order requires the respondent to remove from its "Standards for Advertising Motor Vehicles" any provision, policy statement or guideline that is inconsistent with the terms of the settlement, to distribute copies to each member, and to publish the revised standards in the AADA member magazine.

DATES: Complaint and Order issued May 31, 1994.[1]

FOR FURTHER INFORMATION CONTACT: Ralph Stone, FTC/San Francisco Regional Office, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 744-7920.

SUPPLEMENTARY INFORMATION: On Monday, March 21, 1994, there was published in the **Federal Register**, 59 FR 13325, a proposed consent agreement with analysis In the Matter of Arizona Automobile Dealers Association, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H-130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 94-16177 Filed 7-1-94; 8:45 am]

BILLING CODE 6750-01-M

[Dkt. C-3495]

Orkin Exterminating Company, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a Georgia pesticides corporation from advertising or representing that its pesticides used in its lawn care service programs are as safe as some common household products or that they pose no significant risk to human health or the environment, without possessing competent and reliable scientific evidence to substantiate the claims.

DATES: Complaint and Order issued May 25, 1994.[1]

FOR FURTHER INFORMATION CONTACT: Michael Dershowitz, FTC/S-4002, Washington, DC 20580. (202) 326-3158.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H-130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On Wednesday, April 14, 1993, there was published in the **Federal Register,** 58 FR 19444, a proposed consent agreement with analysis In the Matter of Orkin Exterminating Company, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

A comment was filed and considered by the Commission. The Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 94–16178 Filed 7–1–94; 8:45 am]

BILLING CODE 6750–01–M

[Dkt. C–3496]

Samick Music Corporation; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a California subsidiary of a Korean piano manufacturer from misrepresenting the composition of any of its piano soundboards or any other piano parts in the future, and requires the respondent to pay, to the U.S. Treasury, $266,000 in disgorgement.

DATES: Complaint and Order issued May 27, 1994.[1]

FOR FURTHER INFORMATION CONTACT: Darren Bowie, FTC/H–200, Washington, DC 20580. (202) 326–2018.

SUPPLEMENTARY INFORMATION: On Monday, March 21, 1994, there was published in the **Federal Register,** 59 FR 13332, a proposed consent agreement with analysis In the Matter of Samick Music Corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 94–16179 Filed 7–1–94; 8:45 am]

BILLING CODE 6750–01–M

[Docket 9190]

Ticor Title Insurance Company, et al.; Prohibited Trade Practices and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Modifying order.

SUMMARY: This order modifies the Commission's Final Order, issued in 1989, by deleting references to the states of New Jersey and Pennsylvania. Therefore, in accordance with the decision and judgment of the court of appeal, the order, as modified by the Commission, prohibits the companies from discussing, proposing, setting or filing any rates for title search and examination services through a rating bureau in the states of Connecticut, Wisconsin, Arizona, and Montana.

DATES: Final Order issued September 19, 1989. Modifying Order issued April 22, 1994.[1]

FOR FURTHER INFORMATION CONTACT: David Von Nirschl, FTC/S–2115, Washington, DC 20580. (202) 326–3213.

SUPPLEMENTARY INFORMATION: In the Matter of Ticor Title Insurance Company, et al. The prohibited trade practices and/or corrective actions as set forth at 55 FR 363, are changed, in part, as indicated in the summary.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 94–16180 Filed 7–1–94; 8:45 am]

BILLING CODE 6750–01–M

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[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

[1] Copies of the Modifying Order are available from the Commission's Public Reference Branch, H–130, 6th & PA. Ave., NW., Washington, DC 20580.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register.**

The Secretary of the Treasury has certified a rate of 13% for the quarter ended June 30, 1994. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: June 22, 1994.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 94–16184 Filed 7–1–94; 8:45 am]

BILLING CODE 4150–04–M

Centers for Disease Control and Prevention

Prevention Centers Grant Review Committee: Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

NAME: Prevention Centers Grant Review Committee.

Time and Dates: 8 a.m.-5 p.m., July 21–22, 1994.

Place: Hotel Nikko Atlanta, 3300 Peachtree Road, NE, Atlanta, Georgia 30305.

Status: Open 8 a.m.–8:45 a.m., July 21, 1994; Closed 9 a.m., July 21, through 5 p.m., July 22, 1994.

Purpose: This committee is charged with advising the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the scientific merit of grant applications relating to the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention.

Matters to be Discussed: Agenda items for the meeting will include announcements, discussion of review procedures, future meeting dates, and review of cooperative agreement applications. Beginning at 9 am., July 21, through 5 p.m., July 22, the committee will conduct its review of cooperative agreement applications. This portion of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S. Code, and the Determination of the Acting Associate Director for Policy Coordination, CDC, pursuant to Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for more information: Diane H. Jones, Ph.D., Project Officer, Office of Surveillance and Analysis, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, NE, Mailstop K–30, Atlanta, Georgia 30341–3724, telephone 404/488–5395.

Dated: June 28, 1994.

William H. Gimson,

Acting Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 94–16156 Filed 7–1–94; 8:45 am]

BILLING CODE 4163–18–D–M

National Institutes of Health

Division of Research Grants; Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting:

Name of SEP: Behavioral and Neurosciences.

Date: July 6, 1994.

Time: 2:00 p.m.

Place: NIH, Westwood Bldg., Room 306B (Telephone Conference).

Contact Person: Ms. Carol Campbell, Scientific Review Administrator, 5333 Westbard Ave., Room 306B, Bethesda, MD 20892, (301) 594–7165.

Purpose/Agenda: To review individual grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the difficulty of coordinating the attendance of members because of conflicting schedules.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 28, 1994

Susan K. Feldman,

Committee Management Officer, NIH

[FR Doc. 94–16253 Filed 7–1–94; 8:45 am]

BILLING CODE 4140–01–M

Social Security Administration

Rescission of Social Security Acquiescence Ruling 86–1(9)—Summy v. Schweiker, 688 F.2d 1233 (9th Cir. 1982)

AGENCY: Social Security Administration, HHS.

ACTION: Rescission of Social Security Acquiescence Ruling.

SUMMARY: In accordance with 20 CFR 416.1485(e) and 422.406(b)(2), the Commissioner of Social Security gives notice of the rescission of Social Security Acquiescence Ruling 86–1(9).

EFFECTIVE DATE: July 5, 1994.

FOR FURTHER INFORMATION CONTACT: Darlynda Bogle, Litigation Staff, Social Security Administration, 6401 Security Blvd., Baltimore, MD 21235, (410) 965–4237.

SUPPLEMENTARY INFORMATION: A Social Security Acquiescence Ruling explains how we will apply a holding in a decision of a United States Court of Appeals that we determine conflicts with our interpretation of a provision of the Social Security Act or regulations when the Government has decided not to seek further review of the case or is unsuccessful on further review.

As provided by 20 CFR 416.1485(e)(4), a Social Security Acquiescence Ruling may be rescinded as obsolete if we subsequently clarify, modify or revoke the regulation or ruling that was the subject of the circuit court holding for which the Acquiescence Ruling was issued.

On January 23, 1986, we issued Acquiescence Ruling 86–1(9) to reflect the holding in *Summy* v. *Schweiker*, 688 F.2d 1233 (9th Cir. 1982), that an additional pension or compensation payment from the Veterans Administration (now the Department of Veterans Affairs) as a result of unreimbursed medical expenses is not income for Supplemental Security Income purposes.

Concurrent with the rescission of this ruling, we are adding a new paragraph (a)(7) to section 416.1103 of Social Security Regulations No. 16 (20 CFR 416.1103), which provides that payments from the Department of Veterans Affairs resulting from unusual medical expenses are not income for Supplemental Security Income purposes. Because the change in the regulations adopts the court's holding *Summy* on a nationwide basis, we are rescinding the current Acquiescence Ruling.

(Catalog of Federal Domestic Assistance Programs Nos. 93.802 Social Security-Disability Insurance; 93.803 Social Security-Retirement Insurance; 93.805 Social Security-Survivors Insurance; 93.806—Special Benefits for Disabled Coal Miners; 93.807—Supplemental Security Income.)

Dated: May 25, 1994.

Shirley S. Chater,

Commissioner of Social Security.

[FR Doc. 94–16049 Filed 7–1–94; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF THE INTERIOR

National Park Service

Creve Coeur Lake Memorial Park Draft Supplemental Environmental Impact Statement

AGENCY: National Park Service, Interior.

ACTION: Availability of draft supplemental environmental impact statement for determination of section 6(f) replacement lands for Creve Coeur Lake Memorial Park, St. Louis County, Missouri.

SUMMARY: The National Park Service, in compliance with section 102(2)(c) of the National Environmental Policy Act of 1069 (NEPA) [42 United States Code (U.S.C.) 4321 et seq. and 42 U.S.C. 4332, as amended] and with section 6(f) of the Land and Water Conservation Fund (LWCF) Act (Public Law 88–578, as amended), announces the availability of a draft supplemental environmental impact statement (DSEIS) evaluating additional replacement land for the 184 acres of Creve Coeur Lake Memorial Park converted from outdoor recreation use. Creve Coeur Lake Memorial Park is a county park which has received Federal financial assistance from the LWCF program. This DSEIS will supplement the final environmental impact statement (FEIS) for Page Avenue (Route D) extension, St. Louis and St. Charles Counties, Missouri, approved in a Record of Decision on January 6, 1993, by the Federal Highway Administration (FHWA).

The FHWA FEIS addressed construction of a ten-land elevated extension of Page Avenue across the southern tip of the park site assuming all necessary coordination with other Federal agencies has been satisfactorily accomplished. The National Park Service on December 11, 1992, adopted

the FEIS for use in the environmental evaluation requirements of section 6(f) of the LWCF Act.

The initial proposal of 265 acres, submitted by the State of Missouri to replace the converted 184 acres was determined by the National Park Service as not offering "reasonably equivalent usefulness" to the extent necessary to reflect appropriately the loss of this unique natural area. Secretary Babbitt announced on May 18, 1993, in letters to Senators Danforth and Bond, that he did not intend to use his authority under section 6(f)(3) to block the construction of this highway project. He further stated that ". . . it is necessary to identify a significant amount of additional lands to be included in the mitigation package."

The DSEIS identifies a range of alternative land proposals, including additional substitution properties, and analyzes the "equivalent usefulness" of each candidate replacement land parcel. In addition, each of the replacement parcels have been evaluated for impacts on natural and cultural resources, the socioeconomic environment, and current uses.

The State of Missouri's and the NPS's preferred alternative for additional replacement land is identified in the DSEIS as Alternative B (Little Creve Coeur Lake Proposal). The alternative, consisting of approximately 440 acres and located southwest of the present Creve Coeur Lake Memorial Park, consists primarily of wetlands presently in agricultural use.

Copies of the DSEIS may be obtained from the responsible official, Mr. William Schenk, Acting Regional Director (refer to address below). Comments on the DSEIS should be received no later than August 8, 1994.

ADDRESSES: Comments on the DSEIS should be submitted to: Mr. William W. Schenk, Acting Regional Director National Park Service, Midwest Region, 1709 Jackson Street, Omaha, Nebraska 68102, (402) 221–3432.

Public reading copies of the DSEIS will be available for review at: Office of Public Affairs, Department of the Interior, National Park Service, 18th and C Streets, N.W., Washington, D.C. 20240, (202) 343–6843.

PUBLIC MEETING: A public meeting, at a date to be announced later, will be held in the St. Louis area during this 45-day review period to solicit public comments on the DSEIS.

FOR FURTHER INFORMATION CONTACT: Mr. Clay McDermeit, Chief, Western Heartland Division, Recreation Assistance Programs, National Park Service, Midwest Region, 1709 Jackson Street, Omaha, Nebraska 68102, (402) 221–3203.

Dated: June 16, 1994.

William W. Schenk,

Acting Regional Director, Midwest Region.

[FR Doc. 94–16162 Filed 7–1–94; 8:45 am]

BILLING CODE 4310–70–P

Federal Subsistence Sheep Season; Baird Mountains, Alaska; Public Hearing

AGENCY: National Park Service, Interior.

ACTION: Public hearing regarding the federal subsistence sheep season in a portion of Unit 23 in the Baird Mountains, Alaska.

SUMMARY: A public hearing is scheduled regarding the federal subsistence sheep season in the Baird Mountain portion of Unit 23. Dependent upon the status of the sheep population, the Federal Subsistence Board may have to exercise its closure authority to conserve healthy and natural populations of sheep in the area. If such a closure becomes necessary, this public meeting will have fulfilled the requirements of 50 CFR 100.19. The purpose of the meeting will be to inform the public of the status of the sheep population and of potential proposals to the Federal Subsistence Board for action. Public comment will be accepted.

BACKGROUND: Aerial surveys conducted in the Baird Mountains (that area of Unit 23 south and east of the Noatak River) show a dramatic decline in the sheep population since 1989. In an effort to protect this population and facilitate its recovery, this area has been closed to all hunting of sheep since 1991, through closure actions of the Federal Subsistence Board. Survey results from July 1992 indicate the sharp decline has at least temporarily stopped; however, the population has not significantly grown. A sheep survey by the Alaska Department of Fish and Game and the National Park Service is scheduled for mid-July 1994. These survey results are expected to be available for discussion at the July 21 meeting. Should the survey and past biological data indicate a continuing threat to the conservation of a health population of sheep in the Baird Mountains of Unit 23, a proposal will be advanced to the Federal Subsistence Board to once again close federal public lands to sport hunting, under Alaska regulations, and, perhaps, to the subsistence seasons currently scheduled for August 10–September 20, 1994, and October 1–April 30, 1995. The Federal Subsistence Board will make a final determination on any such proposed closure, if advanced.

The National Park Service is hosting this meeting as the principal federal land manager in the Baird Mountains area. The federal lands in the Baird Mountain area are within the Noatak National Preserve, Kobuk Valley National Park, and Kobuk District, Bureau of Land Management.

DATE/LOCATION: The meeting will be held July 21, 1994, at 7:00 p.m. in the Public Lands Information Center, Kotzebue, Alaska.

FOR FURTHER INFORMATION CONTACT: Bob Gerhard, Superintendent, Northwest Alaska Areas, P.O. Box 1029 Kotzebue, Alaska 99752, telephone: (907) 442–3890.

David B. Ames,

Acting Regional Director.

[FR Doc. 94–16163 Filed 7–1–94; 8:45 am]

BILLING CODE 4310–70–M

Mtgs: Gettysburg National Park Service

Gettysburg National Military Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the date of the eleventh meeting of the Gettysburg National Military Park Advisory Commission.

Meeting Date and Time: July 21, 1994; 2 p.m. until 5 p.m.

Address: Holiday Inn, 516 Baltimore Street, Gettysburg, Pennsylvania 17325.

The Agenda for the meeting will focus on Sub-Committee Reports, briefing on traffic surveys—Federal Highway Program, report on status of Environmental Impact Statement—deer management, briefing on Gettysburg College land exchange status, and an operational update on park activities.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning agenda items. The statement should be addressed to the Advisory Commission, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325. Minutes of the meeting will be available for inspection four weeks after the meeting at the permanent headquarters of the Gettysburg National Military Park located at 95 Taneytown Road, Gettysburg, Pennsylvania 17325.

FOR FURTHER INFORMATION CONTACT: Jose A. Cisneros, Superintendent,

Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325–1080, (717) 334–1124.

Dated: June 20, 1994.

Karen Wade,

Acting Regional Director, Mid-Atlantic Region.

[FR Doc. 92–16161 Filed 7–1–94; 8:45 am]

BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 22–55]

Peanut Butter and Peanut Paste

AGENCY: United States International Trade Commission.

ACTION: Indefinite suspension of investigation and cancellation of public hearing.

SUMMARY: The Commission has indefinitely suspended this investigation pursuant to a request for such action by the President dated and received June 28, 1994 and has cancelled the hearing in this investigation scheduled for June 30, 1994.

EFFECTIVE DATE: June 28, 1994.

FOR FURTHER INFORMATION CONTACT: Jim McClure (202–205–3191), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION: The subject investigation was instituted by the Commission on January 18, 1994. Notice of the investigation and the schedule for its conduct was published in the **Federal Register** of January 26, 1994 (59 FR 3734). Notice of the rescheduling of the public hearing to June 30 was published in the **Federal Register** of May 16, 1994 (59 FR 25503).

For further information concerning the conduct of this investigation and rules of general application see the Commission's notice of investigation cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 204, (19 CFR part 204).

This notice is published pursuant to section 204 of the Commission's rules (19 CFR 204.4).

Issued: June 29, 1994.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 94–16183 Filed 7–1–94; 8:45 am]

BILLING CODE 7020–02–P

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32527]

CSX Transportation, Inc.—Trackage Rights Exemption—Wheeling & Lake Erie Railway Company

Wheeling & Lake Erie Railway Company (W&LE) has agreed to grant to CSX Transportation, Inc. (CSXT), overhead trackage rights over approximately 101 miles of rail line, between W&LE's milepost 73.6, at Harmon, near Brewster, OH, and W&LE's milepost A–101.5, at Greenwich, OH, where CSXT's and W&LE's lines connect. The trackage rights will, in effect, substitute for trackage rights CSXT held over another W&LE line, between Brewster and Creston, OH. CSXT's discontinuance of its trackage rights and W&LE's abandonment of that line were the subject of a notice of exemption in *CSX Transportation, Inc.—Discontinuance of Trackage Rights Exemption—In Stark and Wayne Counties, OH*, Docket No. AB–55 (Sub–No. 445) (ICC served Sept. 22, 1992), and a petition for exemption in *The Wheeling & Lake Erie Railway Company—Abandonment Exemption—In Stark, Wayne, and Medina Counties, OH*, Docket No. AB–227 (Sub–No. 2X) (ICC served Oct. 1, 1992), respectively. The trackage rights were to become effective on June 23, 1994.

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Charles M. Rosenberger, CSX Transportation, Inc., 500 Water Street J150, Jacksonville, FL 32202.

As a condition to the use of this exemption, any employees affected by the trackage rights will be protected under *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: June 24, 1994.

By the Commission, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 94–16228 Filed 7–1–94; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Nagel Motors, Inc., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been lodged with the United States District Court for the District of Wyoming in *United States of America v. Nagel Motors, Inc., et al.*, Civil Action No. 94CV146–J. The Complaint in this case alleges that the three defendant corporations and co-conspirators agreed to participate in discussions and information exchanges to facilitate an increase in the rates charged for automobile body repair services in the Casper, Wyoming area in violation of Section 1 of the Sherman Act, 15 U.S.C. 1. The proposed Final Judgment enjoins the defendants from agreeing with any other automobile body repair shop to fix an hourly rate or part price or discount. It also enjoins the defendants from participating in any discussion with or communicating with any other automobile repair shop concerning adherence to or changes to, or the need or desirability of adhering to or changing, any hourly rate or part price or discount. The proposed Final Judgment further enjoins the defendants from disseminating any information to any automobile body repair shop concerning any planned or contemplated change in an hourly rate or part price or discount. Each defendant is required to establish an antitrust compliance program.

Public comment on the proposed Final Judgment is invited within the statutory 60-day comment period. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Gary R. Spratling, Chief, San Francisco Office, Box 36046, Antitrust Division, U.S. Department of

Justice, San Francisco, California 94102 (telephone: (415) 556–6300).

Constance K. Robinson,

Director of Operations, Antitrust Division.

In the United States District Court, District of Wyoming

United States of America, Plaintiff, vs. *Nagel Motors, Inc., Greiner Motor Company, Inc., and Benson Chevrolet, Inc.*, Defendants. Civil No. 94–CV–146–J.

Complaint

The United States of America, plaintiff, by its attorneys, acting under the direction of the Attorney General of the United States, brings this civil action to obtain equitable relief against the defendants named herein, and complains and alleges as follows:

I. Jurisdiction and Venue

1. This Complaint is filed under Section 4 of the Sherman Act, 15 U.S.C. 4, as amended, in order to prevent and restrain the continuing violations by the defendants of Section 1 of the Sherman Act, 15 U.S.C. 1.

2. Each of the defendants maintains an office, transacts business, and is found within the District of Wyoming, within the meaning of 15 U.S.C. 22 and 28 U.S.C. 1391(c).

II. Defendants

3. Nagel Motors, Inc. ("Nagel") is made a defendant herein. Nagel operates a General Motors Corporation dealership with its principal place of business in Casper, Wyoming. Nagel sells both new and used automobiles and offers a full range of automobile repair services, including automobile body repair services. Nagel is engaged in interstate commerce and in activities substantially affecting interstate commerce.

4. Greiner Motor Company, Inc., d/b/a Greiner Motor & Marine ("Greiner"), is made a defendant herein. Greiner operates a Ford Motor Company dealership with its principal place of business in Casper, Wyoming. Greiner sells both new and used automobiles and offers a full range of automobile repair services, including automobile body repair services. Greiner is engaged in interstate commerce and in activities substantially affecting interstate commerce.

5. Benson Chevrolet, Inc. ("Benson") is made a defendant herein. Benson operates a General Motors Corporation dealership with its principal place of business in Casper, Wyoming. Benson sells both new and used automobiles and offers a full range of automobile repair services, including automobile body repair services. Benson is engaged in interstate commerce and in activities substantially affecting interstate commerce.

6. Whenever this Complaint refers to any corporation's act, deed, or transaction, it means that such corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or other representatives while they actively were engaged in the management, direction, control, or transaction of its business or affairs.

III. Co-Conspirators

7. Various firms and individuals, not named as defendants in this Complaint, have participated as co-conspirators with defendants in the violations alleged in this Complaint, and have performed acts and made statements in furtherance thereof.

IV. Trade and Commerce

8. During the period covered by this Complaint, each of the defendants has engaged in the business of providing automobile repair services, including automobile body repair services, in Casper, Wyoming.

9. Between January 1, 1991 and June 30, 1993 the defendants' total revenue from automobile body repair services was approximately $3,250,000.

10. During the period covered by this Complaint, the activities of each of the defendants that are the subject of this Complaint, and the activities of their co-conspirators, have been within the flow of, and have substantially affected, interstate trade and commerce.

11. Each of the defendants and their co-conspirators perform automobile body repair services for out-of-state customers as well as Wyoming customers.

12. Each of the defendants and their co-conspirators purchase substantial quantities of parts, paints and materials for use in automobile body repair from various sources located outside the State of Wyoming.

13. Each of the defendants and their co-conspirators do business with insurance carriers with headquarters located outside the State of Wyoming and receive payments from such insurance carriers which are issued from offices located outside the State of Wyoming.

V. Violation Alleged

14. During the period beginning at least as early as December 1990 and continuing through at least July 1993, the defendants and their co-conspirators engaged in a combination and conspiracy in unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. 1. This offense is likely to recur unless the relief hereinafter sought is granted.

15. This combination and conspiracy consisted of a continuing agreement, understanding, and concert of action among the defendants and co-conspirators to participate in discussions and information exchanges to facilitate an increase in the rates charged for automobile body repair services in the Casper, Wyoming area.

16. For the purpose of forming and effectuating this combination and conspiracy, the defendants and their co-conspirators did the following things, among others:

(a) discussed insurance company requirements that an automobile body repair rate increase would not be accepted unless a requisite number of area automobile body repair shops had adopted such a rate increase;

(b) disseminated information relating to possible changes in automobile body repair rates; and

(c) discussed plans of various area automobile body repair shops concerning possible rate increases.

17. This combination and conspiracy had the following effects, among others:

(a) coordinated interaction among the defendants and co-conspirators was made more successful and more complete;

(b) price competition among the defendants and their co-conspirators for providing automobile body repair services in the Casper, Wyoming area has been unreasonably restrained and eliminated; and

(c) consumers have been deprived of the benefits of free and open competition in the purchase of automobile body repair services.

VI. Prayer

WHEREFORE, the plaintiff prays:

1. That the Court adjudge and decree that the defendants and their co-conspirators engaged in unlawful agreements, combinations and conspiracies in unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

2. That each defendant, its officers, directors, agents, employees, and successors and all other persons acting or claiming to act on its behalf be enjoined, restrained ad prohibited for a period of ten years from:

(a) agreeing with any other automobile body repair shop to fix, establish, raise, stabilize or maintain any hourly rate or part price of discount;

(b) participating in any discussion with or communicating with any other

automobile body repair shop concerning adherence to or changes to, or the need or desirability of adhering to or changing, any hourly rate or part price or discount; and

(c) disseminating any information to any automobile body repair shop concerning any planned or contemplated change in an hourly rate or part price or discount.

3. That each defendant shall establish and maintain an antitrust compliance program.

4. That for ten years after the entry of the Final Judgment, on or before its anniversary date, each defendant shall file with plaintiff an annual Declaration reporting that such defendant has complied with the terms of the Final Judgment and has engaged in no activities of the type prohibited by the Final Judgment.

5. That plaintiff have such other relief as the nature of the case may require and the Court may deem just and proper.

6. That plaintiff recover the costs of this suit.

Dated: June 2, 1994.

Anne K. Bingaman,

Assistant Attorney General.

Robert E. Litan,

Deputy Assistant Attorney General.

March C. Schechter,

Gary R. Spratling,

Attorneys, U.S. Department of Justice.

David D. Freudenthal,

United States Attorney, District of Wyoming.

Richard B. Cohen,

Carla G. Addicks,

Attorneys, U.S. Department of Justice, Antitrust Division, Box 36046, 450 Golden Gate Avenue, San Francisco, CA 94102, (415) 556–6300.

In The United States District Court, District of Wyoming

United States of America, Plaintiff, vs. *Nigel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc.*, Defendants. Civil No. 94–CV–146.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties thereto, and venue of this action is proper in the District of Wyoming;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. 16), and without further notice to any party or other proceedings, provided that Plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on Defendants and by filing that notice with the Court;

3. In the event Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever and the making of this Stipulation shall be without prejudice to any party in this or any other proceeding.

Dated: June 2, 1994.

For Plaintiff United States of America.

Anne K. Bingaman,

Assistant Attorney General.

Robert E. Litan,

Deputy Assistant Attorney General.

Mark C. Schechter,

Gary R. Spratling,

Attorneys, U.S. Department of Justice.

David D. Freudenthal,

United States Attorney, District of Wyoming.

Richard B. Cohen,

Carla G. Addicks,

Attorneys, U.S. Department of Justice, Antitrust Division, Box 36046, 450 Golden Gate Avenue, San Francisco, California 94102, (415) 556–6300.

For Defendant Nagel Motors, Inc.: Stoel, Rives, Boley, Jones & Grey.

By:

J. Ronald Sim,

One Union Square, 36th Floor, 600 University Street, Seattle, Washington 98101, (206) 386–7592.

For Defendant Greiner Motor Company, Inc.: Brown and Drew.

By:

W. Thomas Sullins II,

123 West 1st Street, Suite 800, Casper, Wyoming 82601, (307) 234–1000.

For Defendant Benson Chevrolet, Inc: By: Keith P. Tyler, Esq., P.O. Box 2671, Casper, Wyoming 82602, (307) 266–0129.

In The United States District Court, District of Wyoming

United States of America, Plaintiff, vs. *Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc.*, Defendants. Civil No. 94–CV–146.

Final Judgment

Plaintiff, United States of America, filed its Complaint on June 2, 1994. Plaintiff and defendants, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law. This Final Judgment shall not be evidence against or an admission by any party with respect to any issue of fact or law. Therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon consent of the parties, it is hereby

Ordered, Adjudged, and Decreed, as follows:

I. Jurisdiction

This Court has jurisdiction of the subject matter of this action and of each of the parties consenting hereto. The Complaint states a claim upon which relief may be granted against the defendants under Section 1 of the Sherman Act, 15 U.S.C. 1.

II. Definitions

As used herein, the term:

(A) "Automobile body repair services" means work performed by automobile body repair shops applying new or used parts and labor to the damaged bodies and frames of automobiles and trucks for the purpose of repairing them;

(B) "Automobile body repair shop" means any person engaged in the performance and sale of automobile body repair services;

(C) "Hourly rate" means the dollar charge per hour in connection with time spent on automobile body repair services; and

(D) "Person" means any individual, partnership, corporation, association, firm, or any other business or legal entity.

III. Applicability

(A) This Final Judgment applies to the defendants and to each of their successors, assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of the Final Judgment by personal service or otherwise.

(B) Nothing herein contained shall suggest that any portion of this Final Judgment is or has been created for the benefit of any third party and nothing herein shall be construed to provide any rights to any third party.

IV. Prohibited Conduct

Each of the defendants is enjoined and restrained from:

(A) Agreeing with any other automobile body repair shop to fix, establish, raise, stabilize or maintain any hourly rate or part price or discount;

(B) Participating in any discussion with or communicating with any other automobile body repair shop concerning adherence to or changes to, or the need or desirability of adhering to or changing, any hourly rate or part price or discount; and

(C) Disseminating any information to any automobile body repair shop concerning any planned or contemplated change in an hourly rate or part price or discount.

V. Compliance Program

(A) Each defendant is ordered to establish and maintain an antitrust compliance program which shall include designating, within 30 days of entry of this Final Judgment, an Antitrust Compliance Officer with responsibility for accomplishing the antitrust compliance program and achieving compliance with this Final Judgment. The Antitrust Compliance Officer shall, on a continuing basis, supervise the review of the current and proposed activities of his or her defendant company to ensure that the company complies with this Final Judgment. The Antitrust Compliance Officer shall be responsible for accomplishing the following requirements:

(1) Distributing, within 60 days of the entry of this Final Judgment, a copy of this Final Judgment to all officers and to employees who have any responsibility for approving, disapproving, monitoring, recommending, or implementing any hourly rate or part price or discount;

(2) Distributing in a timely manner a copy of this Final Judgment to any officer or employee who succeeds to a position described in Section V(A)(1);

(3) Briefing annually those persons designated in Section V(A)(1) on the meaning and requirements of this Final Judgment and the antitrust laws and advising them that the defendant's legal advisors are available to confer with them regarding compliance with the Final Judgment and the antitrust laws;

(4) Obtaining from each officer or employee designated in section V(A)(1) an annual written certification that he or she: (a) Has read, understands, and agrees to abide by the terms of this Final Judgment; (b) has been advised and understands that his or her failure to comply with this Final Judgment may result in conviction for criminal contempt of court; and (c) is not aware of any violation of the Final Judgment that has not been reported to the Antitrust Compliance Officer;

(5) Maintaining a record of persons to whom the Final Judgment has been distributed and from whom the certification in section V(A)(4) has been obtained; and

(6) Reporting to the Department of Justice any violation of the Final Judgment.

(B) Each defendant is ordered to distribute, within 60 days of entry of this Final Judgment, a copy of this Final Judgment to an owner or manager of each automobile body repair shop located within 50 miles of Casper, Wyoming, which is presently in business and which has purchased parts or automobile body repair services from the defendant in the last five years.

VI. Certification

(A) Within 75 days of the entry of this Final Judgment, each defendant shall certify to the plaintiff whether it has designated an Antitrust Compliance Officer and has distributed the Final Judgment in accordance with section V (A)(1) and (B) above.

(B) For ten years after the entry of this Final Judgment, on or before its anniversary date, each defendant shall file with the plaintiff an annual Declaration as to the fact and manner of its compliance with the provisions of sections IV and V(A).

VII. Plaintiff Access

(A) To determine or secure compliance with this Final Judgment and for no other purpose, duly authorized representatives of the plaintiff shall, upon written request of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to any defendant made to its principal office, be permitted, subject to any legally recognized privilege:

(1) Access during such defendant's office hours to inspect and copy all documents in the possession or under the control of such defendant, who may have counsel present, relating to any matters contained in this Final Judgment; and

(2) Subject to the reasonable convenience of such defendant and without restraint or interference from it, to interview officers, employees or agents of such defendant, who may have such defendant's counsel and/or their own counsel present, regarding such matters.

(B) Upon the written request of the Assistant Attorney General in charge of the Antitrust Division made to any defendant's principal office, such defendant shall submit such written reports, under oath if requested, relating to any matters contained in this Final Judgment as may be reasonably requested, subject to any legally recognized privilege.

(C) No information or documents obtained by the means provided in section VII shall be divulged by the plaintiff to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

(D) If at the time information or documents are furnished by any defendant to plaintiff, such defendant represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and such defendant marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then 10 days notice shall be given by plaintiff to such defendant prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which that defendant is not a party.

(E) Nothing set forth in this Final Judgment shall prevent the Antitrust Division from utilizing other investigative alternatives, such as the Civil Investigative Demand process provided by 15 U.S.C. 1311–1314 or a Federal grand jury, to determine if the defendant has complied with this Final Judgment.

VIII. Further Elements of the Final Judgment

(A) This Final Judgment shall expire ten years from the date of its entry.

(B) Jurisdiction is retained by this Court for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

(C) Entry of this Final Judgment is in the public interest.

In The United States District Court, District of Wyoming

United States of America, Plaintiff, vs. *Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc.*, Defendants. Civil No. 94–CV–146.

Competitive Impact Statement

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), the United States submits this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry with the consent of Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On June 2, 1994, the United States filed a civil antitrust complaint alleging that Nagel Motors, Inc., Greiner Motor Company, Inc., Benson Chevrolet, Inc. and their co-conspirators conspired to unreasonably restrain competition among Casper, Wyoming automobile body repair shops in violation of Section 1 of the Sherman Act, 15 U.S.C. 1. The Complaint asks the Court to find that Nagel Motors, Inc., Greiner Motor Company, Inc., and Benson Chevrolet, Inc. have violated Section 1 of the Sherman Act and further requests the Court to enjoin the continuance of the conspiracy.

Entry of the proposed Final Judgment will terminate the action, except that the Court will retain jurisdiction over the matter for further proceedings which may be required to interpret, enforce or modify the Judgment or to punish violations of any of its provisions.

II. Practices Giving Rise to the Alleged Violations

Defendants, Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. are automobile dealerships operating in Casper, Wyoming. They each offer a full range of automobile repair services, including automobile body repair work.

The Government contends, and was prepared to show at trial, that during the period beginning as early as December 1990 and continuing through at least July 1993, the defendants and their co-conspirators agreed, combined and conspired to unreasonably restrain competition among Casper, Wyoming area automobile body repair shops in violation of Section 1 of the Sherman Act. These agreements, combinations and conspiracies consisted of discussions and information exchanges aimed at increasing the rates charged for automobile body repair services in the Casper area.

For the purpose of forming and effectuating these agreements, combinations and conspiracies, Nagel Motors, Inc., Greiner Motor Company, Inc., Benson Chevrolet, Inc., and their co-conspirators, communicated with each other concerning the need to increase automobile body repair rates and, in conjunction with these discussions, disseminated to each other information concerning contemplated changes in automobile body repair rates. As a result of their discussions and exchange of contemplated changes in repair rates, coordinated rate increases were put into effect.

These agreements, combinations and conspiracies suppressed price competition among the defendants and their co-conspirators for providing automobile body repair services in the Casper area and deprived consumers of the benefits of free and open competition in the purchase of automobile body repair services.

III. Explanation of the Proposed Final Judgment

The United States and Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. have stipulated that the Court may enter the proposed Final Judgment after compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h). The proposed Final Judgment provides that its entry does not constitute any evidence against or admission of any party with respect to any issue of fact or law.

Under the provisions of Section 2(e) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(e), the proposed Final Judgment may not be entered unless the Court finds that entry is in the public interest. Section VIII of the proposed Final Judgment sets forth such a finding.

The proposed Final Judgment is intended to ensure that Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. discontinue all practices which unreasonably restrain competition among automobile body repair shops.

A. Prohibitions and Obligations

Under Section IV of the proposed Final Judgment, Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. are enjoined and restrained from: (1) Agreeing with any other automobile body repair shop to fix, establish, raise, stabilize or maintain any hourly rate or part price or discount; (2) participating in any discussion with or communicating with any other automobile body repair shop concerning adherence to or changes to, or the need or desirability of adhering to or changing, any hourly rate or part price or discount; and (3) disseminating any information to any automobile body repair shop concerning any planned or contemplated change in an hourly rate or part price or discount.

Section V of the proposed Final Judgment obligates Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. to implement and maintain an antitrust compliance program. This program would require each defendant to designate an Antitrust Compliance Officer within 30 days of entry of the Final Judgment. The Antitrust Compliance Officer for each defendant would be responsible for implementing and supervising the antitrust compliance program and compliance with the Final Judgment. Section V also obligates Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. to distribute within 60 days from entry of the Final Judgment, a copy of the Final Judgment to all officers and employees responsible for approving, disapproving, monitoring, recommending, or implementing any hourly rate or part price or discount, as well as any officer or employee who succeeds to such a position, and briefing those persons annually on the meaning and requirements of the Final Judgment and the antitrust laws and advising them that the defendant's legal advisors are available to confer with them regarding compliance with the Final Judgment and the antitrust laws. Further the Antitrust Compliance Officer must obtain from each such officer or employee, annual written certifications stating that he or she: (1) Has read, understands, and agrees to abide by the terms of the Final Judgment; (2) has been advised and understands that his or her failure to comply with the Final Judgment may result in conviction for criminal contempt of court; and (3) is not aware of any violation of the Final Judgment that has not been reported to the Antitrust Compliance Officer. The Antitrust Compliance Officer must maintain a record of recipients to whom the Final Judgment has been distributed and from whom certifications have been obtained. He or she must also report to the Department of Justice any violation of the Final Judgment. Finally, the Antitrust Compliance Officer must also distribute copies of the Final Judgment to the owner or manager of each automobile body repair shop, located within 50 miles of Casper, Wyoming, which is presently in business and has purchased parts or body repair services from the defendant in the last five years.

In addition to the prohibitions and obligations contained in Section IV and V, Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. are further obligated, under Section VI, to certify, within 75 days after the entry of the Final Judgment, that they have designated an Antitrust Compliance Officer and have distributed the Final Judgment in accordance with the Section V requirement. Section VI also requires Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc., for a period of ten years after the entry of the Final Judgment, on or before its anniversary date, to file with the Government, a statement as to the fact and manner of compliance with the

provisions of Section V of the Final Judgment.

B. Scope of the Proposed Final Judgment

Section VIII of the proposed Final Judgment provides that the Final Judgment shall remain in effect for ten years.

Section III of the proposed Final Judgment provides that the Final Judgment shall apply to Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. and to each of their successors, assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of the Final Judgment by personal service or otherwise.

C. Effect of the Proposed Final Judgment on Competition

The relief set out in the proposed Final Judgment is designed to prevent recurrence of the activities alleged in the Complaint. The proposed Final Judgment's provisions are designed to remove the artificial restraints that the defendants have imposed on competition among automobile body repair shops and create an environment in which more vigorous competition may take place. It is intended to ensure that marketing and pricing decisions of Nagel Motors, Inc., Greiner Motor Company, Inc. and Benson Chevrolet, Inc. are made independently, without any discussions and conversations with each other. The Department of Justice believes that the proposed Final Judgment contains sufficient provisions to prevent further violations of the type alleged in the Complaint.

IV. Alternatives to the Proposed Final Judgment

The alternative to the proposed Final Judgment would be a full trial of the case. In the view of the Department of Justice, such a trial would involve substantial cost to the United States and is not warranted because the proposed Final Judgment provides relief that will remedy the violations of the Sherman Act alleged in the United States' Complaint.

V. Remedies Available to Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and reasonable attorney's fees. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the Final Judgment has no *prima facie* effect in any subsequent lawsuits that may be brought against any defendant in this matter.

VI. Procedures Available for Modification of the Proposed Judgment

As provided by the Antitrust Procedures and Penalties Act, any person believing that the proposed judgment should be modified may submit written comments to Gary R. Spratling, Chief, San Francisco Office, Department of Justice, Antitrust Division, 450 Golden Gate Avenue, San Francisco, California 94102, within the 60-day period provided by the Act. These comments, and the Government's responses to them, will be filed with the Court and published in the **Federal Register**. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed judgment at any time prior to its entry if it should determine that some modification of the judgment is necessary to the public interest. The proposed judgment itself provides that the Court will retain jurisdiction over this action, and that the parties may apply to the court for such orders as may be necessary or appropriate for the modification or enforcement of the judgment.

VII. Determinative Documents

No materials and documents of the type described in Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b), were considered in formulating the proposed judgment. Consequently, none are filed herewith.

Gary R. Spratling,
Richard B. Cohen,
Carla G. Addicks,
Attorneys, U.S. Department of Justice.

[FR Doc. 94–15911 Filed 7–1–94; 8:45 am]
BILLING CODE 4410–01–M

LEGAL SERVICES CORPORATION

Correction of Notice of Intent To Designate Recipient for the Provision of State Support for the Delivery of Legal Services in the State of Louisiana

AGENCY: Legal Services Corporation.
ACTION: Correction of notice of intention to award grant.

SUMMARY: In a Notice published on May 27, 1994 (59 FR 27585), the Legal Services Corporation announced its intention to make a grant to Louisiana Legal Consortium, Inc. to provide state support services to the Legal Services Corporation's recipient programs in the State of Louisiana. The intended grant for the remainder of 1994 was erroneously stated as $94,314. The correct amount is $78,596.

FOR FURTHER INFORMATION CONTACT: John Tull, Director, Office of Program Services, (202) 336–7264.

Dated: June 28, 1994.

John A. Tull,
Director, Office of Program Services.

[FR Doc. 94–16176 Filed 7–1–94; 8:45 am]
BILLING CODE 7050–010–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Humanities Panel; Meetings

AGENCY: National Endowment for the Humanities.
ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, as amended), notice is hereby given that the following meeting of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: David C. Fisher, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* July 21, 1994

Time: 8:00 a.m. to 5:30 p.m.
Room: 315
Program: This combined meeting will review Fellowships for University Teachers and Fellowships for College Teachers applications in Art History I, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

2. *Date:* July 22, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 315
Program: This meeting will review Fellowships for University Teachers applications in American History and Studies, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

3. *Date:* July 22, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 415
Program: This meeting will review Fellowships for College Teachers applications in Anthropology, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

4. *Date:* July 25, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 315
Program: This meeting will review Fellowships for University Teachers applications in Music, Dance, Theater and Film History and Criticism, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

5. *Date:* July 25, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 415
Program: This meeting will review Fellowships for College Teachers applications in Music, Theater and Film, submitted to the Division of Fellowships and Seminars, for projects after June 1, 1995.

6. *Date:* July 26, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 415
Program: This combined meeting will review Fellowships for University and Fellowships for College Teachers applications in Art History II, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

7. *Date:* July 27, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 315
Program: This meeting will review Fellowships for College Teachers applications in Languages and Literatures I, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

8. *Date:* July 27, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 415
Program: This meeting will review Fellowships for College Teachers applications in Languages and Literatures II, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

9. *Date:* July 28, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 415
Program: This meeting will review Fellowships for College Teachers applications in American History I, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

10. *Date:* July 29, 1994
Time: 8:00 a.m. to 5:30 p.m.
Room: 315
Program: This meeting will review Fellowships for College Teachers applications in Sociology Psychology, and Education, submitted to the Division of Fellowships and Seminars, for projects beginning after June 1, 1995.

David Fisher,

Advisory Committee Management Officer.

[FR Doc. 94–16192 Filed 7–1–94; 8:45 am]

BILLING CODE 7536–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–213]

Connecticut Yankee Atomic Power Company; Haddam Neck Plant Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–61, issued to Connecticut Yankee Atomic Power Company (CYAPCO, the licensee), for operation of the Haddam Neck Plant, located in Middlesex County, Connecticut.

Environmental Assessment

Identification of the Proposed Action

The proposed amendment will revise Technical Specification (TS) Section 3/4.5.1, "ECCS Subsystems—Tavg Greater Than or Equal to 350 °F," by adding a new ACTION Statement "a" which increases the allowed outage time for the centrifugal charging pumps from 72 hours to 7 days. The Technical Specification changes will reduce the risk of an unnecessary shutdown to perform charging pump repairs. The proposed action is in accordance with the licensee's amendment request dated November 2, 1993, as supplemented February 28, 1994, and May 31, 1994.

The Need for the Proposed Action

The current TS allows a charging pump to be inoperable for a period of up to 72 hours. Experience at the plant has shown that 72 hours may not be sufficient to accomplish certain repairs such as rebuilding the rotating assembly or complete pump replacement. Increasing the allowed outage time to 7 days provides sufficient time to perform such repairs without having to shut the plant down.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed revision to the TS. The increase in the core damage frequency due to internal events as result of the increased allowed outage time is 3.0E–7 per year or less than 1 percent of the current core damage frequency of 1.8E–4 per year for internal events. The increase in the core damage frequency due to external events as result of the increased outage time has been determined to be insignificant for external events. The unavailability of the charging pumps has limited effects on the risk because the charging pumps are not credited for during the injection phase of a design basis accident and are the backup to the high-pressure safety injection pumps during the recirculation phase if power is available. The only use of the charging pumps credited in the safety analysis is for two path sump recirculation, which is later in the accident and is manually initiated.

The TS change will not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with this proposed TS amendment.

With regard to potential nonradiological impacts, the proposed amendment involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed amendment.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed amendment, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to the amendment would be to deny the amendment request. Such action would not enhance the protection of the environment and would result in unjustified cost to the licensee.

Alternative Use of Resources

This action does not involve the use of resources not considered previously

in the Final Environmental Statement for the Haddam Neck Plant.

Agencies and Persons Consulted

The NRC staff consulted with the Connecticut State official regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed amendment.

For further details with respect to this proposed action, see the licensee's letters dated November 2, 1993, as supplemented February 28, and May 31, 1994. These letters are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC 20555, and at the local public document room located at the Russell Library, 123 Broad Street, Middletown Connecticut 06547.

Dated at Rockville, Maryland, this 27th day of June 1994.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–4, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 94–16196 Filed 7–1–94; 8:45 am]

BILLING CODE 7590–01–M

GPU Nuclear Corporation; Notice of Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–16 issued to GPU Nuclear Corporation (GPUN, the licensee) for operation of the Oyster Creek Nuclear Generating Station located in Ocean County, New Jersey.

The proposed amendment would revise Technical Specification Section 2.3.D to change the setpoints "Reactor High Pressure, Relief Valve Initiation" by increasing the setpoint value by 15 psig for each of the Electromatic Relief Values in the Automatic Depressurization System.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By August 4, 1994, 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 request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition 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. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC 20555 and at the local public document room located at Ocean County Library, Reference Department, 101 Washington Street, Toms River, New Jersey 08753. 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 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 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. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. 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.

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 Services Branch, or may be delivered to the Commission's Public Document Room, The Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last 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 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to John F. Stolz: 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, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW.,

Washington, DC 20037 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 the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

If a request for a hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

For further details with respect to this action, see the application for amendment dated June 15, 1994, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room located at the Ocean County Library, Reference Department, 101 Washington Street, Toms River, New Jersey 08753.

Dated At Rockville, Maryland, this 27th day of June 1994.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–4, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 94–16195 Filed 7–1–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. EA 93–236, IA 94–003; ASLBP Nos. 94–692–05–EA, 94–691–04–EA]

Nuclear Support Services, Inc., EA 93–236: Order Requiring the Removal of an Individual From NRC Licensed or Regulated Activities and Order Directing Review of Personnel Security Files (Effective Immediately) and Robert C. Dailey IA 94–003: Order Prohibiting Involvement in Certain NRC–Licensed or Regulated Activities (Effective Immediately); Hearing and Prehearing Conference

This Licensing Board has been established to preside over the hearing requested on April 29, 1994 by Nuclear Support Services, Inc. (NSSI) and Mr. Robert C. Dailey, challenging two enforcement actions issued by the NRC Staff on March 22, 1994. The enforcement actions were published at 59 FR 14429 (March 28, 1994) (NSSI) and 59 FR 14688 (March 29, 1994) (Dailey). The first of these actions would order NSSI to remove an individual from NRC-licensed or regulated activities for five years; the second would prohibit that same individual from participating in NRC-licensed or regulated activities for the same period. In each case, the issue for hearing, as specified in the respective enforcement actions, is whether the particular order should be sustained.

By Memorandum and Order (Consolidating Proceedings and Granting Extension of Time), dated May 4, 1994 (unpublished), the Licensing Board granted the hearing requests and consolidated the two proceedings.

Notice is hereby given that the Atomic Safety and Licensing Board will conduct a prehearing conference in this consolidated proceeding on Tuesday, July 12, 1994, beginning at 2:00 p.m. The conference will be held in the new Commission hearing room, 3rd floor, Two White Flint North, 11545 Rockville Pike, North Bethesda, Maryland. Members of the public are invited to attend but may not participate in the course of the conference.

Among matters to be discussed will be the precise issues for the hearing, discovery, and scheduling. Parties are invited to submit proposed agenda for the conference, to be in the hands of Board members by close of business Thursday, July 7, 1994.

As permitted by 10 CFR 2.715(a), persons who are not parties to the proceeding are invited to submit limited appearance statements. Such statements do not constitute testimony or evidence but, to the extent pertinent to issues in these proceedings, may assist the Board and/or parties in their deliberations as to scope of the issues to be considered. Such statements should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. A copy should also be served on the Chairman of this Licensing Board, Atomic Safety and Licensing Board Panel, Mail Station T–3F23, Washington, D.C. 20555. Oral limited appearance statements may be heard during the course of the proceeding but will not be entertained at the July 12, 1994 prehearing conference.

Bethesda, Maryland, June 17, 1994.

For the Atomic Safety and Licensing Board.

Charles Bechhoefer,

Chairman, Administrative Judge.

[FR Doc. 94–16197 Filed 7–1–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–397]

Washington Public Power Supply System; Notice of Partial Denial of Amendment to Facility Operating License and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) has denied a portion of a request by the Washington Public Power Supply System, (the licensee) for an amendment to Facility Operating License No. NPF–21 issued to the licensee for operation of the Washington Nuclear Project No. 2, located in Benton County, Washington. Notice of Consideration of Issuance of this amendment was published in the **Federal Register** on April 13, 1994 (59 FR 17609).

The purpose of the licensee's amendment request was to revise the Technical Specifications (TS) to reflect management and organizational changes at the Washington Public Power Supply System (the licensee) for operation of the WNP–2 facility. The proposed changes would (1) modify the reporting responsibility of the quality assurance organization from the Managing Director to the Assistant Managing Director, Operations (AMDO), and (2) modify the appointment authority for the Corporate Nuclear Safety Review Board (CNSRB) from the Managing Director to the AMDO. These changes are proposed to reflect the current designation of the AMDO as the licensee's designated official with corporate responsibility for overall plant nuclear safety, and as the direct report for the CNSRB.

In addition, the proposed change would (1) delete the specific requirement for health physics/chemistry program procedures, (2) modify the titles of two positions on the Plant Operations Committee (POC) to reflect revised organizational titles, (3) modify the CNSRB composition requirements from nine personnel to a minimum of nine personnel, and (4) delete the requirement that the CNSRB Executive Secretary be designated from the CNSRB membership. The NRC staff has concluded that part of the licensee's request cannot be granted. The staff denied the proposed change to modify the CNSRB composition requirements from nine personnel to a minimum of nine personnel, because the proposed change does not specify a maximum number of CNSRB members and is inconsistent with the existing TS provision that 5 persons shall constitute a quorum of the CNSRB. The licensee was notified of the Commission's partial denial of the proposed change by a letter dated June 28, 1994.

By August 4, 1994, the licensee may demand a hearing with respect to the denial described above. Any person whose interest may be affected by this proceeding may file a written petition for leave to intervene.

A request for hearing or 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 Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date.

A copy of any petitions should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to M.H. Philips, Jr., Esq., Winston and Strawn, 1400 L Street NW., Washington, DC 20005–3502, attorney for the licensee.

For further details with respect to this action, see (1) the application for amendment dated February 17, 1994, and (2) the Commission's letter to the licensee dated June 28, 1994.

These documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the Richland Public Library, 955 Northgate Street, Richland, Washington 99352. A copy of item (2) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Document Control Desk.

Dated at Rockville, Maryland, this 28th day of June 1994.

For the Nuclear Regulatory Commission.

Theodore R. Quay,

Project Director, Project Directorate IV–2, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 94–16198 Filed 7–1–94; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Notice of Request for Reclearance of SF 3106 and SF 3106A

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (title 44, U.S. Code, chapter 35), this notice announces a request for a reclearance of an information collection. Form SF 3106 and SF 3106A are used by former Federal employees who contributed to the Federal Employee's Retirement System to receive a refund of retirement deductions and any other money to their credit in the Retirement fund.

There are estimated to be 81,000 respondents for SF 3106 and 40,500 respondents for SF 3106A. It takes approximately 27 minutes to complete SF 3106 and 6 minutes to complete SF 3106A. The annual burden for SF 3106 is 36,450 hours and the annual burden for SF 3106A is 4,050.

For copies of this proposal, contact C. Ronald Trueworthy on (703) 908–8550.

DATES: Comments on this proposal should be received on or before August 4, 1994.

ADDRESSES: Send or deliver comments to—

Daniel A. Green, Retirement and Insurance Group, FERS Division, U.S. Office of Personnel Management, 1900 E Street NW., room 4429, Washington, DC 20415

and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building NW., room 3002, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Mary Beth Smith-Toomey, Chief, Forms Analysis and Design, (202) 606–0623.

Office of Personnel Management.

Lorraine A. Green,

Deputy Director.

[FR Doc. 94–16053 Filed 7–1–94; 8:45 am]

BILLING CODE 6325–01–M

Request for Reclearance of Form RI 20–80

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (title 44, U.S. Code, chapter 35), this notice announces a request for reclearance of an information collection. Form RI 20–80, Alternative Annuity Election, is used for individuals who are eligible to elect whether to receive a reduced annuity and a lump-sum payment equal to their retirement contributions (alternative form of annuity) or an unreduced annuity and no lump sum.

Approximately 9,600 RI 20–80 forms are completed annually. The form requires approximately 20 minutes to complete. The annual burden is 3,200 hours.

For copies of this proposal, contact C. Ronald Trueworthy on (703) 908–8550.

DATES: Comments on this proposal should be received within 30 calendar days from the date of this publication.

ADDRESS: Send or deliver comments to—

Lorraine E. Dettman, Chief, Retirement and Insurance Group, Operations Support Division, Office of Personnel Management, 1900 E Street, NW., Room 3349, Washington, DC 20415

and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3002, Washington, DC 20503

FOR INFORMATION REGARDING ADMINISTRATIVE COOPERATION CONTACT: Mary Beth Smith-Toomey, Chief, Forms Analysis & Design, (202) 606–0623.

Office of Personnel Management.

Lorraine A. Green,

Deputy Director.

[FR Doc. 94–16051 Filed 7–1–94; 8:45 am]

BILLING CODE 6325–01–M

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This gives notice of positions placed or revoked under Schedules A and B, and placed under Schedule C in the excepted service, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

FOR FURTHER INFORMATION CONTACT: Sherry Turpenoff, (202) 606–0940.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management published its last monthly notice updating appointing authorities established or revoked under the Excepted Service provisions of 5 CFR 213 on June 15, 1994 (59 FR 30815). Individual authorities established or revoked under Schedules A and B and established under Schedule C between May 1 and May 31, 1994, appear in the listing below. Future notices will be published on the fourth Tuesday of each month, or as soon as possible thereafter. A consolidated listing of all authorities as of June 30, is published each year.

Schedule A

No Schedule A authorities were established or revoked during May 1994.

Schedule B

Department of Commerce

Revoked on position, of Minority Business Opportunity Specialist, at

grades GS–9 through GS–15, in the Minority Business Development agency. Effective May 2, 1994.

National Endowment for the Humanities

Established one position, Humanities Administrator, in the Division of Research Programs by amending as established position. Effective May 2, 1994.

Schedule C

Agency for International Development

Administrative Operations Assistant to the Chief of Staff. Effective May 19, 1994.

Department of Agriculture

Staff Assistant to the Administrator, Farmers Home Administration. Effective May 4, 1994.

Confidential Assistant to the Administrator, Agricultural Marketing Service. Effective May 10, 1994.

Confidential Assistant to the Administrator, Rural Electrification Administration. Effective May 10, 1994.

Confidential Assistant to the Administrator, Farmers Home Administration. Effective May 17, 1994.

Department of the Air Force (DOD)

Confidential Assistant for Environmental Legislation to the Deputy Assistant Secretary for Environmental Safety and Occupational Health. Effective May 12, 1994.

Department of the Army (DOD)

Executive Assistant to the Secretary of the Army. Effective May 19, 1994.

Department of Commerce

Director, Office of Energy, Infrastructure and Machinery to the Deputy Assistant Secretary for Basic Industries. Effective May 10, 1994.

Special Assistant to the General Counsel. Effective May 11, 1994.

Department of Defense

Special Assistant to the Deputy to the Under Secretary of Defense for Policy Support. Effective May 4, 1994.

Paralegal Specialist to a Judge, U.S. Court of Military Appeals. Effective May 23, 1994.

Paralegal Specialist to a Judge, U.S. Court of Military Appeals. Effective May 23, 1994.

Paralegal Specialist to the Chief Judge, U.S. Court of Military Appeals. Effective May 23, 1994.

Personal and Confidential Assistant to the Assistant Secretary of Defense for Economic Security. Effective May 26, 1994.

Department of Education

Confidential Assistant to the Deputy Assistant Secretary. Effective May 5, 1994.

Special Assistant to the Deputy Chief of Staff. Effective May 6, 1994.

Director, Scheduling and Briefing Staff to the Chief of Staff, Office of the Secretary. Effective May 23, 1994.

Department of Energy

Special Assistant to the Assistant Secretary for Energy Efficiency and Renewable Energy. Effective May 2, 1994.

Staff Assistant to the Deputy Associate Deputy Secretary for Field Management. Effective May 3, 1994.

Staff Assistant to the Assistant Secretary for Environmental Restoration and Waste Management. Effective May 3, 1994.

Policy Analyst to the Assistant Secretary for Policy, Planning and Program Evaluation. Effective May 4, 1994.

Staff Assistant to the Director, Office of Public Accountability. Effective May 10, 1994.

Special Assistant to the Press Secretary, Press Services Division, Office of Public and Consumer Affairs. Effective May 31, 1994.

Department of Health and Human Services

Special Assistant to the Director, Office of Community Services, Administration for Children and Families. Effective May 2, 1994.

Special Outreach Coordinator to the Deputy Assistant Secretary for Public Affairs (Policy and Strategy). Effective May 5, 1994.

Special Assistant to the Director, Office of Public Affairs, Administration for Children and Families. Effective May 6, 1994.

Special Assistant to the Director, Office of Community Services, Administration for Children and Families. Effective May 6, 1994.

Special Assistant to the Deputy Assistant Secretary for Legislation (Human Services). Effective May 19, 1994.

Department of Housing and Urban Development

Special Assistant to the Deputy Assistant Secretary for Multifamily Housing Programs. Effective May 4, 1994.

Special Assistant to the Assistant Secretary for Community Planning and Development. Effective May 10, 1994.

Special Assistant to the Assistant Secretary for Community Planning and Development. Effective May 10, 1994.

Deputy Assistant Secretary for Operations to the Assistant Secretary for Community Planning and Development. Effective May 10, 1994.

Special Advisor to the Assistant Secretary for Community Planning and Development. Effective May 10, 1994.

Deputy Assistant Secretary for Planning to the Assistant Secretary for Community Planning. Effective May 10, 1994.

Department of Justice

Secretary (OA) to the United States Attorney. Effective May 10, 1994.

Deputy Assistant Attorney General to the Assistant Attorney General, Office of Legislative Affairs. Effective May 16, 1994.

Department of Labor

Legislative Officer to the Assistant Secretary for Congressional and Intergovernmental Affairs. Effective May 10, 1994.

Special Assistant to the Assistant Secretary for Public Affairs. Effective May 10, 1994.

Special Assistant to the Administrator, Wage and Hour Division Effective May 26, 1994.

Department of State

Staff Assistant to the Deputy Secretary of State. Effective May 5, 1994.

Staff Assistant to the Population Coordinator, Bureau of Oceans and International Environment and Scientific Affairs. Effective May 5, 1994.

Department of Transportation

Deputy Director of Public Affairs to the Assistant to the Secretary and Director of Public Affairs. Effective May 4, 1994.

Special Assistant to the General Counsel. Effective May 12, 1994.

Scheduling Assistant to the Special Assistant for Scheduling and Advance. Effective May 12, 1994.

Special Assistant to the Director, Small and Disadvantaged Business Utilization. Effective May 19, 1994.

Department of Treasury

Confidential Assistant to the Deputy Secretary of the Treasury. Effective May 9, 1994.

Senior Advisor to the Treasurer of the United States. Effective May 9, 1994.

Policy Advisor to the Assistant Secretary (Enforcement). Effective May 19, 1994.

Policy Advisor to the Assistant Secretary (Enforcement). Effective May 19, 1994.

Policy Advisor to the Assistant Secretary (Enforcement). Effective May 19, 1994.

Policy Advisor to the Assistant Secretary (Enforcement). Effective May 19, 1994.

Staff Assistant to the Deputy Executive Secretary (Public Liaison). Effective May 25, 1994.

Deputy Executive Director for Special Programs to the Executive Director, United States Bond Division, Bureau of Public Debt. Effective May 25, 1994.

Federal Mine Safety and Health Review Commission

Attorney-Advisor (General) to the Chairman. Effective May 5, 1994.

General Services Administration

Special Assistant to the Chief of Staff. Effective May 31, 1994.

National Aeronautics and Space Administration

Public Affairs Specialist to the Senior Public Affairs Specialist. Effective May 2, 1994.

Legislative Affairs Specialist to the Special Assistant to the Associate Administrator for Legislative Affairs. Effective May 12, 1994.

White House Liaison Officer to the Administrator. Effective May 31, 1994.

National Credit Union Administration

Deputy Director to the Director of Community Development Credit Unions. Effective May 12, 1994.

Executive Assistant to the Board Member. Effective May 24, 1994.

National Endowment for the Arts

Executive Secretary to the Chairman. Effective May 12, 1994.

National Mediation Board

Confidential Assistant to the Chairman. Effective May 19, 1994.

Small Business Administration

Assistant Administrator for Marketing and Outreach to the Associate Administrator for Communications and Public Liaison. Effective May 23, 1994.

Special Assistant to the Associate Administrator for Communications and Public Liaison. Effective May 26, 1994.

Associate Administrator for Field Operations to the Administrator. Effective May 26, 1994.

Director of Intergovernmental Affairs to the Associate Administrator for Communications and Public Liaison. Effective May 26, 1994.

Special Assistant to the Administrator and Director of Special Capital Initiatives to the Associate Deputy Administrator for Economic Development. Effective May 26, 1994.

United States Information Agency

Director, Policy and Planning Unit to the Deputy Director, United States Information Agency. Effective May 10, 1994.

Public Affairs Specialist to the Director, New York Foreign Press Center, New York, NY. Effective May 16, 1994.

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR 1994–1958 Comp., P.218

Office of Personnel Management.

Lorraine A. Green,

Deputy Director.

[FR Doc. 94–16052 Filed 7–1–94; 8:45 am]

BILLING CODE 6325–01–M

POSTAL RATE COMMISSION

[Docket No. A94–12 Order No. 1019]

Petroleum, West Virginia 26161 (Nancy L. Putnam, et al., Petitioners); Notice and Order Accepting Appeal and Establishing Procedural Schedule Under 39 U.S.C. § 404(b)(5)

Issued June 28, 1994.

Docket Number: A94–12
Name of Affected Post Office: Petroleum, West Virginia 26161
Name(s) of Petitioner(s): Nancy L. Putnam and others
Type of Determination: Closing
Date of Filing of Appeal Papers: June 22, 1994
Categories of Issues Apparently Raised:

1. Effect on postal services [39 U.S.C. § 404(b)(2)(C)].
2. Effect on the community [39 U.S.C. § 404(b)(2)(A)].

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than those set forth above. Or, the Commission may find that the Postal Service's determination disposes of one or more of those issues.

The Postal Reorganization Act requires that the Commission issue its decision within 120 days from the date this appeal was filed (39 U.S.C. § 404 (b)(5)). In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service to submit memoranda of law on any appropriate issue. If requested, such memoranda will be due 20 days from the issuance of the request and the Postal Service shall serve a copy of its memoranda on the petitioners. The Postal Service may incorporate by reference in its briefs or motions, any arguments presented in memoranda it previously filed in this docket. If necessary, the Commission also may ask petitioners or the Postal Service for more information.

The Commission orders:

(a) The Postal Service shall file the record in this appeal by July 7, 1994.

(b) The Secretary of the Postal Rate Commission shall publish this Notice and Order and Procedural Schedule in the **Federal Register**.

By the Commission.

Charles L. Clapp,

Secretary.

Appendix

June 22, 1994—Filing of Appeal letters
June 28, 1994—Commission Notice and Order of Filing of Appeal
July 18, 1994—Last day of filing of petitions to intervene [*see* 39 C.F.R. § 3001.111(b)]
July 27, 1994—Petitioners' Participant Statements or Initial Briefs [*see* 39 C.F.R. § 3001.115 (a) and (b)]
August 17, 1994—Postal Service's Answering Brief [*see* 39 C.F.R. § 3001.115(c)]
September 1, 1994—Petitioners' Reply Briefs should Petitioners choose to file them [*see* 39 C.F.R. § 3001.115(d)]
September 8, 1994—Deadline for motions by any party requesting oral argument. The Commission will schedule oral argument only when it is a necessary addition to the written filings [*see* 39 C.F.R. § 3001.116]
October 21, 1994—Expiration of the Commission's 120-day decisional schedule [*see* 39 U.S.C. § 404(b)(5)]

[FR Doc. 94–16129 Filed 7–1–94; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–34270; File No. SR–CBOE–94–02]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to Equity and SPX RAES Participation Requirements

June 28, 1994.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("ACT"), 15 U.S.C. 78s(b)(1), notice is hereby given that on January 22, 1994, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-

regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend its rules to impose fees on market makers who fail to observe certain participation duties on the Retail Automated Execution System ("RAES") for equity and Standard & Poor's 500 Index ("SPX") classes of options. Specifically, the CBOE proposes to amend CBOE Rules 8.16m, "RAES Eligibility in Equity Options" and 24.16, "RAES Eligibility in SPX/NDX," to impose the following fees for failures to satisfy the rules' log-off requirements: (1) a fee of $100.00 for one to three failures within one twelve-month period; (2) a fee of $250.00 for four to six failures within one twelve-month period; and (3) a fee of $500.00 for seven or more failures within one twelve-month period. In addition, the CBOE proposes to issue a Regulatory Circular clarifying market makers' RAES responsibilities with respect to equity and SPX options classes and indicating that members who fail to meet the long-on requirements of CBOE Rules 8.16(b) or 24.16(b) ordinarily will be suspended from participation on RAES at the applicable trading station for a period of 21 consecutive business days.[1]

The text of the proposal is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The CBOE stats that the purpose of the proposed rule change is to impose fees on members who fail to observe the RAES log-off requirements set forth in CBOE Rules 8.16(a) and 24.16(a) relative to equity options and SPX index options. The CBOE proposes to incorporate the following fee schedule into CBOE Rules 8.16(a) for equity options) and 24.16(a) (for SPX options) for failures to comply with the log-off requirements: (1) a fee of $100.00 for one to three failures within one twelve-month period; (2) a fee of $250.00 for four to six failures within one twelve-month period; and (3) a fee of $500.00 for seven or more failures within one twelve-month period.

The proposed fees for failures to observe the log-off requirements for equity and SPX RAES are identical in amounts and graduated structure to the fees proposed for Standard & Poor's 100 Index ("OEX") options in File No. SR–CBOE–94–12. Under both proposals, the fee amounts will increase in relation to the number of times each calendar year that a member does not log off as required.

As is the case of fees applicable to OEX RAES participants under existing CBOE Rule 24.17, "RAES Eligibility in "OEX," the proposed fees do not constitute disciplinary action, although the CBOE's review procedures in Chapter XIX, "Hearings and Review." of the CBOE's rules will be available for review of fees assessed under the proposal. The Commission has noted the appropriateness of such fees and appeal rights in a related context.[2]

In addition to establishing a fee schedule, the CBOE proposes to issue a Regulatory Circular that will reaffirm the nature of CBOE market makers' RAES log-on and log-off responsibilities in respect of equity and SPX options classes and will describe the consequences that attach to any market maker's failure to observe these responsibilities. The Regulatory Circular addresses four points. First, CBOE Rules 8.16(a)(iii) and 24.16(a)(iii) require any market maker who has logged onto RAES at a trading station on any given trading day to log off RAES whenever the market maker leaves the trading crowd for more than "a brief interval." The Regulatory Circular interprets "a brief interval" to mean "five consecutive minutes." Under this interpretation any market maker who signs onto RAES at a particular trading station during a trading session must log off the system prior to leaving that station for more than five consecutive minutes. The CBOE believes that this interpretation should eliminate ambiguity about the amount of time a market maker may be away from the trading crowd without signing off RAES.

Second, the Regulatory Circular notes that graduated fees will be assessed under CBOE Rules 8.16(a) and 24.16(a) for failure to observe the RAES log-off requirement.

Third, the Regulatory Circular reflects the MPC's designation pursuant to CBOE Rules 8.16(b) and 24.16(b) that the expiration month log-on requirements reflected in those rules will be enforced in all classes of equity and SPX options for which RAES is available. Accordingly, any market maker who has logged onto RAES in accordance with CBOE Rules 8.16(a) or 24.16(a) during an expiration month for a given class of options must log on whenever present at the applicable trading station, until expiration.

Fourth, the Regulatory Circular reflects a determination by the MPC, pursuant to its authority under CBOE Rules 8.16(d) and 24.16(d), that any market maker who fails to meet the log-on requirements under CBOE Rules 8.16(b) or 24.16(b) ordinarily will be suspended from participation on RAES at the applicable trading station for a period of 21 consecutive business days.[3]

The CBOE believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5), in particular, in that it is designed to enable the CBOE to enforce compliance with the Act, to promote just and equitable principles of trade, and to

[1] CBOE Rule 8.16(b) states that in option classes designated by the market Performance Committee ("MPC"), any market maker who has logged on RAES at any time during an expiration month must log on the RAES system in that option class whenever he is present in that trading crowd until the next expiration. CBOE Rule 24.(b) states that unless exempted by the MPC, any market maker who has logged on RAES at any time during an expiration month must log on the RAES system in SPX/NSX whenever he is present in that trading crowd until the expiration.

[2] Specifically, in approving a CBOE proposal that included procedures for contesting the fees assessed for delayed submission of trade data the Commission stated that "Although such formalized procedures are unusual for challenging fee assessments, they actually make the imposition of the fee fairer by allowing members to challenge erroneous fee charges. Moreover, these procedures are reasonably designed to afford a member assessed fee the opportunity to challenge the veracity of the assessments." *See* Securities Exchange Act Release No. 30001 (November 26, 1991), 56 FR 63529 (order approving File No. SR–CBOE–90–06).

[3] In contrast to this suspension provision, File No. SR–CBOE–94–12 proposes that members who fail to observe the RAES log-on requirements for OEX options would be subject to a fee. The CBOE has determined that suspensions, not fees, are the appropriate mechanisms to promote compliance with RAES log-on requirements for equity and SPX options. The CBOE states that it may introduce fees for failures to observe the log-on requirements for equity and SPX options at a later date if experience so dictates.

protect investors and the public interest by assuring that equity and SPX options market makers are aware of and meet their responsibilities pertaining to RAES.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reason for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by July 26, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16186 Filed 7–1–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–34268; File No. SR–CHX–94–12]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Stock Exchange, Inc., Relating to Disclosure of Pending Formal Exchange Disciplinary Proceeding to the CRD

June 28, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice if hereby given that on May 6, 1994, the Chicago Stock Exchange, Inc. ("CHX") or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CHX proposes to add Rule 9 to Article XII of the Exchange's Rules. Rule 9 to Article XII is proposed to be provided as follows:

The initiation of, and all significant changes in the status of, a formal disciplinary proceeding brought by the Exchange shall be reported by the Exchange to the Central Registration Depository operated by the National Association of Securities Dealers, Inc. For purposes of this Rule, significant changes in the status of a pending formal disciplinary proceeding shall include, but are not limited to, issuance of a decision by the President, the filing of an appeal; to and/or the issuance of a decision by, a Judiciary Committee, the Exchange's Executive Committee or Board of Governors.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements governing the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The proposed rule change authorizes the Exchange to provide information to the Central Registration Depository ("CRD")[1] concerning pending formal Exchange disciplinary proceedings for disclosure to the public. A formal disciplinary proceeding is considered to be pending from the time charges are issued[2] until the proceeding is completed.[3] Currently, the Exchange discloses information only on final Exchange disciplinary actions to the CRD.

Information concerning final disciplinary actions taken by the Exchange and other SROs and regulatory organizations and certain criminal convictions contained in the CRD has been disclosed to the public pursuant to the NASD's 800 number service since October 1991.[4]

On July 1, 1993, the SEC approved an NASD rule change to make more information available to the general public regarding pending disciplinary proceedings or actions taken by federal or state securities agencies and SROs that relate to securities or commodities transactions, and regarding criminal indictments and informations.[5]

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[4] 17 CFR 200.30–3(a)(12) (1993).

[1] The CRD is an automated industry database containing employment and disciplinary history of members and associated persons registered with self-regulatory organizations ("SROs") and state securities agencies. The CRD is operated by the National Association of Securities Dealers, Inc. ("NASD") with input on policy and other matters from federal and state agencies and other SROs, including the Exchange.

[2] CHX Article XII, Rule 1(b) provides, in part, that if in the judgment of the President it shall appear that an accused has committed a default or other offense in violation of the Constitution or Rules of the Exchange the President shall, except as hereinafter provided, direct the staff to prefer written charges against the accused. A copy of such charges shall be served upon the accused. The accused shall also be served with written notice of when and where the charges will be heard.

[3] *See* CHX Article XII, Rule 7.

[4] The Commission subsequently approved the NASD's procedures for operating its 800 number service in Securities Exchange Act Release No. 30629 (April 23, 1992), 57 FR 18535 (April 30, 1992) (File No. SR–NASD–91–39) ("800 Number Service Plan Approval Order").

[5] *See* Securities Exchange Act Release No. 32568 (July 1, 1993), 59 FR 36723 (July 8, 1993) (File No.

Continued

Information on pending SRO disciplinary proceedings, among other events, is currently also in the CRD, to the extent that reports are made by members, member organizations and associated persons pursuant to their reporting obligations on the Uniform Application for Securities Industry Registration or Transfer (Form U–4) and Form BD, the uniform applications form for broker-dealer registration. However, the Exchange does not currently report such pending events to the CRD.

The submission of information concerning pending formal disciplinary proceedings directly by the Exchange would enhance the CRD database since the CRD would not have to rely solely on reports from members, member organizations and associated persons.

(2) Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 450 Fifth Street NW., Washington, DC 20549. Copies of the filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR–CHX–94–12 and should be submitted by July 26, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16189 Filed 7–1–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–34257; File No. SR–NSCC–94–11]

Self Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Modifying Fund/Serv Fee

June 24, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] notice is hereby given that on June 21, 1994, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by NSCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The text of the proposed rule change is as follows:

Italicized text indicates additions

Bracketed text indicates deletions

Addendum A.

* * * * *

IV. Other Service Fees

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Q. Fund/Serv (FN10), $0.40 per side per order.

* * * * *

(10) This fee applies to Members utilizing the revised Fund/Serv service available after December 31, 1992. [Members not utilizing the revised service will continue to be charged $.50 per side per settled transaction.] *Effective July 1, 1994 for Members who do not convert to the revised Fund/Serv service by July 31, 1994, the fee will be $.75 per side per settled transaction.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

NSCC advised its members that it would discontinue the old Fund/Serv service on June 30, 1994. Because some members have not completed the conversion from the old Fund/Serv service to the new Fund/Serv service, NSCC has determined not to discontinue the old Fund/Serv service on June 30, 1994, as originally planned.

The purpose of the proposed rule change is to modify the fees charged by NSCC for the old Fund/Serv service so as to reflect, in part, the additional cost of simultaneously maintaining both versions of the Fund/Serv system. Currently, old Fund/Serv transactions are $.50 per side per settled transaction. Effective July 1, 1994, for members who do not convert to the revised Fund/Serv service by July 31, 1994, the fee will be $.75 per side per settled transaction. Members who successfully achieve conversion from the old Fund/Serv service to the new Fund/Serv service by July 31, 1994, therefore, are being given an additional one-month grace period from the effectiveness of the new fee.

SR–NASD–93–26) ("Pending Event Disclosure Approval Order").

[1] 15 U.S.C. § 78s(b)(1) (1988).

B. Self-Regulatory Organization's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have an impact on or impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments have been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act and subparagraph (e)(2) of Securities Exchange Act Rule 19b–4 in that the proposed rule change establishes or changes a due, fee, or other charge imposed by NSCC. At any time within sixty days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to File No. SR–NSCC–94–11 and should be submitted by July 26, 1994.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[2]

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16185 Filed 7–1–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–34269; File No. SR–NYSE–94–16]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the New York Stock Exchange, Inc., Relating to Audit Trail Account Identification Codes

June 28, 1994.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on April 20, 1994, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of the addition of identification codes to the Exchange's audit trail to indicate transactions that are exempt from the short sale rules.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

NYSE Rule 132 requires a clearing member firm submitting a trade to comparison to include specified audit trail data elements, including a specification of the account type for which that trade was effected according to specified account categories. Currently, the Exchange uses 12 identifiers. Three additional account type identifiers, relating to orders of competing dealers, have been approved by the Commission, but have not yet been implemented.[1] These three identifiers would be implemented upon Commission approval of the new identifiers being proposed herein.

The Exchange is proposing to expand use of the audit trail account type field to require designation of a type of trade, namely, "short exempt" trades. Four identifiers would be added to the audit trail account type field to identify "short exempt" trades for:

- The proprietary account of a clearing member organization or an affiliated member/member organization—to be designated E.
- The proprietary account of an unaffiliated member/member organization—to be designated F.
- An Individual customer account—to be designated H.
- Other agency customer account—to be designated B.

In addition, three identifiers would be added to identify "short exempt" trades of competing dealers. A competing dealer is defined as a registered specialist on another stock exchange or a marker-maker bidding and offering over-the-counter in a NYSE traded security. The identifiers, as proposed, are:

L—to designate a "short exempt" transaction for the account of a competing dealer that is a member or member organization trading for its own account

X—to designate a "short exempt" transaction where one member is acting as agent for another member's competing dealer account

Z—to designate a "short exempt" transaction for the account of a non-member competing dealer.

The Exchange is proposing the addition of older type identifiers to enhance its ability to identify violations

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[2] 17 CFR 200.30–3(a)(12) (1993).

[1] The three identifiers recently approved by the Commission consist of O, T, and R and will denote that a transaction was effected for the account of a competing dealer. The identifier "O" denotes a proprietary order for the account of a competing dealer. The identifier "T" denotes an order where one member is acting as an agent for another member's competiting dealer account. The identifier "R" denotes an order for the account of a non-member competiting dealer. *See* Securities Exchange Act Release No. 33662 (February 23, 1994), 59 FR 10027 (March 2, 1994) (order approving File No. SR–NYSE–91–46).

of SEC Rule 10a–1 [2] and Exchange Rule 440B, which prohibit short selling under specified circumstances. The rules require orders to sell to be marked as "long," or "short," or "exempt." [3]

SEC Rule 10a–1(e) [4] provides exemptions for certain orders to the prohibitions against short selling. These are limited to types of trades that are believed to be beneficial to the market or that carry little risk of the kind of manipulative or destabilizing trading that Rule 10a–1 was designed to address. By requiring identification of "short exempt" orders in the Exchange's post trade audit trail process, the Exchange will enhance its ability to examine whether trades effected pursuant to such orders were in compliance with the exceptions set forth in SEC Rule 10a–1(e).

Member firms would be given a reasonable period of time (approximately six months) to make their own system enhancements so that they may be in compliance with the new trade type identification requirements.

The Exchange is also proposing to amend its definition of competing dealer and to change the term "competing dealer" to "competing market-maker" in order to correspond more closely with the definition of market-maker included in the Act.[5]

(b) Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes the addition of the identifiers for "short exempt" trades will add to the protection of investors by enhancing the Exchange's surveillance capabilities with respect to "short" sales.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR–NYSE–94–16 and should be submitted by July 26, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16183 Filed 7–1–94; 8:45 am]

BILLING CODE 8010–01–M

[2] SEC Rule 10a–1 states, in part, that no person shall, for his own account or for the account of any other person, effect a short sale of any security registered on, or admitted to unlisted trading privileges on, a national securities exchange, if trades in such security are reported pursuant to an effective transaction reporting plan as defined in Rule 11Aa3–1, and information as to such trades is made available in accordance with such plan on a real-time basis to vendors of market transaction information, (A) below the price at which the last sale thereof, regular way, was reported pursuant to an effective transaction reporting plan; or (B) at such price unless such price is above the next preceding different price at which a sale of such security, regular way, was reported pursuant to an effective transaction reporting plan. *See* 17 CFR 240.10a–1 (1993).

[3] SEC Rule 10a–1 requires only that orders be marked "long" or "short." NYSE Rule 440B.20 provides, in effect, that orders relying on an exception to Rule 10a–1 should be marked "short exempt."

[4] 17 CFR 240.10a–1(e) (1993).

[5] The term "competing market-maker" is proposed to be defined as any person acting as a market-maker, as defined in Section 3(a)(38) of the Act, in a NYSE traded security. A person acting solely in the capacity of a block positioner would not be considered to be a competing market-maker.

[Release No. 34–34271; File No. SR–PSE–94–14]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by Pacific Stock Exchange, Inc., Relating to Assessments and Fees on Members

June 28, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 24, 1994, the Pacific Stock Exchange Incorporated ("PSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the PSE. The PSE has designated this proposal as one establishing or changing a fee under Section 19(b)(3)(A)(ii) of the Act, which renders the rule effective upon the Commission's receipt of this filing. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PSE is proposing to add new Rule 12.32 to the Rules of the Board of Governors of the PSE to require that any member named as a party to an arbitration proceeding shall be assessed a $200 non-refundable surcharge when the Arbitration Department perfects service of the claim naming the member on any party to the proceeding. Below is the text of the proposed rule change. Proposed new language is italicized.

* * * * *

Member Surcharge

Rule 12.32

(a) Each member, member organization, or associated person who is named as a party to an arbitration proceeding, whether in a Claim,

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1994).

Counterclaim, Third-Party Claim, or Crossclaim, shall be assessed a $200 non-refundable surcharge when the Arbitration Department perfects service of the claim naming the member, member organization or associated person on any party to the proceeding. For each associated person who is named, the surcharge shall be assessed against the member(s) or member organization(s) which employed the associated person at the time of the events which gave rise to the dispute, claim or controversy. No member or member organization shall be assessed more than a single surcharge in any arbitration proceeding. The surcharge shall not be subject to reimbursement under Rule 12.31.

(b) For the purposes of this Rule, service is perfected when the Arbitration Department properly serves the Respondent(s) to the arbitration proceeding under Rule 12.13(c).

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis For, The Proposed Rule Change

In its filing with the Commission, the PSE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The PSE has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The PSE is proposing to add new Rule 12.32 to provide that any member, member organization or associated person named as a party to an arbitration proceeding shall be assessed a $200 non-refundable surcharge when the Arbitration Department perfects service of the claim naming the member, member organization or associated person on any party to the proceeding. In addition, the firm whose associated persons are named in an arbitration proceeding will be assessed the surcharge.

Historically, the revenue-to-expense ratio of the PSE's arbitration service has resulted in a deficit, which has been subsidized by other revenues of the PSE. Although the deficit has declined in recent years, the Arbitration Department has determined in a recent review of the arbitration process that the deficit will begin to rise in the immediate future as a result of significantly increased resourcing needs. The PSE anticipates such needs to be ongoing. The increased resourcing needs result from a number of factors, including case growth, more complex cases being filed, more selective arbitrator recruitment, increased arbitrator training, and increased arbitrator compensation. Cost recovery for increased resourcing needs should be directed at those member firms using the PSE's arbitration service.

Proposed new Rule 12.32(a) would require each member, member organization or associated person who is named as a party to an arbitration proceeding, as a Claimant or a Respondent, in a Claim, Counterclaim, Third-Party Claim, or Crossclaim, to be assessed a $200 non-refundable surcharge when the Arbitration Department perfects service of the Claim naming the member, member organization or associated person on any party to the proceeding. This fee would be in addition to fees assessed pursuant to Rule 12.31. The fee applies both to members, member organizations and associated persons who file as Claimants and to members, member organizations and associated persons who are served by the Arbitration Department as Respondents. In a claim brought by a member, member organization or associated person against a customer, the $200 fee would be assessed in addition to the $500 claim filing fee described in the current fee schedule in Rule 12.31. For an associated person who is named as a party to an arbitration proceeding, the fee would be assessed against the member or member organization which employed the associated person at the time of the events which gave rise to the claim. However, no member or member organization will be assessed more than a single charge in any arbitration proceeding. Finally, Rule 12.32(a) clarifies that the surcharge is not subject to reimbursement under Rule 12.31.

Proposed new Rule 12.32(b) clarifies that service is considered to have been perfected when the Arbitration Department serves the Claim under Rule 12.13.

The PSE believes that the proposed rule change is consistent with the provisions of Section 6(b)(5) of the Act, which require that the rules of the Exchange provide for the equitable allocation of reasonable dues, fees and other charges among members, member organizations and associated persons in that the proposed rule equitably assesses a surcharge on each member, member organization and associated person who is named and for whom service is perfected in an arbitration proceeding and applies such revenue to additional costs resulting from increased arbitration resourcing needs.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing For Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act and subparagraph (e) of Rule 19b–4 thereunder in that it constitutes a due, fee or other charge. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the PSE. All submissions should refer to File No. SR–PSE–94–14 and should be submitted by July 26, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16187 Filed 7–1–94; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organization; Applications for Unlisted Trading Privileges; Notice and Opportunity for Hearing; Chicago Stock Exchange, Inc.

June 27, 1994.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Jalate, Ltd.
Common Stock, No Par Value (File No. 7–12589)
Alliances Entertainment Corp.
Warrants A 5/13/95 (File No. 7–12590)
Alliances Entertainment Corp.
Warrants B 5/13/95 (File No. 7–12591)
Energy Ventures, Inc.
Common Stock, $1.00 Par Value (File No. 7–12592)
Highwoods Properties, Inc.
Common Stock, $.01 Par Value (File No. 7–12593)
International Lottery, Inc.
Common Stock, $.01 Par Value (File No. 7–12594)
Liberty Property Trust
Shares of Beneficial Interest, $.001 Par Value (File No. 7–12595)
Watsco, Inc.
Common Stock, $.50 Par Value (File No. 7–12596)

These securities are listed and registered on one or more other national securities exchanges and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before July 19, 1994, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16120 Filed 7–1–94; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF THE TREASURY

Debt Management Advisory Committee; Meeting

Notice is hereby given, pursuant to 5 U.S.C. App. 10(a)(2), that a meeting will be held at the U.S. Treasury Department, 15th and Pennsylvania Avenue, NW., Washington, DC, on August 2 and 3, 1994, of the following debt management advisory committee:

Public Securities Association, Treasury Borrowing Advisory Committee

The agenda for the meeting provides for a technical background briefing by Treasury staff on August 2, followed by a charge by the Secretary of the Treasury or his designate that the committee discuss particular issues, and a working session. On August 3, the committee will present a written report of its recommendations.

The background briefing by Treasury staff will be held at 11:30 a.m. Eastern time on August 2 and will be open to the public. The remaining sessions on August 2 and the committee's reporting session on August 3 will be closed to the public, pursuant to 5 U.S.C. App. 10(d).

This notice shall constitute my determination, pursuant to the authority placed in heads of departments by 5 U.S.C. App. 10(d) and vested in me by Treasury Department Order No. 101–05, that the closed portions of the meeting are concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decision on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. App. 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the advisory committee, premature disclosure of the committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, these meetings fall within the exemption covered by U.S.C. 552b(c)(9)(A).

The Office of the Under Secretary for Domestic Finance is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552b.

Dated: June 28, 1994.

Frank N. Newman,

Under Secretary of the Treasury, Domestic Finance.

[FR Doc. 94–16154 Filed 7–1–94; 8:45 am]

BILLING CODE 4810–25–M

Fiscal Service

Renegotiation Board Interest Rate, Prompt Payment Interest Rate, Contracts Disputes Act

Although the Renegotiation Board is no longer in existence, other Federal Agencies are required to use interest rates computer under the criteria established by the Renegotiation Act of 1971 (P.L. 92–41). For example, the Contracts Disputes Act of 1978 (P.L. 95–563) and the Prompt Payment Act (P.L. 97–177) are required to calculate interest due on claims at a rate established by the Secretary of the Treasury pursuant to Public Law 92–41 (85 Stat. 97) for the Renegotiation Board (31 U.S.C. 3902).

Therefore, notice is hereby given that, pursuant to the above mentioned sections, the Secretary of the Treasury has determined that the rate of interest applicable for the purpose of said sections, for the period beginning July 1, 1994 and ending on December 31, 1994, is 7% per centum per annum.

Dated: June 28, 1994.

Marcus W. Page,

Acting Fiscal Assistant Secretary.

[FR Doc. 94–16116 Filed 7–1–94; 8:45 am]

BILLING CODE 4810–35–M

Sunshine Act Meetings

Federal Register
Vol. 59, No. 127
Tuesday, July 5, 1994

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).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Thursday, July 7, 1994.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 2lst Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Publication for comment of a draft policy statement containing standards for privately operated large-dollar multilateral netting systems.
2. Proposed 1995 Federal Reserve Board budget objective.
3. Any items carried forward from a previously announced meeting.

Note: This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: June 30, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16307 Filed 6–30–94; 3:03 pm]

BILLING CODE 6210–01–P

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: Approximately 11:00 a.m., Thursday, July 7, 1994.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 2lst Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. 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: June 30, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94–16308 Filed 6–30–94; 3:03 pm]

BILLING CODE 6210–01–P

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of July 4, 1994.

A closed meeting will be held on Thursday, July 7, 1994, at 10 a.m.

Commissioners, Counsel of the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Roberts, as duty officer, voted to consider the items listed for the closed meeting in the closed session.

The subject matter of the closed meeting scheduled for Thursday, July 7, 1994, at 10 a.m., will be:

Institution of administrative proceedings of an enforcement nature.
Settlement of administrative proceedings of an enforcement nature.
Institution of injunctive actions.
Settlement of injunctive actions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Paul Atkins (202) 942–0100.

Dated: June 29, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–16268 Filed 6–30–94; 11:44 am]

BILLING CODE 8010–01–M

Federal Register

Tuesday
July 5, 1994

Part II

Environmental Protection Agency

Sole Source Aquifer Designation of the Vashon-Maury Island Aquifer System, King County, Washington; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5006–8]

Sole Source Aquifer Designation of the Vashon-Maury Island Aquifer System, King County, Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final determination.

SUMMARY: The Region 10 Administrator of the Environmental Protection Agency (EPA) has determined that the Vashon-Maury Island Aquifer System is a sole or principal source of drinking water, and if contaminated, would create a significant hazard to public health. This action was taken under the authority of section 1424(e) of the Safe Drinking Water Act in response to a petition submitted to EPA by the Seattle-King County Department of Public Health on April 2, 1992. As a result of this determination, all federal financially assisted projects proposed in the designated area will be subject to EPA review to ensure that they do not create a significant hazard to public health.

EFFECTIVE DATE: This determination shall be promulgated for purposes of judicial review at 1:00 p.m. Eastern time on July 19, 1994.

ADDRESSES: The information upon which this determination is based is available to the public and may be inspected during normal business hours at the EPA Library, 10th Floor, Park Place Building, 1200 Sixth Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Scott E. Downey, Environmental Protection Specialist, Ground-Water Section, WD–133, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Seattle, Washington 98101, 206–553–0682.

SUPPLEMENTARY INFORMATION: This action is being taken under the authority of section 1424(e) of the Safe Drinking Water Act (42 United States Code, 300f, 300h-3(e), Public Law 93–523). The information upon which EPA is issuing this final determination has been summarized in the "Support Document for Sole Source Aquifer Designation of the Vashon-Maury Island Aquifer System", EPA 910/K–94–002.

I. Background

Section 1424(e) of the Safe Drinking Water Act states:

> If the Administrator determines, on his own initiative or upon petition, that an area has an aquifer which is the sole or principal drinking water source for the area and which, if contaminated, would create a significant hazard to public health, he shall publish notice of that determination in the **Federal Register**. After the publication of any such notice, no commitment for federal financial assistance (through a grant, contract, loan guarantee, or otherwise) may be entered into for any project which the Administrator determines may contaminate such aquifer through a recharge zone so as to create a significant hazard to public health, but a commitment for federal assistance may, if authorized under another provision of law, be entered into to plan or design the project to assure that it will not so contaminate the aquifer.

Although EPA has the authority to initiate "sole source aquifer" designations, the Agency has a policy of acting only in response to petitions. Petitions may be submitted to EPA by any individual or organization and must address procedures and criteria outlined in EPA's "Sole Source Aquifer Designation Petitioner Guidance", EPA 440/6–87–003.

On April 2, 1992, EPA Region 10 received a petition from the Seattle-King County Department of Public Health requesting that EPA designate Vashon-Maury Island as a sole source aquifer. The petition was developed in cooperation with the Vashon-Maury Island Ground Water Advisory Committee and the Vashon-Maury Island Water Utilities Coordinating Committee. Recognizing the value of the aquifer as a present and future source of drinking water, the petition was submitted as an additional way to protect the Island's ground water resources.

EPA's initial review of the petition led to a request for additional hydrogeologic and water usage information. This information was subsequently submitted to EPA by the petitioner. On October 21, 1992, the petition was considered complete enough to undergo a more detailed technical review. The technical review was completed in April of 1994 and EPA's findings and basis for the proposed designation were documented in EPA's Support Document.

II. Basis for Determination

The Region 10 Administrator has determined that the Vashon-Maury Island Aquifer System meets all applicable sole source aquifer designation criteria established through Federal statute and EPA guidance documents, as follows:

(1) Sole or Principal Source of Drinking Water: Sole source aquifers must supply at least 50 percent of the drinking water to persons living in the area overlying the aquifer and in areas supplied by the aquifer. The Vashon-Maury Island Aquifer System supplies approximately 71 percent of the drinking water to persons living on the Island.

(2) Potential Public Health Hazard: Contamination of the sole source aquifer must create a significant hazard to public health. As the principal drinking water source for the area, contamination of the Vashon-Maury Island Aquifer System would create a significant hazard to public health.

(3) Definable Aquifer Boundaries: EPA guidance allows designations to be made for entire aquifers, hydrogeologically connected aquifers (aquifer systems), or part of an aquifer if that portion is hydrogeologically separated from the rest of the aquifer. The Vashon-Maury Aquifer System boundary is based on hydrogeological principles and EPA's interpretation of available data. The Island's hydrogeology is representative of an aquifer system, as data indicate that water from shallow aquifers infiltrates to underlying deeper aquifers. The sole source aquifer boundary is coincident with the shoreline of the Island, and at depth includes all geologic units that can supply significant quantities of drinking water to wells. This boundary is assumed because stratigraphic data are not available to fully map the vertical extent of the aquifer materials.

(4) No Alternative Source of Drinking Water: There can be no physical, legal, or economically feasible alternative source(s) of drinking water of sufficient volume that could replace the sole source aquifer, should it become contaminated. EPA has determined that there are no reasonably available alternative source(s) of drinking water that could replace the aquifer.

III. Description of the Vashon-Maury Island Aquifer System

Note: Information in this section represents an unfootnoted summary from EPA's Support Document, EPA 910/K–94–002.

Vashon-Maury Island is located near the southern end of Puget Sound in the southwestern corner of King County, Washington. The Island covers an area of 36.7 square miles and its population has been estimated at approximately 7,800 persons. Recorded data indicates an average rainfall of 46.53 inches.

The aquifer system is composed of both interbedded glacial and non-glacial deposits. In general, the water table elevation reflects the surface topography and the ground water moves radially outward from the interior to the shorelines of the Island.

The uppermost and most recent deposits (Quaternary Vashon unit) are mainly stratified sand and gravel overlying glacial till and sandy gravel

interbedded with medium and fine-grained sand. The Vashon unit contains a surficial aquifer comprised primarily of glacial till which has poor water-bearing characteristics, and the uppermost fresh water aquifer (Principal Aquifer) comprised of outwash sand and gravel beds. The Principal Aquifer is found at an elevation of between 0 and 400 feet above mean sea level. Recharge of the Principal Aquifer is probably highest along a north-south corridor of west-central Vashon Island, and is estimated to be approximately 9 million gallons per day. The Principal Aquifer supplies ninety-five percent of the wells located on the Island.

Underlying the Vashon unit are non-glacial deposits (Quaternary Olympia beds) generally consisting of thin-bedded sand and silt with local layers of gravel, massive silt and clayey silt. The Olympia beds serve as a leaky aquitard between the upper Principal Aquifer and the lower Deep Aquifer. The Deep Aquifer underlies the Olympia beds and consists of a variety of interbedded glacial tills, sand and gravel units and laminated silts and clays. The Deep Aquifer is located at an elevation of between about 100 to 300 feet below mean sea level. Recharge to the Deep Aquifer is estimated at between 1.73 and 3.46 million gallons per day.

Ground water quality data was sampled from 72 wells in the aquifer area. In general, deeper wells exhibited higher specific conductance values. Elevated chloride concentrations were found in near-shore wells on the northern and eastern edges of the Island. Ground water quality trend data is limited, but combined water system and spring data indicate that source water nitrate concentrations show a generally increasing trend.

The sand interbeds within the surficial glacial till deposits allow easy infiltration, and although discontinuous, make much of the Principal Aquifer vulnerable to contamination. The Deep Aquifer is also vulnerable to contamination from activities occurring on the land surface, as evidence suggests that it receives recharge from the Principal Aquifer.

Potential sources of contamination include landfill leachate, on-site sewage disposal systems, leaky sewer lines, underground storage tanks, agricultural chemicals, small hazardous waste generators, accidental spills, seawater intrusion, and improper household, forestry and farm practices.

The Island has one publicly-owned water well (the largest water system on the Island), at least six large private water systems, and more than 100 smaller water systems. Some purveyors use both surface water and ground water to supply their distribution system. In addition, private wells provide water to a considerable number of houses and businesses across the Island. It is estimated that 71% of the water supplied to households on the Island is from ground water and 29% is from surface water sources. There are no alternative sources of drinking water for the Island that can be physically, legally, and economically supplied.

IV. Project Reviews

Designation of a sole source aquifer authorizes EPA to review federal financially-assisted projects proposed within the designated area. The principal mechanism used by EPA Region 10 to identify projects for review are Memorandums of Understanding (MOUs) with federal funding agencies. These MOUs outline procedures for screening and referring projects to EPA in order to ensure that only projects which may have a significant impact to ground water quality are reviewed.

Most projects referred to EPA for review meet all federal, state, and local ground water protection standards and are approved without any additional conditions being imposed. Occasionally, site or project-specific concerns for ground water quality protection lead to specific recommendations or additional pollution prevention requirements as a condition of funding. In rare cases, federal funding has been denied when the applicant has been either unwilling or unable to modify the project.

Whenever feasible, EPA coordinates the review of proposed projects with other offices within EPA and with various federal, state, or local agencies that have a responsibility for ground water quality protection. Relevant information from these sources is given full consideration in the sole source aquifer review process. Such coordination can complement, support, and strengthen existing ground water protection mechanisms.

V. Public Comments

EPA issued a news release (April 12, 1994) and a public notice (April 14, 1994) to request comments and announce the proposed designation. Both stated that a public hearing would be held if sufficient interest were expressed to EPA in advance. No requests for a formal hearing were received and it was subsequently cancelled.

Five written comments were received prior to the expiration of the public comment period on June 1, 1994. Three letters were from Vashon Island residents and expressed support for the proposed designation. One letter was from the King County Department of Public Works, Roads and Engineering Division, and requested information and coordination of future federal financially-assisted road projects on the Island. Another letter was from the Bureau of Reclamation and stated there were no ongoing or proposed federal financially-assisted projects within the area. No controversial issues were raised as a result of this proposed action.

VI. Summary

This determination affects only the Vashon-Maury Island Aquifer System located in King County, Washington. As a result of this determination, all federal financially-assisted projects proposed in the designated area will be subject to EPA review to ensure that they do not create a significant hazard to public health.

Dated: June 17, 1994.

Chuck Clarke,

Regional Administrator, U.S. Environmental Protection Agency, Region 10.

[FR Doc. 94–16220 Filed 7–1–94; 8:45 am]

BILLING CODE 6560–60–P

federal register

Tuesday
July 5, 1994

Part III

Department of Health and Human Services

National Institutes of Health

Recombinant DNA Research: Actions Under the Guidelines; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research: Actions Under the Guidelines

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of actions under the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: This notice sets forth four actions to be taken by the Director, National Institutes of Health (NIH), under the May 7, 1986, NIH Guidelines (51 FR 16958).

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities (ORDA), Office of Science Policy and Technology Transfer, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

SUPPLEMENTARY INFORMATION: Today four actions are being promulgated under the NIH Guidelines. These four proposed actions were published for comment in the **Federal Register** announcements of August 11, 1987 (52 FR 29800); April 18, 1988 (53 FR 12752); December 30, 1988 (53 FR 53262); April 29, 1991 (56 FR 19776); November 9, 1993 (58 FR 59612); and February 11, 1994 (59 FR 6702). These proposed actions were reviewed and recommended for approval by the NIH Recombinant DNA Advisory Committee (RAC) at its meetings on September 21, 1987; December 3, 1988; January 30, 1989; May 30–31, 1991; December 2–3, 1993; and March 3–4, 1994.

In accordance with Section IV-C-1-b of the NIH Guidelines, these actions have been found to comply with the NIH Guidelines and to present no significant risk to health or the environment.

A revised version of the NIH Guidelines is published in a separate section of the **Federal Register** following this announcement. These revised NIH Guidelines differ from the previous version promulgated on May 7, 1986 (51 FR 16958) by incorporating within them the major actions to the NIH Guidelines that were promulgated on August 24, 1987 (52 FR 31848); July 29, 1988 (53 FR 28819); October 26, 1988 (53 FR 43410); March 13, 1989 (54 FR 10508); March 1, 1990 (55 FR 7438); September 12, 1990 (55 FR 37565); July 18, 1991 (56 FR 33174); October 15, 1991 (56 FR 51784); November 21, 1991 (56 FR 58800); January 28, 1992 (57 FR 3212); April 22, 1992 (57 FR 14774); August 26, 1992 (57 FR 38734); February 18, 1993 (58 FR 9102); April 23, 1993 (58 FR 21738); September 13, 1993 (58 FR 47906); October 18, 1993 (58 FR 53814); and the changes that are promulgated in this announcement.

I. Background Information and Decision on Action Under the NIH Guidelines

A. Amendment to Sections II, III–C, III–D, V, Appendices C–I, and G and Addition of Appendix P, Physical and Biological Containment for Recombinant DNA Research Involving Plants, and Appendix Q, Physical and Biological Containment for Recombinant DNA Research Involving Animals of the NIH Guidelines

The NIH Guidelines were originally developed to cover research in laboratories in which recombinant DNA techniques were used. It is recognized today that these techniques are being used by scientists working with plants and large animals, and that procedures for containment of these plants and animals have not been specifically described in the NIH Guidelines. Institutional Biosafety Committees (IBCs) have requested guidance on the containment procedures that should be recommended for specific experiments with these organisms since they have the responsibility of approving such experiments under containment appropriate for the organisms. The principles of biological safety that are used to categorize experiments involving microorganisms, for example, are equally applicable to plants and animals. These safety procedures have been employed successfully for many years and have been recognized for their efficacy in biological containment.

Appendices P and Q are the result of several years of meetings and discussions involving research scientists and representatives from university, government, and industrial research sectors with expertise in several disciplines, including plant genetics, plant physiology, plant pathology, entomology, animal (including arthropod and aquatic species) physiology and reproduction, molecular biology, veterinary medicine, and human biomedical research. The Federal agencies involved in the development of Appendices P and Q include the NIH, the National Science Foundation (NSF), and the U.S. Department of Agriculture (USDA).

The process of developing Appendices P and Q was initiated when the USDA published an Advanced Notice of Proposed USDA Guidelines (USDA Guidelines) in the **Federal Register** on June 26, 1986 (51 FR 23367). This notice was followed by an announcement by the USDA regarding its intent to propose new guidelines for conducting all phases of research with domestic agriculture species, including both plants and animals modified through the application of genetic engineering techniques, in the **Federal Register** on December 9, 1986 (51 FR 44397). At that time, the NIH Guidelines did not include specific descriptions for containment conditions for research involving recombinant DNA containing whole plants and animals. The USDA convened a working group composed of university, government, and industrial scientists on December 13–14, 1986, with the purpose of discussing and redrafting guidelines for physical and biological containment of transgenic plant and animal species, and associated microorganisms. This meeting came to be known as the "Arlington House Workshop."

Participants of the "Arlington House Workshop," including former members of the RAC, agreed that the USDA Guidelines should be incorporated into the NIH Guidelines. The workshop participants noted that merging these two documents would offer the distinct advantage of providing a single comprehensive source of information regarding conduct of research involving organisms containing recombinant DNA and plants and animals exposed to microorganisms containing recombinant DNA.

A staff working group representing the Office of Recombinant DNA Activities, NIH, and the Cooperative State Research Service, USDA, held meetings during the following six months. This working group met with the purpose of revising the containment section and developing a final incorporated document for RAC review, approval by the NIH Director, and incorporation into the NIH Guidelines.

On June 28, 1987, and July 16, 1987, the RAC appointed the Working Group on Revision of the NIH Guidelines to meet and consider the draft documents, Appendices P and Q, and minor modifications to the NIH Guidelines, that would accommodate the proposed appendices. Appendices P and Q and the proposed revisions to the NIH Guidelines were published for public comment in the **Federal Register** on August 11, 1987 (52 FR 29800). Additional revisions to Appendices P and Q were proposed by the RAC and the Agricultural Research Service, USDA, at the September 17, 1987, RAC meeting. These modifications were

published for public comment in the Federal Register on December 30, 1988 (53 FR 53262). The RAC Working Group on Transgenic Animals proposed additional modifications to Appendices P and Q which were published for public comment in the Federal Register on April 18, 1988 (53 FR 12752). Further revisions were approved by the RAC at its January 30, 1989, meeting.

Throughout all of the meetings, discussions, and revisions, the intent of the Federal agencies and interested parties has been to describe working conditions that would minimize the risk to both the researcher and the environment from any possible harm or adverse effects due to the conduct of research involving recombinant DNA containing organisms.

On June 24, 1994, an Environmental Assessment of Appendices P and Q was completed by the NIH and USDA, and there was a finding of no significant impact. Copies of the Environmental Assessment are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

The actions are detailed in Section II—Summary of Actions. I accept these recommendations, and the NIH Guidelines will be amended accordingly.

B. Amendment to Sections I-C-1-b-(2) and Deletion of Section III–A–2 of the NIH Guidelines Regarding Deliberate Release

On December 6, 1990, the RAC Planning Subcommittee recommended that the requirement for RAC review of experiments involving deliberate environmental release of organisms containing recombinant DNA be eliminated from the NIH Guidelines. This recommendation reflects the fact that the Federal regulatory agencies, the USDA, and the Environmental Protection Agency (EPA), are responsible for the review and approval of environmental release experiments. The proposed amendment was published for public comment in the Federal Register on April 29, 1991 (56 FR 19776). The RAC reviewed and recommended approval of the proposed amendment at its May 30–31, 1991, meeting.

The actions are detailed in Section II—Summary of Actions. I accept these recommendations, and the NIH Guidelines will be amended accordingly.

C. Amendments to Sections I, III, IV, and V, and Appendix M of the NIH Guidelines Regarding NIH/ORDA Review and Approval of Certain Categories of Human Gene Transfer Experiments That Qualify for the Accelerated Review Process

On December 3, 1993, and March 3–4, 1994, the Working Group on Accelerated Review Protocols presented an overview of the proposed amendments to the NIH Guidelines. The proposed amendments will: (1) Establish an accelerated review process for certain categories of human gene transfer experiments, (2) allow the NIH/Office of Recombinant DNA Activities to assign the appropriate review category to all human gene transfer proposals that are submitted in compliance with the NIH Guidelines, (3) allow the NIH/Office of Recombinant DNA Activities to approve those categories of human gene transfer experiments that qualify for the accelerated review process in consultation with the Chair and one or more RAC members, as necessary, and (4) exempt certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects which are not covered by Section V–U. All human gene transfer experiments approved by the NIH/Office of Recombinant DNA Activities through the accelerated review process will be provided in a report by the RAC Chair at the next regularly scheduled RAC meeting and will be included in the list of approved experiments which is available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

The proposed amendments were published for public comment in the Federal Register on November 9, 1993 (58 FR 59612) and February 11, 1994 (59 FR 6702). The RAC reviewed and unanimously recommended approval of the proposed amendments at its March 3–4, 1994, meeting.

The actions are detailed in Section II—Summary of Actions. I accept these recommendations, and the NIH Guidelines will be amended accordingly.

D. Amendments to Section V–U of the NIH Guidelines Regarding Recombinant DNA Vaccines

On March 3, 1994, the Working Group on Vaccines presented an overview of the proposed amendment to the footnote in Section V–U. The proposed amendment will define those categories of experiments involving the administration of recombinant DNA vaccines that are exempt from RAC review and NIH and Institutional Biosafety Committee approval.

The proposed amendment was published for public comments in the Federal Register on February 11, 1994 (59 FR 6702). The proposed amendment was revised by the RAC at its March 3–4, 1994, meeting. The revised amendment was unanimously approved.

The action is detailed in Section II—Summary of Actions. I accept this recommendation, and the NIH Guidelines will be amended accordingly.

II. Summary of Actions

A. Amendment to Section I, Scope of the NIH Guidelines

The amended version of Section I reads as follows:

Section I. Scope of the NIH Guidelines

Section I–A. Purpose

The purpose of the NIH Guidelines is to specify practices for constructing and handling: (i) Recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

Section I–A–1. Any recombinant DNA experiment, which according to the NIH Guidelines requires approval by the NIH, must be submitted to the NIH or to another Federal agency that has jurisdiction for review and approval. Once approval, or other applicable clearances, has been obtained from a Federal agency other than the NIH (whether the experiment is referred to that agency by the NIH or sent directly there by the submitter), the experiment may proceed without the necessity for NIH review or approval (see exceptions in Sections I–A–2 and I–A–3).

Section I–A–2. Certain experiments that involve the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) shall be considered Major Actions (see Section IV-C-1-b-(1)), and shall require RAC review and NIH Director approval, if determined by NIH/ORDA in consultation with the RAC Chair and/or one or more RAC members, as necessary, to: (i) Represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review (see Section III–A–2).

Section I–A–3. Experiments involving the transfer of recombinant DNA to one or more human subjects that are not considered under Section III–A–2 may qualify for Accelerated Review (see Section III–B–2 and Appendix M–V) and will be considered as Minor Actions (see Section IV-C-1-b-(2)-(a)). Actions that qualify for Accelerated Review will be reviewed and approved by NIH/ORDA in consultation with the RAC Chair and/or one or more RAC members, as necessary.

Certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) may be considered exempt from RAC and/or NIH/ORDA review and/or NIH Director approval and only require registration with NIH/ORDA (see Section III–C–7).

Section I–B. Definition of Recombinant DNA Molecules

In the context of the NIH Guidelines, recombinant DNA molecules are defined as either: (i) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

Section I–C. General Applicability

Section I–C–1. The NIH Guidelines are applicable to:

Section I-C-1-a. All recombinant DNA research within the United States (U.S.) or its territories that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from the NIH, including research performed directly by the NIH. An individual who receives support for research involving recombinant DNA must be associated with or sponsored by an institution that assumes the responsibilities assigned in the NIH Guidelines.

Section I-C-1-b. All recombinant DNA research performed abroad: Specifically:

Section I-C-1-b-(1). Research supported by NIH funds.

Section I-C-1-b-(2). If they involve testing in humans of materials containing recombinant DNA developed with NIH funds and if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section I-C-1-b-(3). If the host country has established rules for the conduct of recombinant DNA research, then the research must be in compliance with those rules. If the host country does not have such rules, the proposed research must be reviewed and approved by an NIH-approved Institutional Biosafety Committee or equivalent review body and accepted in writing by an appropriate national governmental authority of the host country. The safety practices that are employed abroad must be reasonably consistent with the NIH Guidelines.

Section I-D. General Definitions

The following terms, which are used throughout the NIH Guidelines, are defined as follows:

Section I-D–1. An 'institution' is any public or private entity (including Federal, state, and local government agencies).

Section I-D–2. An 'Institutional Biosafety Committee' is a committee that: (i) meets the requirements for membership specified in Section IV-B–2, and (ii) reviews, approves, and oversees projects in accordance with the responsibilities defined in Section IV-B–2.

Section I-D–3. The 'Office of Recombinant DNA Activities (ORDA)' is the office within the NIH that is responsible for: (i) Reviewing and coordinating all activities relating to the NIH Guidelines, and (ii) performing other duties as defined in Section IV-C–3.

Section I-D–4. The 'Recombinant DNA Advisory Committee' is the public advisory committee that advises the Department of Health and Human Services (DHHS) Secretary, the DHHS Assistant Secretary for Health, and the NIH Director concerning recombinant DNA research. The RAC shall be constituted as specified in Section IV-C–2.

Section I-D–5. The 'NIH Director' is the Director of the National Institutes of Health, or any other officer or employee of NIH to whom authority has been delegated.

Section I-D–6. 'Deliberate release' is defined as a planned introduction of recombinant DNA-containing microorganisms, plants, or animals into the environment.

B. Amendment to Section II, Containment, of the NIH Guidelines

The amended version of Section II reads as follows:

Section II. Containment

Effective biological safety programs have been operative in a variety of laboratories for many years. Considerable information already exists about the design of physical containment facilities and selection of laboratory procedures applicable to organisms carrying recombinant DNA (see Section V-A). The existing programs rely upon mechanisms that can be divided into two categories: (i) A set of standard practices that are generally used in microbiological laboratories; and (ii) special procedures, equipment, and laboratory installations that provide physical barriers that are applied in varying degrees according to the estimated biohazard. Four biosafety levels are described in Appendix G. These biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and are based on the potential hazards imposed by the agents used and for the laboratory function and activity. Biosafety Level 4 provides the most stringent containment conditions, Biosafety Level 1 the least stringent.

Experiments involving recombinant DNA lend themselves to a third containment mechanism, namely, the application of highly specific biological barriers. Natural barriers exist that limit either: (i) The infectivity of a vector or vehicle (plasmid or virus) for specific hosts, or (ii) its dissemination and survival in the environment. Vectors, which provide the means for recombinant DNA and/or host cell replication, can be genetically designed to decrease, by many orders of magnitude, the probability of dissemination of recombinant DNA outside the laboratory (see Appendix I).

Since these three means of containment are complementary, different levels of containment can be established that apply various combinations of the physical and biological barriers along with a constant use of standard practices. Categories of containment are considered separately in order that such combinations can be conveniently expressed in the NIH Guidelines.

Physical containment conditions within laboratories, described in Appendix G, may not always be appropriate for all organisms because of their physical size, the number of organisms needed for an experiment, or the particular growth requirements of the organism. Likewise, biological containment for microorganisms described in Appendix I may not be appropriate for all organisms, particularly higher eukaryotic organisms. However, significant information exists about the design of research facilities and experimental procedures that are applicable to organisms containing recombinant DNA that is either integrated into the genome or into microorganisms associated with the higher organism as a symbiont, pathogen, or other relationship. This information describes facilities for physical containment of organisms used in non-traditional laboratory settings and special practices for limiting or excluding the unwanted establishment, transfer of genetic information, and dissemination of organisms beyond the intended location, based on both physical and biological containment principles. Research conducted in accordance with these conditions effectively confines the organism.

For research involving plants, four biosafety levels (BL1–P through BL4–P) are described in Appendix P. BL1–P is designed to provide a moderate level of containment for experiments for which there is convincing biological evidence that precludes the possibility of survival, transfer, or dissemination of recombinant DNA into the environment, or in which there is no recognizable and predictable risk to the environment in the event of accidental release. BL2–P is designed to provide a greater level of containment for experiments involving plants and certain associated organisms in which there is a recognized possibility of survival, transmission, or dissemination of recombinant DNA containing organisms, but the consequence of such an inadvertent release has a predictably minimal biological impact. BL3–P and BL4–P describe additional containment conditions for research with plants and certain pathogens and other organisms that require special containment because of their recognized potential for significant detrimental impact on managed or natural ecosystems. BL1–P relies upon accepted scientific practices for conducting research in most ordinary greenhouse or growth chamber facilities and incorporates accepted procedures for good pest control and cultural practices. BL1–P facilities and procedures provide a modified and protected environment for the propagation of plants and microorganisms associated with the plants and a degree of containment that adequately controls the potential for release of biologically viable plants, plant parts, and microorganisms associated with them. BL2–P and BL3–P rely upon accepted scientific practices for conducting research in greenhouses with organisms infecting or infesting plants in a manner that minimizes or prevents inadvertent contamination of plants within or surrounding the greenhouse. BL4–P describes facilities and practices known to provide containment of certain exotic plant pathogens.

For research involving animals, which are of a size or have growth requirements that preclude the use of conventional primary containment systems used for small laboratory animals, four biosafety levels (BL1–N through BL4–N) are described in Appendix Q. BL1–N describes containment for animals that have been modified by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms and is designed to eliminate the possibility of sexual transmission of the modified genome or transmission of recombinant DNA-derived viruses known to be transmitted from animal parent to offspring only by sexual reproduction. Procedures, practices, and facilities follow classical methods of avoiding genetic exchange between animals. BL2–N describes containment which is used for transgenic animals associated with recombinant DNA-derived organisms and is designed to eliminate the possibility of vertical or horizontal transmission. Procedures, practices, and facilities follow classical methods of avoiding genetic exchange between animals or controlling arthropod transmission. BL3–N and BL4–N describe higher levels of containment for research with certain transgenic animals involving agents which pose recognized hazard.

In constructing the NIH Guidelines, it was necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. These definitions do not take into account all existing and anticipated information on special procedures that will allow particular experiments to be conducted under different conditions than indicated here without affecting risk. Individual investigators and Institutional Biosafety Committees are urged to devise simple and more effective containment procedures and to submit recommended changes in the NIH Guidelines to permit the use of these procedures."

C. Amendment to Section III, Experiments Covered by the NIH Guidelines

The previous version of Section III-A–2 will be deleted as follows:

Section III-A–2. Deliberate release into the environment of any organism containing recombinant DNA except those listed below. The term 'deliberate release' is defined as a planned introduction of recombinant DNA-containing microorganisms, plants, or animals into the environment.

Section III-A–2-a. Introduction conducted under conditions considered to be accepted scientific practices in which there is adequate evidence of biological and/or physical control of the recombinant DNA-containing organisms. The nature of such evidence is described in Appendix L.

Section III-A–2-b. Deletion derivatives and single base changes not otherwise covered by the NIH Guidelines.

Section III-A–2-c. For extrachromosomal elements and microorganisms (including viruses), rearrangements and amplifications within a single genome. Rearrangements involving the introduction of DNA from different strains of the same species would not be covered by this exemption."

The amended version of Section III reads as follows:

Section III. Experiments Covered by the NIH Guidelines.

This section describes five categories of experiments involving recombinant DNA: (i) Those that require RAC review and NIH and Institutional Biosafety Committee approval before initiation (see Section III-A), (ii) those that require NIH/ORDA and Institutional Biosafety Committee approval before initiation (see Section III-B); (iii) those that require Institutional Biosafety Committee approval before initiation (see Section III-C), (iv) those that require Institutional Biosafety Committee notification simultaneous with initiation (see Section III-D), and (v) those that are exempt from the NIH Guidelines (see Section III-E).

Note: If an experiment falls into either Section III-A or Section III-B and one of the other categories, the rules pertaining to Section III-A or Section III-B shall be followed. If an experiment falls into Section III-E and into either Sections III-C or III-D categories as well, the experiment is considered exempt from the NIH Guidelines.

Any change in containment level, which is different from those specified in the NIH Guidelines, may not be initiated without the express approval of NIH/ORDA (see Minor Actions, Section IV-C-1-b-(2) and its subsections).

Section III–A. Experiments That Require Institutional Biosafety Committee Approval, RAC Review, and NIH Approval Before Initiation

Experiments in this category are considered Major Actions (see Section IV-C-1-b-(1)) and cannot be initiated without submission of relevant information on the proposed experiment to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838, the publication of the proposal in the **Federal Register** for 15 days of comment, reviewed by the RAC, and specific approval by the NIH (not applicable for Expedited Review single patient human gene transfer experiments considered under Appendix M-VI). The containment conditions for such experiments will be recommended by the RAC and set by the NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D which may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section III–A–1. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V–B), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

Section III–A–2. Certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) shall be considered Major Actions (see Section IV–C–1–b–(1) and Appendix M–III), and shall require RAC review and NIH Director approval, if determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, to: (i) represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review. The requirement for RAC review shall not be considered to preempt any other required review or approval of experiments with one or more human subjects. Relevant Institutional Biosafety Committee and Institutional Review Board reviews and approvals of the proposal should be completed before submission to NIH. Certain experiments involving deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects may qualify for the Accelerated Review process (see Section III–B–2). Certain categories of experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects and that are not covered by Section V–U, may be considered exempt from RAC and/or NIH/ORDA review and/or NIH Director approval and only require registration with NIH/ORDA (see Section III–C–7).

Section III–B. Experiments That Require NIH/ORDA and Institutional Biosafety Committee Approval Before Initiation

Section III–B–1. Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less Than 100 Nanograms per Kilogram Body Weight

Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin). Specific approval has been given for the cloning in *Escherichia coli* K–12 of DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 nanograms to 100 micrograms per kilogram body weight. Specific experiments already approved under this section may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section III–B–1–(a). Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH/ORDA. The containment conditions for such experiments will be determined by NIH/ORDA in consultation with ad hoc experts. Such experiments require Institutional Biosafety Committee approval before initiation (see Section IV–B–2–b–(1)).

Section III–B–2. Accelerated Review of Human Gene Transfer Experiments

As determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, certain categories of human gene transfer experiments may be considered as Minor Actions and qualify for Accelerated Review and approval (see Section IV–C–1–b–(2)–(a), Appendix M–III–A, and Appendix M–V). The RAC Chair will present a report of all NIH/ORDA approved human gene transfer protocols at the next regularly scheduled RAC meeting. If NIH/ORDA determines that an experiment does not qualify for the Accelerated Review process, the Principal Investigator must submit the proposal for full RAC review ≥ 8 weeks prior to the next scheduled RAC meeting (See Section III–A–2).

Section III–B–3. Minor Modifications to Human Gene Transfer Experiments

A minor modification in a human gene transfer protocol is a modification that does not significantly alter the basic design of the protocol and that does not increase risk to human subjects or the environment. After approval has been obtained by the relevant Institutional Biosafety Committee and Institutional Review Board, NIH/ORDA will consider the change in consultation with the RAC Chair and one or more RAC members, as necessary. Submit minor modifications to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. The RAC Chair will provide a report on any such approvals at the next regularly scheduled RAC meeting.

Section III–C. Experiments That Require Institutional Biosafety Committee Approval Before Initiation

Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information: (i) The source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the NIH Guidelines. For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee. The Institutional Biosafety Committee shall review and approve all

experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by NIH (see Section IV–C–1–b–(2)–(c)).

Section III–C–1. Experiments Using Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 Agents (See Section V–A) as Host-Vector Systems

Section III–C–1–a. Experiments involving the introduction of recombinant DNA into Class 2 agents shall be conducted at Biosafety Level (BL) 2 containment. Experiments with such agents shall be conducted with whole animals at BL2 or BL2–N (Animals) containment.

Section III–C–1–b. Experiments involving the introduction of recombinant DNA into Class 3 agents shall be conducted at BL3 containment. Experiments with such agents shall be conducted with whole animals at BL3 or BL3–N containment.

Section III–C–1–c. Experiments involving the introduction of recombinant DNA into Class 4 agents shall be conducted at BL4 containment. Experiments with such agents shall be conducted with whole animals at BL4 or BL4–N containment.

Section III–C–1–d. Containment conditions for experiments involving the introduction of recombinant DNA into Class 5 agents shall be set on a case-by-case basis following NIH/ORDA review. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Sections V–R and V–T). Experiments with such agents shall be conducted with whole animals at BL4 or BL4–N containment.

Section III–C–2. Experiments in Which DNA From Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 Agents (See Section V–A) is Cloned Into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems

Section III–C–2–a. Experiments in which DNA from Class 2 or Class 3 agents (see Section V–A) is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment. Experiments in which DNA from Class 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. In the absence of such a demonstration, BL4 containment shall be used. The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BL1. Many experiments in this category are exempt from the NIH Guidelines (see Section III–E). Experiments involving the formation of recombinant DNA for certain genes coding for molecules toxic for vertebrates require NIH/ORDA approval (see Section III–B–1) or shall be conducted under NIH specified conditions as described in Appendix F.

Section III–C–2–b. Containment conditions for experiments in which DNA from Class 5 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes shall be determined by NIH/ORDA following a case-by-case review. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Sections V–R and V–T).

Section III–C–3. Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems

Caution: Special care should be used in the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of viral vectors under conditions that permit a productive infection. In such cases, serious consideration should be given to increasing physical containment by at least one level.

Note: Recombinant DNA or RNA molecules derived therefrom, which contain less than two–thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V–Q) being considered identical (see Section V–S), are considered defective and may be used in the absence of helper under the conditions specified in Section III–D–1.

Section III–C–3–a. Experiments involving the use of infectious or defective Class 2 animal viruses (see Section V–A, Appendix B–II, and Appendix B–II–E) in the presence of helper virus may be conducted at BL2.

Section III–C–3–b. Experiments involving the use of infectious or defective Class 3 animal viruses (see Section V–A and Appendix B–III–D) in the presence of helper virus may be conducted at BL3.

Section III–C–3–c. Experiments involving the use of infectious or defective Class 4 animal viruses (see Section V–A and Appendix B–IV–D) in the presence of helper virus may be conducted at BL4.

Section III–C–3–d. Experiments involving the use of infectious or defective Class 5 viruses (see Section V–A and Appendix B–V) in the presence of helper virus shall be determined on a case-by-case basis following NIH/ORDA review. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Sections V–R and V–T).

Section III–C–3–e. Experiments involving the use of infectious or defective animal or plant viruses in the presence of helper virus are not covered in Sections III–C–3–a through III–C–3–d and may be conducted at BL1.

Section III–C–4. Experiments Involving Whole Animals

This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BL1–N containment. A minimum containment of BL2 or BL2–N is required.

Caution—Special care should be used in the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions.

Section III–C–4–a. Recombinant DNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1–N and appropriate to the organism under study (see Section V–B).

Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1–N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III–C–4–b. For experiments involving recombinant DNA-modified Class 2, 3, 4, or 5 organisms, see Section V–A. It is important that the investigator

demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Section V–R and V–T).

Section III–C–4–b. For experiments involving recombinant DNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III–C–1 or III–C–4–a, the appropriate containment shall be determined by the Institutional Biosafety Committee.

Section III–C–5. Experiments Involving Whole Plants

Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA, may be conducted under the containment conditions described in Sections III–C–5–a through III–C–5–e. If experiments involving whole plants are not described in Section III–C–5 and do not fall under Sections III–A, III–B, or III–E, they are included in Section III–D.

Note. For recombinant DNA experiments falling under Sections III–C–5–a through III–C–5–d, physical containment requirements may be reduced to the next lower level by appropriate biological containment practices, such as conducting experiments on a virus with an obligate insect vector in the absence of that vector or using a genetically attenuated strain.

Section III–C–5–a. BL3–P (Plants) or BL2–P + biological containment is recommended for experiments involving most exotic (see Section V–W) infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants.

Section III–C–5–b. BL3–P or BL2–P + biological containment is recommended for experiments involving plants containing cloned genomes of readily transmissible exotic (see Section V–W) infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation *in planta*.

Section III–C–5–c. BL4–P containment is recommended for experiments with a small number of readily transmissible exotic (see Section V–W) infectious agents, such as the soybean rust fungus (*Phakospora pachyrhizi*) and maize streak or other viruses in the presence of their specific arthropod vectors, that have the potential of being serious pathogens of major U.S. crops.

Section III–C–5–d. BL3–P containment is recommended for experiments involving sequences encoding potent vertebrate toxins introduced into plants or associated organisms. Recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of <100 nanograms per kilogram body weight fall under Section III–B–1 and require NIH/ORDA and Institutional Biosafety Committee approval before initiation.

Section III–C–5–e. BL3–P or BL2–P + biological containment is recommended for experiments with microbial pathogens of insects or small animals associated with plants if the recombinant DNA-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems.

Section III–C–6. Experiments Involving More than 10 Liters of Culture

The appropriate containment will be decided by the Institutional Biosafety Committee. Where appropriate, Appendix K, Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules, shall be used. Appendix K describes containment conditions Good Large Scale Practice through BL3–Large Scale.

Section III–C–7. Human Gene Transfer Experiments Not Covered by Sections III–A–2, III–B–2, III–B–3, and Not Considered Exempt Under Section V–U

Certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that are not covered by Sections III–A–2, III–B–2, III–B–3, and that are not considered exempt under Section V–U must be registered with NIH/ORDA. The relevant Institutional Biosafety Committee and Institutional Review Board must review and approve all experiments in this category prior to their initiation.

Section III–D. Experiments That Require Institutional Biosafety Committee Notice Simultaneous With Initiation

Experiments not included in Sections III–A, III–B, III–C, III–E, and their subsections are considered in Section III–D. All such experiments may be conducted at BL1 containment. For experiments in this category, a registration document (see Section III–C) shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated. The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required (see Section IV–A). For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under Section III–D and may be conducted at BL1 containment.

Section III–D–1. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More Than Two-Thirds of the Genome of Any Eukaryotic Virus

Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V–Q) being considered identical (see Section V–S)) may be propagated and maintained in cells in tissue culture using BL1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III–C–3 should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Section III-D–2. Experiments Involving Whole Plants

This section covers experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-C, or III-E. It should be emphasized that knowledge of the organisms and judgment based on accepted scientific practices should be used in all cases in selecting the appropriate level of containment. For example, if the genetic modification has the objective of increasing pathogenicity or converting a non-pathogenic organism into a pathogen, then a higher level of containment may be appropriate depending on the organism, its mode of dissemination, and its target organisms. By contrast, a lower level of containment may be appropriate for small animals associated with many types of recombinant DNA-modified plants.

Section III-D-2-a. BL1–P is recommended for all experiments with recombinant DNA-containing plants and

plant-associated microorganisms not covered in Section III-D–2-b or other sections of the NIH Guidelines. Examples of such experiments are those involving recombinant DNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area, and experiments involving whole plants and recombinant DNA-modified non-exotic (see Section V-W) microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., *Rhizobium* spp. and *Agrobacterium* spp.).

Section III-D–2-b. BL2–P or BL1–P + biological containment is recommended for the following experiments:

Section III-D–2-b-(1). Plants modified by recombinant DNA that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.

Section III-D–2-b-(2). Plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent (see Section V-W).

Section III-D–2-b-(3). Plants associated with recombinant DNA-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems (see Section V-W).

Section III-D–2-b-(4). Plants associated with recombinant DNA-modified exotic microorganisms that have no recognized potential for serious natural ecosystems (see Section V-W).

Section III-D–2-b-(5). Experiments with recombinant DNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant DNA-modified microorganisms associated with them if the recombinant DNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems (see Section V-W).

Section III-E. Exempt Experiments

The following recombinant DNA molecules are exempt from the NIH Guidelines and registration with the Institutional Biosafety Committee is not required:

Section III-E–1. Those that are not in organisms or viruses.

Section III-E–2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

Section III-E–3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

Section III-E–4. Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

Section III-E–5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C–1-b-(1)-(c)). See Appendices A-I through A-VI for a list of natural exchangers that are exempt from the NIH Guidelines.

Section III-E–6. Those that do not present a significant risk to health or the environment (see Section IV-C–1-b-(1)-(c)), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C for other classes of experiments which are exempt from the NIH Guidelines."

D. Amendment to Section IV, Roles and Responsibilities of the NIH Guidelines

The amended version of Section IV-C–1-b reads as follows:

Section IV-C–1-b. Specific Responsibilities [NIH Director]

In carrying out the responsibilities set forth in this section, the NIH Director, or a designee shall weigh each proposed action through appropriate analysis and consultation to determine whether it complies with the NIH Guidelines and presents no significant risk to health or the environment.

Section IV-C–1-b-(1). Major Actions

To execute Major Actions, the NIH Director shall seek the advice of the RAC and provide an opportunity for public and Federal agency comment. Specifically, the Notice of Meeting and Proposed Actions to the NIH Guidelines shall be published in the **Federal Register** at least 15 days before the RAC meeting (not applicable for Expedited Review single patient human gene transfer experiments considered under Appendix M-VI). The NIH Director's decision, at his/her discretion, may be published in the **Federal Register** for 15 days of comment before final action is taken. The NIH Director's final decision, along with responses to public comments, shall be published in the **Federal Register**. The RAC and Institutional Biosafety Committee Chairs shall be notified of the following decisions:

Section IV-C–1-b-(1)-(a). Changing containment levels for types of experiments that are specified in the NIH Guidelines when a Major Action is involved;

Section IV-C–1-b-(1)-(b). Assigning containment levels for types of experiments that are not explicitly considered in the NIH Guidelines when a Major Action is involved;

Section IV–C–1–b–(1)–(c). Promulgating and amending a list of classes of recombinant DNA molecules to be exempt from the NIH Guidelines because they consist entirely of DNA segments from species that exchange DNA by known physiological processes or otherwise do not present a significant risk to health or the environment;

Section IV–C–1–b–(1)–(d). Permitting experiments specified by Section III–A;

Section IV–C–1–b–(1)–(e). Certifying new host-vector systems with the exception of minor modifications of already certified systems (the standards and procedures for certification are described in Appendix I–II). Minor modifications constitute (e.g., those of minimal or no consequence to the properties relevant to containment); and

Section IV–C–1–b–(1)–(f). Adopting other changes in the NIH Guidelines.

Section IV–C–1–b–(2). Minor Actions

NIH/ORDA shall carry out certain functions as delegated to it by the NIH Director (see Section IV–C–3). Minor Actions (as determined by NIH/ORDA in consultation with the RAC Chair and one or more RAC members, as necessary) will be transmitted to the RAC and Institutional Biosafety Committee Chairs:

Section IV–C–1–b–(2)–(a). Reviewing and approving certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that qualify for the Accelerated Review process (see Section III–B–2);

Section IV–C–1–b–(2)–(b). Reviewing and approving minor changes to human gene transfer protocols under Section III–A–2 and III–B–2;

Section IV–C–1–b–(2)–(c). Changing containment levels for experiments that are specified in Section III;

Section IV–C–1–b–(2)–(d). Assigning containment levels for experiments not explicitly considered in the NIH Guidelines; and

Section IV–C–1–b–(2)–(e). Revising the Classification of Etiologic Agents for the purpose of these NIH Guidelines (see Section V–A).

Section IV–C–1–b–(2)–(f). Interpreting the NIH Guidelines for experiments to which the NIH Guidelines do not specifically assign containment levels;

Section IV–C–1–b–(2)–(g). Setting containment under Sections III–C–1–d and III–C–2–b;

Section IV–C–1–b–(2)–(h). Approving minor modifications of already certified host-vector systems (the standards and procedures for such modifications are described in Appendix I–II);

Section IV–C–1–b–(2)–(i). Decertifying already certified host-vector systems;

Section IV–C–1–b–(2)–(j). Adding new entries to the list of molecules toxic for vertebrates (see Appendix F); and

Section IV–C–1–b–(2)–(k). Determining appropriate containment conditions for experiments according to case precedents developed under Section IV–C–1–b–(2)–(c).

The amended version of Section IV–C–2 reads as follows:

Section IV–C–2. Recombinant DNA Advisory Committee (RAC). The RAC shall be responsible for advising the Director, NIH, on the actions listed in Section IV–C–1–b–(1).

The amended version of Section IV–C–3 reads as follows:

Section IV–C–3. Office of Recombinant DNA Activities (ORDA)

ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH including institutions, Biological Safety Officers, Principal Investigators, Federal agencies, state and local governments, and institutions in the private sector. ORDA shall carry out such other functions as may be delegated to it by the NIH Director, including those authorities described in Section IV–C–1–b–(2). ORDA's responsibilities include, but are not limited to the following:

Section IV–C–3–a. Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes encoding for toxin molecules that are lethal for vertebrates at an $LD_{50} \leq 100$ nanograms per kilogram body weight in organisms other than *Escherichia coli* K–12 (see Section III–B–1 and Appendices F–I and F–II);

Section IV–C–3–b. Reviewing and approving certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects, in consultation with the RAC Chair and one or more RAC members, as necessary, that qualify for the Accelerated Review process (see Section III–B–2);

Section IV–C–3–c. Reviewing and approving minor changes to human gene transfer protocols approved under Sections III–A–2 and III–B–2, in consultation with the RAC Chair and one or more RAC members, as necessary;

Section IV–C–3–d. Reviewing and approving the membership of an institution's Institutional Biosafety Committee, and where it finds the Institutional Biosafety Committee meets the requirements set forth in Section IV–B–2 will give its approval to the Institutional Biosafety Committee membership;

Section IV–C–3–e. Publishing in the Federal Register:

Section IV–C–3–e–(1). Announcements of RAC meetings and agendas at least 15 days in advance (Note—If the agenda for a RAC meeting is modified, ORDA shall make the revised agenda available to anyone upon request at least 72 hours in advance of the meeting);

Section IV–C–3–e–(2). Proposed Major Actions to the NIH Guidelines (see Section IV–C–1–b–(1)) at least 15 days prior to the RAC meeting;

Section IV–C–3–f. Serve as the focal point for data management of NIH-approved human gene transfer protocols approved under Sections III–A–2 and III–B–2 and registered with NIH/ORDA as required under Section III–C–7;

Section IV–C–3–g. Serve as the executive secretary of the RAC; and

Section IV–C–3–h. Maintain a list of Major and Minor Actions approved under Section III–A–2 and III–B–3 and a list of experiments registered with NIH/ORDA as described in Section III–C–7.

E. Amendment and Addition to Section V, Footnotes and References of Sections I–IV of the NIH Guidelines

The amended version of Section V–U reads as follows:

Section V–U. Human studies in which the induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected, are not covered under Sections III–A–2, III–B–2, or III–B–3. Such studies may be initiated without RAC review and NIH approval if approved by another Federal agency."

The following new footnote, V–W is added to Section V:

Section V–W. In accordance with accepted scientific and regulatory practices of the discipline of plant pathology, an exotic plant pathogen (e.g., virus, bacteria, or fungus) is one that is unknown to occur within the U.S. (see Section V–R). Determination of whether a pathogen has a potential for serious detrimental impact on managed (agricultural, forest, grassland) or natural ecosystems should be made by the Principal Investigator and the Institutional Biosafety Committee, in consultation with scientists knowledgeable of plant diseases, crops, and ecosystems in the geographic area of the research.

F. Addition to Appendix C–I, Recombinant DNA in Tissue Culture, of the NIH Guidelines

The amended version of Appendix C–I reads as follows:

Appendix C–I. Recombinant DNA in Tissue Culture

Recombinant DNA molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family (see Appendix C–VI–D) being considered identical (see Appendix C–VI–E), that are propagated and maintained in cells in tissue culture are exempt from these NIH Guidelines with the exceptions listed in Appendix C–I–A.

Appendix C–I–A. Exceptions

The following categories are not exempt from the NIH Guidelines: (i) Experiments described in Section III–A which require specific RAC review and NIH and Institutional Biosafety Committee approval before initiation, (ii) experiments described in Section III–B which require NIH/ORDA and Institutional Biosafety Committee approval before initiation, (iii) experiments involving DNA from Class 3, 4, or 5 organisms (see Appendix C–VI–A) or cells known to be infected with these agents, (iv) experiments involving the deliberate introduction of genes coding for the biosynthesis of molecules that are toxic for vertebrates (see Appendix F), and (v) whole plants regenerated from plant cells and tissue cultures are covered by the exemption provided they remain axenic cultures even though they differentiate into embryonic tissue and regenerate into plantlets.

G. Addition to Appendix G, Physical Containment, of the NIH Guidelines

Appendix G through G–I is amended to read as follows:

Appendix G specifies physical containment for standard laboratory experiments and defines Biosafety Level

1 through Biosafety Level 4. For large scale (over 10 liters) research or production, Appendix K supersedes Appendix G. Appendix K defines Good Large Scale Practice through Biosafety Level 3—Large Scale. For certain work with plants, Appendix P supersedes Appendix G. Appendix P defines Biosafety Levels 1 through 4—Plants. For certain work with animals, Appendix Q supersedes Appendix G. Appendix Q defines Biosafety Levels 1 through 4—Animals.

Appendix G–I. Standard Practices and Training

The first principle of containment is strict adherence to good microbiological practices (see Appendices G–III–A through G–III–J). Consequently, all personnel directly or indirectly involved in experiments using recombinant DNA shall receive adequate instruction (see Sections IV–B–1–e and IV–B–4–d). At a minimum, these instructions include training in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.

Any research group working with agents that are known or potential biohazards shall have an emergency plan that describes the procedures to be followed if an accident contaminates personnel or the environment. The Principal Investigator shall ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan (see Sections IV–B–4–d and IV–B–4–e). If a research group is working with a known pathogen for which there is an effective vaccine, the vaccine should be made available to all workers. Serological monitoring, when clearly appropriate, will be provided (see Section IV–B–1–f).

The Laboratory Safety Monograph (see Appendix G–III–O) and Biosafety in Microbiological and Biomedical Laboratories (see Appendix G–III–B) describe practices, equipment, and facilities in detail.

H. Addition of Appendix P, Physical and Biological Containment for Recombinant DNA Research Involving Plants, to the NIH Guidelines

The following new appendix, Appendix P, reads as follows:

Appendix P specifies physical and biological containment conditions and practices suitable to the greenhouse conduct of experiments involving recombinant DNA-containing plants, plant-associated microorganisms, and small animals. All provisions of the NIH Guidelines apply to plant research activities with the following modifications:

Appendix P shall supersede Appendix G when the research plants are of a size, number, or have growth requirements that preclude the use of containment conditions described in Appendix G. The plants covered in Appendix P include but are not limited to mosses, liverworts, macroscopic algae, and vascular plants including terrestrial crops, forest, and ornamental species.

Plant-associated microorganisms include viroids, virusoids, viruses, bacteria, fungi, protozoans, certain small algae, and microorganisms that have a benign or beneficial association with plants, such as certain *Rhizobium* species and microorganisms known to cause plant diseases. The appendix applies to microorganisms which are being modified with the objective of fostering an association with plants.

Plant-associated small animals include those arthropods that: (i) Are in obligate association with plants, (ii) are plant pests, (iii) are plant pollinators, or (iv) transmit plant disease agents, as well as other small animals such as nematodes for which tests of biological properties necessitate the use of plants. Microorganisms associated with such small animals (e.g., pathogens or symbionts) are included.

The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P require prior approval by the Institutional Biosafety Committee.

Appendix P–I. General Plant Biosafety Levels

Appendix P–I–A. The principal purpose of plant containment is to avoid the unintentional transmission of a recombinant DNA-containing plant genome, including nuclear or organelle hereditary material or release of recombinant DNA-derived organisms associated with plants.

Appendix P–I–B. The containment principles are based on the recognition that the organisms that are used pose no health threat to humans or higher animals (unless deliberately modified for that purpose), and that the containment conditions minimize the possibility of an unanticipated deleterious effect on organisms and ecosystems outside of the experimental facility, e.g., the inadvertent spread of a serious pathogen from a greenhouse to a local agricultural crop or the unintentional introduction and establishment of an organism in a new ecosystem.

Appendix P–I–C. Four biosafety levels, referred to as Biosafety Level (BL) 1—Plants (P), BL2–P, BL3–P, and BL4–P, are established in Section II. The selection of containment levels required for research involving recombinant DNA molecules in plants or associated with plants is specified in Section III. These biosafety levels are described in Appendix P–II. This appendix describes greenhouse practices and special greenhouse facilities for physical containment.

Appendix P–I–D. BL1–P through BL4–P are designed to provide differential levels of biosafety for plants in the absence or presence of other experimental organisms that contain recombinant DNA. These biosafety levels, in conjunction with biological containment conditions described in Appendix P–III, provide flexible approaches to ensure the safe conduct of research.

Appendix P–I–E. For experiments in which plants are grown at the BL1 through BL4 laboratory settings, containment practices shall be followed as described in Appendix G. These containment practices include the use of plant tissue culture rooms, growth chambers within laboratory facilities, or experiments performed on open benches. Additional biological containment practices should be added by the Greenhouse Director or Institutional Biosafety Committee as necessary (see Appendix P–III), if botanical reproductive structures are produced that have the potential of being released.

Appendix P–II. Physical Containment Levels

Appendix P–II–A. Biosafety Level 1—Plants (BL1–P)

Appendix P–II–A–1. Standard Practices (BL1–P)

Appendix P–II–A–1–a. Greenhouse Access (BL1–P)

Appendix P–II–A–1–a–(1). Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Director, when experiments are in progress.

Appendix P–II–A–1–a–(2). Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL1–P greenhouse practices and procedures. All procedures shall be performed in accordance with accepted greenhouse practices that are appropriate to the experimental organism.

Appendix P-II-A–1-b. Records (BL1–P)

Appendix P-II-A–1-b-(1). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P-II-A–1-c. Decontamination and Inactivation (BL1–P)

Appendix P-II-A–1-c-(1). Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Appendix P-II-A–1-d. Control of Undesired Species and Motile Macroorganisms (BL1–P)

Appendix P-II-A–1-d-(1). A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens), by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Appendix P-II-A–1-d-(2). Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Appendix P-II-A–1-e. Concurrent Experiments Conducted in the Greenhouse (BL1–P)

Appendix P-II-A–1-e-(1). Experiments involving other organisms that require a containment level lower than BL1–P may be conducted in the greenhouse concurrently with experiments that require BL1–P containment, provided that all work is conducted in accordance with BL1–P greenhouse practices.

Appendix P-II-A–2. Facilities (BL1–P)

Appendix P-II-A–2-a. Definitions (BL1–P)

Appendix P-II-A–2-a-(1). The term 'greenhouse' refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

Appendix P-II-A–2-a-(2). The term 'greenhouse facility' includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area.

Appendix P-II-A–2-b. Greenhouse Design (BL1–P)

Appendix P-II-A–2-b-(1). The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended.

Appendix P-II-A–2-b-(2). Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

Appendix P-II-B. Biosafety Level 2—Plants (BL2–P)

Appendix P-II-B–1. Standard Practices (BL2–P)

Appendix P-II-B–1-a. Greenhouse Access (BL2–P)

Appendix P-II-B–1-a-(1). Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Director, to individuals directly involved with the experiments when they are in progress.

Appendix P-II-B–1-a-(2). Personnel shall be required to read and follow instructions on BL2–P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms.

Appendix P-II-B–1-b. Records (BL2–P)

Appendix P-II-B–1-b-(1). A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.

Appendix P-II-B–1-b-(2). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P-II-B–1-b-(3). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Greenhouse Director, Institutional Biosafety Committee, NIH/ORDA and other appropriate authorities immediately (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Documentation of any such accident shall be prepared and maintained.

Appendix P-II-B–1-c. Decontamination and Inactivation (BL2–P)

Appendix P-II-B–1-c-(1). Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Appendix P-II-B–1-c-(2). Decontamination of run-off water is not necessarily required. If part of the greenhouse is composed of gravel or similar material, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel.

Appendix P-II-B–1-d. Control of Undesired Species and Motile Macroorganisms (BL2–P)

Appendix P-II-B–1-d-(1). A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Appendix P-II-B–1-d-(2). Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Appendix P-II-B–1-e. Concurrent Experiments Conducted in the Greenhouse (BL2–P)

Appendix P-II-B–1-e-(1). Experiments involving other organisms that require a containment level lower than BL2–P may be conducted in the greenhouse concurrently with experiments that require BL2–P containment provided that all work is conducted in accordance with BL2–P greenhouse practices.

Appendix P-II-B–1-f. Signs (BL2–P)

Appendix P-II-B–1-f-(1). A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) The plants in use, and (iii) any special requirements for using the area.

Appendix P-II-B–1-f-(2). If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors.

Appendix P-II-B–1-f-(3). If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Appendix P-II-B–1-g. Transfer of Materials (BL2–P)

Appendix P-II-B–1-g-(1). Materials containing experimental microorganisms, which are brought into or removed from the greenhouse facility in a viable or intact state, shall be transferred in a closed non-breakable container.

Appendix P-II-B–1-h. Greenhouse Practices Manual (BL2–P)

Appendix P-II-B–1-h-(1). A greenhouse practices manual shall be

prepared or adopted. This manual shall: (i) Advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms.

Appendix P-II-B–2. Facilities (BL2–P)

Appendix P-II-B–2-a. Definitions (BL2–P)

Appendix P-II-B–2-a-(1). The term 'greenhouse' refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

Appendix P-II-B–2-a-(2). The term 'greenhouse facility' includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas and is considered part of the confinement area.

Appendix P-II-B–2-b. Greenhouse Design (BL2–P)

Appendix P-II-B–2-b-(1). A greenhouse floor composed of an impervious material. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through soil. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil.

Appendix P-II-B–2-b-(2). Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds).

Appendix P-II-B–2-c. Autoclaves (BL2–P)

Appendix P-II-B–2-c-(1). An autoclave shall be available for the treatment of contaminated greenhouse materials.

Appendix P-II-B–2-d. Supply and Exhaust Air Ventilation Systems (BL2–P)

Appendix P-II-B–2-d-(1). If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.

Appendix P-II-B–2-e. Other (BL2–P)

Appendix P-II-B–2-e-(1). BL2–P greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macroorganisms in a manner that satisfies the intent of the foregoing clauses.

Appendix P-II-C. Biosafety Level 3—Plants (BL3–P)

Appendix P-II-C–1. Standard Practices (BL3–P)

Appendix P-II-C–1-a. Greenhouse Access (BL3–P)

Appendix P-II-C–1-a-(1). Authorized entry into the greenhouse shall be restricted to individuals who are required for program or support purposes. The Greenhouse Director shall be responsible for assessing each circumstance and determining those individuals who are authorized to enter the greenhouse facility.

Appendix P-II-C–1-a-(2). Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL3–P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms.

Appendix P-II-C–1-b. Records (BL3–P)

Appendix P-II-C–1-b-(1). A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.

Appendix P-II-C–1-b-(2). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P-II-C–1-b-(3). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, Greenhouse Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities immediately (if applicable).

Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Documentation of any such accident shall be prepared and maintained.

Appendix P-II-C–1-c. Decontamination and Inactivation (BL3–P)

Appendix P-II-C–1-c-(1). All experimental materials shall be sterilized in an autoclave or rendered biologically inactive by appropriate methods before disposal, except those that are to remain in a viable or intact state for experimental purposes; including water that comes in contact with experimental microorganisms or with material exposed to such microorganisms, and contaminated equipment and supplies.

Appendix P-II-C–1-d. Control of Undesired Species and Motile Macroorganisms (BL3–P)

Appendix P-II-C–1-d-(1). A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Appendix P-II-C–1-d-(2). Arthropods and other motile macroorganisms shall be housed in appropriate cages. When appropriate to the organism, experiments shall be conducted within cages designed to contain the motile organisms.

Appendix P-II-C–1-e. Concurrent Experiments Conducted in the Greenhouse (BL3–P)

Appendix P-II-C–1-e-(1). Experiments involving organisms that require a containment level lower than BL3–P may be conducted in the greenhouse concurrently with experiments that require BL3–P containment provided that all work is conducted in accordance with BL3–P greenhouse practices.

Appendix P-II-C–1-f. Signs (BL3–P)

Appendix P-II-C–1-f-(1). A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) The name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

Appendix P-II-C–1-f-(2). If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence should be indicated on a sign posted on the greenhouse access doors.

Appendix P-II-C–1-f-(3). If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Appendix P-II-C–1-g. Transfer of Materials (BL3–P)

Appendix P-II-C–1-g-(1). Experimental materials that are brought into or removed from the greenhouse facility in a viable or intact state shall be transferred to a non-breakable sealed secondary container. At the time of transfer, if the same plant species, host, or vector are present within the effective dissemination distance of propagules of the experimental organism, the surface

of the secondary container shall be decontaminated. Decontamination may be accomplished by passage through a chemical disinfectant or fumigation chamber or by an alternative procedure that has demonstrated effective inactivation of the experimental organism.

Appendix P-II-C–1-h. Greenhouse Practices Manual (BL3–P)

Appendix P-II-C–1-h-(1). A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) Advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms with recognized potential for serious detrimental impact.

Appendix P-II-C–1-i. Protective Clothing (BL3–P)

Appendix P-II-C–1-i-(1). Disposable clothing (e.g., solid front or wrap-around gowns, scrub suits, or other appropriate clothing) shall be worn in the greenhouse if deemed necessary by the Greenhouse Director because of potential dissemination of the experimental microorganisms.

Appendix P-II-C–1-i-(2). Protective clothing shall be removed before exiting the greenhouse and decontaminated prior to laundering or disposal.

Appendix P-II-C–1-j. Other (BL3–P)

Appendix P-II-C–1-j-(1). Personnel are required to thoroughly wash their hands upon exiting the greenhouse.

Appendix P-II-C–1-j-(2). All procedures shall be performed carefully to minimize the creation of aerosols and excessive splashing of potting material/soil during watering, transplanting, and all experimental manipulations.

Appendix P-II-C–2. Facilities (BL3–P)

Appendix P-II-C–2-a. Definitions (BL3–P)

Appendix P-II-C–2-a-(1). The term 'greenhouse' refers to a structure with walls, roof, and floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

Appendix P-II-C–2-a-(2). The term 'greenhouse facility' includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area. The need to maintain negative pressure should be considered when constructing or renovating the greenhouse.

Appendix P-II-C–2-b. Greenhouse Design (BL3–P)

Appendix P-II-C–2-b-(1). The greenhouse floor shall be composed of concrete or other impervious material with provision for collection and decontamination of liquid run-off.

Appendix P-II-C–2-b-(2). Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent).

Appendix P-II-C–2-b-(3). The greenhouse shall be a closed self-contained structure with a continuous covering that is separated from areas that are open to unrestricted traffic flow. The minimum requirement for greenhouse entry shall be passage through two sets of self-closing locking doors.

Appendix P-II-C–2-b-(4). The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures.

Appendix P-II-C–2-b-(5). Internal walls, ceilings, and floors shall be resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix P-II-C–2-b-(6). Bench tops and other work surfaces should have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix P-II-C–2-b-(7). The greenhouse contains a foot, elbow, or automatically operated sink, which is located near the exit door for hand washing.

Appendix P-II-C–2-c. Autoclaves (BL3–P)

Appendix P-II-C–2-c-(1). An autoclave shall be available for decontaminating materials within the greenhouse facility. A double-door autoclave is recommended (not required) for the decontamination of materials passing out of the greenhouse facility.

Appendix P-II-C–2-d. Supply and Exhaust Air Ventilation Systems (BL3–P)

Appendix P-II-C–2-d-(1). An individual supply and exhaust air ventilation system shall be provided. The system maintains pressure differentials and directional airflow, as required, to assure inward (or zero) airflow from areas outside of the greenhouse.

Appendix P-II-C–2-d-(2). The exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air-HEPA filters and discharged to the outside. The filter chambers shall be designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. Air filters shall be 80–85% average efficiency by the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 52-68 test method using atmosphere dust. Air supply fans shall be equipped with a back-flow damper that closes when the air supply fan is off. Alternatively, a HEPA filter may be used on the air supply system instead of the filters and damper. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times.

Appendix P–II–C–2–e. Other (BL3–P)

Appendix P–II–C–2–e–(1). BL3–P greenhouse containment requirements may be satisfied using a growth chamber or growth room within a building provided that the location, access, airflow patterns, and provisions for decontamination of experimental materials and supplies meet the intent of the foregoing clauses.

Appendix P–II–C–2–e–(2). Vacuum lines shall be protected with high efficiency particulate air/HEPA or equivalent filters and liquid disinfectant traps.

Appendix P–II–D. Biosafety Level 4—Plants (BL4–P)

Appendix P–II–D–1. Standard Practices (BL4–P)

Appendix P–II–D–1–a. Greenhouse Access (BL4–P)

Appendix P–II–D–1–a–(1). Authorized entry into the greenhouse shall be restricted to individuals who are required for program or support purposes. The Greenhouse Director shall be responsible for assessing each circumstance and determining those individuals who are authorized to enter the greenhouse facility or work in the greenhouse during experiments.

Appendix P–II–D–1–a–(2). Access shall be managed by the Greenhouse Director, Biological Safety Officer, or other individual responsible for physical security of the greenhouse facility; and access limited by means of secure, locked doors.

Appendix P–II–D–1–a–(3). Prior to entering, individuals shall be advised of the potential environmental hazards and instructed on appropriate safeguards for ensuring environmental safety. Individuals authorized to enter the

greenhouse facility shall comply with the instructions and all other applicable entry/exit procedures.

Appendix P–II–D–1–a–(4). Personnel shall enter and exit the greenhouse facility only through the clothing change and shower rooms and shall shower each time they exit the greenhouse facility. Personnel shall use the airlocks to enter or exit the laboratory only in an emergency. In the event of an emergency, every reasonable effort should be made to prevent the possible transport of viable propagules from containment.

Appendix P–II–D–1–a–(5). Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL4–P practices and procedures.

Appendix P–II–D–1–b. Records (BL4–P)

Appendix P–II–D–1–b–(1). A record shall be kept of all experimental materials brought into or removed from the greenhouse.

Appendix P–II–D–1–b–(2). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P–II–D–1–b–(3). A record shall be kept of all personnel entering and exiting the greenhouse facility, including the date and time of each entry.

Appendix P–II–D–1–b–(4). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, Greenhouse Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities immediately (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Documentation of any such accident shall be prepared and maintained.

Appendix P–II–D–1–c. Decontamination and Inactivation (BL4–P)

Appendix P–II–D–1–c–(1). All materials, except for those that are to remain in a viable or intact state for experimental purposes, shall be autoclaved prior to removal from the maximum containment greenhouse. Equipment or material that could be damaged by high temperatures or steam shall be decontaminated by alternative methods (e.g., gas or vapor sterilization) in an airlock or chamber designed for this purpose.

Appendix P–II–D–1–c–(2). Water that comes in contact with experimental microorganisms or with material exposed to such microorganisms (e.g., run-off from watering plants) shall be collected and decontaminated before disposal.

Appendix P–II–D–1–c–(3). Standard microbiological procedures shall be followed for decontamination of equipment and materials. Spray or liquid waste or rinse water from containers used to apply the experimental microorganisms shall be decontaminated before disposal.

Appendix P–II–D–1–d. Control of Undesired Species and Motile Macroorganisms (BL4–P)

Appendix P–II–D–1–d–(1). A chemical control program shall be implemented to eliminate undesired pests and pathogens in accordance with applicable state and Federal laws.

Appendix P–II–D–1–d–(2). Arthropods and other motile macroorganisms used in conjunction with experiments requiring BL4–P level physical containment shall be housed in appropriate cages. When appropriate to the organism, experiments shall be conducted within cages designed to contain the motile organisms.

Appendix P–II–D–1–e. Concurrent Experiments Conducted in the Greenhouse (BL4–P)

Appendix P–II–D–1–e–(1). Experiments involving organisms that require a containment level lower than BL4–P may be conducted in the greenhouse concurrently with experiments that require BL4–P containment provided that all work is conducted in accordance with BL4–P greenhouse practices. When the experimental microorganisms in use require a containment level lower than BL4–P, greenhouse practices reflect the level of containment required by the highest containment level microorganisms being tested.

Appendix P–II–D–1–f. Signs (BL4–P)

Appendix P–II–D–1–f–(1). A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) The name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

Appendix P–II–D–1–f–(2). If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated by a sign posted on the greenhouse access doors.

Appendix P–II–D–1–f–(3). If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Appendix P–II–D–1–g. Transfer of Materials (BL4–P)

Appendix P–II–D–1–g–(1). Experimental materials that are brought into or removed from the greenhouse in a viable or intact state shall be transferred to a non-breakable, sealed, primary container then enclosed in a non-breakable, sealed secondary container. These containers shall be removed from the greenhouse facility through a chemical disinfectant, fumigation chamber, or an airlock designed for this purpose.

Appendix P–II–D–g–(2). Supplies and materials shall be brought into the greenhouse facility through a double-door autoclave, fumigation chamber, or airlock that is appropriately decontaminated between each use. After securing the outer doors, personnel within the greenhouse facility shall retrieve the materials by opening the interior door of the autoclave, fumigation chamber, or airlock. These doors shall be secured after the materials are brought into the greenhouse facility.

Appendix P–II–D–1–h. Greenhouse Practices Manual (BL4–P)

Appendix P–II–D–1–h–(1). A greenhouse practices manual shall be prepared or adopted. This manual shall include contingency plans to be implemented in the event of the unintentional release of experimental organisms.

Appendix P–II–D–1–i. Protective Clothing (BL4–P)

Appendix P–II–D–1–i–(1). Street clothing shall be removed in the outer clothing change room. Complete laboratory clothing (may be disposable) including undergarments, pants, and shirts, jump suits, shoes, and hats shall be provided and worn by all personnel entering the greenhouse facility.

Appendix P–II–D–1–i–(2). Personnel shall remove laboratory clothing when exiting the greenhouse facility and before entering the shower area. This clothing shall be stored in a locker or hamper in the inner change room.

Appendix P–II–D–1–i–(3). All laboratory clothing shall be autoclaved before laundering.

Appendix P–II–D–2. Facilities (BL4–P)

Appendix P–II–D–2–a. Greenhouse Design (BL4–P)

Appendix P–II–D–2–a–(1). The maximum containment greenhouse facility shall consist of a separate building or a clearly demarcated and isolated area within a building. The need to maintain negative pressure

should be considered when constructing or renovating the greenhouse facility.

Appendix P–II–D–2–a–(2). Outer and inner change rooms, separated by a shower, shall be provided for personnel entering and exiting the greenhouse facility.

Appendix P–II–D–2–a–(3). Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent).

Appendix P–II–D–2–a–(4). Access doors to the greenhouse shall be self-closing and locking.

Appendix P–II–D–2–a–(5). The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures.

Appendix P–II–D–2–a–(6). The walls, floors, and ceilings of the greenhouse shall be constructed to form a sealed internal shell that facilitates fumigation and is animal and arthropod-proof. These internal surfaces shall be resistant to penetration and degradation by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix P–II–D–2–a–(7). Bench tops and other work surfaces shall have seamless surfaces impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix P–II–D–2–a–(8). A double-door autoclave, fumigation chamber, or ventilated airlock shall be provided for passage of all materials, supplies, or equipment that are not brought into the greenhouse facility through the change room.

Appendix P–II–D–2–b. Autoclaves (BL4–P)

Appendix P–II–D–2–b–(1). A double-door autoclave shall be provided for the decontamination of materials removed from the greenhouse facility. The autoclave door, which opens to the area external to the greenhouse facility, shall be sealed to the outer wall and automatically controlled so that it can only be opened upon completion of the sterilization cycle.

Appendix P–II–D–2–c. Supply and Exhaust Air Ventilation Systems (BL4–P)

Appendix P–II–D–2–c–(1). An individual supply and exhaust air ventilation system shall be provided. The system shall maintain pressure differentials and directional airflow as required to assure inward (or zero) airflow from areas outside of the greenhouse. Differential pressure transducers shall be used to sense pressure levels. If a system malfunctions, the transducers shall sound an alarm. A backup source of power should be considered. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times. The integrity of the greenhouse shall have an air leak rate (decay rate) not to exceed 7 percent per minute (logarithm of pressure against time) over a 20-minute period at 2 inches of water gauge pressure. Nominally, this is 0.05 inches of water gauge pressure loss in 1 minute at 2 inches water gauge pressure.

Appendix P–II–D–2–c–(2). Exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air/HEPA filters and discharged to the outside and dispersed away from occupied buildings and air intakes. Filter chambers shall be designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. HEPA filters shall be provided to treat air supplied to the greenhouse facility. HEPA filters shall be certified annually.

Appendix P–II–D–2–d. Other (BL4–P)

Appendix P–II–D–2–d–(1). Sewer vents and other ventilation lines contain high efficiency particulate air/HEPA filters. HEPA filters shall be certified annually.

Appendix P–II–D–2–d–(2). A pass-through dunk tank, fumigation chamber, or an equivalent method of decontamination shall be provided to ensure decontamination of materials and equipment that cannot be decontaminated in the autoclave.

Appendix P–II–D–2–d–(3). Liquid effluent from sinks, floors, and autoclave chambers shall be decontaminated by heat or chemical treatment before being released from the maximum containment greenhouse facility. Liquid wastes from shower rooms and toilets may be decontaminated by heat or chemical treatment. Autoclave and chemical decontamination of liquid wastes shall be evaluated by appropriate standard procedures for autoclaved wastes. Decontamination shall be evaluated mechanically and biologically using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes are decontaminated with chemical disinfectants, the chemicals used must have demonstrated efficacy against the target or indicator microorganisms.

Appendix P–II–D–2–d–(4). If there is a central vacuum system, it shall not serve areas outside of the greenhouse facility. In-line high efficiency particulate air/HEPA filters shall be placed as near as practicable to each use point or vacuum service cock. Other liquid and gas services to the greenhouse facility shall be protected by devices that prevent back-flow. HEPA filters shall be certified annually.

Appendix P–III. Biological Containment Practices

Appropriate selection of the following biological containment practices may be used to meet the containment requirements for a given organism. The present list is not exhaustive; there may be other ways of preventing effective dissemination that could possibly lead to the establishment of the organism or its genetic material in the environment resulting in deleterious consequences to managed or natural ecosystems.

Appendix P–III–A. Biological Containment Practices (Plants)

Appendix P–III–A–1. Effective dissemination of plants by pollen or seed can be prevented by one or more of the following procedures: (i) Cover the reproductive structures to prevent pollen dissemination at flowering and seed dissemination at maturity; (ii) remove reproductive structures by employing male sterile strains, or harvest the plant material prior to the reproductive stage; (iii) ensure that experimental plants flower at a time of year when cross-fertile plants are not flowering within the normal pollen dispersal range of the experimental plant; or (iv) ensure that cross-fertile plants are not growing within the known pollen dispersal range of the experimental plant.

Appendix P-III-B. Biological Containment Practices (Microorganisms)

Appendix P-III-B–1. Effective dissemination of microorganisms beyond the confines of the greenhouse can be prevented by one or more of the following procedures: (i) Confine all operations to injections of microorganisms or other biological procedures (including genetic manipulation) that limit replication or reproduction of viruses and microorganisms or sequences derived from microorganisms, and confine these injections to internal plant parts or adherent plant surfaces; (ii) ensure that organisms, which can serve as hosts or promote the transmission of the virus or microorganism, are not present within the farthest distance that the airborne virus or microorganism may be expected to be effectively disseminated; (iii) conduct experiments at a time of year when plants that can serve as hosts are either not growing or are not susceptible

to productive infection; (iv) use viruses and other microorganisms or their genomes that have known arthropod or animal vectors, in the absence of such vectors; (v) use microorganisms that have an obligate association with the plant; or (vi) use microorganisms that are genetically disabled to minimize survival outside of the research facility and whose natural mode of transmission requires injury of the target organism, or assures that inadvertent release is unlikely to initiate productive infection of organisms outside of the experimental facility.

Appendix P-III-C. Biological Containment Practices (Macroorganisms)

Appendix P-III-C–1. Effective dissemination of arthropods and other small animals can be prevented by using one or more of the following procedures: (i) Use non-flying, flight-impaired, or sterile arthropods; (ii) use non-motile or sterile strains of small animals; (iii) conduct experiments at a time of year that precludes the survival of escaping organisms; (iv) use animals that have an obligate association with a plant that is not present within the dispersal range of the organism; or (v) prevent the escape of organisms present in run-off water by chemical treatment or evaporation of run-off water.

I. Addition of Appendix Q, Physical and Biological Containment for Recombinant DNA Research Involving Animals, to the NIH Guidelines

The following new appendix, Appendix Q, reads as follows:

Appendix Q specifies containment and confinement practices for research involving whole animals, both those in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. The appendix applies to animal research activities with the following modifications:

Appendix Q shall supersede Appendix G when research animals are of a size or have growth requirements that preclude the use of containment for laboratory animals. Some animals may require other types of containment (see Appendix Q-III-D). The animals covered in Appendix Q are those species normally categorized as animals including but not limited to cattle, swine, sheep, goats, horses, and poultry.

The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q require Institutional Biosafety Committee prior approval.

The institution shall establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant DNA-containing microorganisms that require Biosafety Level (BL) 3 or greater containment in the laboratory.

Appendix Q-I. General Considerations

Appendix Q-I-A. Containment Levels

The containment levels required for research involving recombinant DNA associated with or in animals is based on classification of experiments in Section III. For the purpose of animal research, four levels of containment are established. These are referred to as BL1–Animals (N), BL2–N, BL3–N, and BL4–N and are described in the following sections of Appendix Q. The descriptions include: (i) standard practices for physical and biological containment, and (ii) animal facilities.

Appendix Q-I-B. Disposal of Animals (BL1–N through BL4–N)

Appendix Q-I-B–1. When an animal covered by Appendix Q containing recombinant DNA or a recombinant DNA-derived organism is euthanized or dies, the carcass shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an appropriate Federal agency.

Appendix Q-I-B–2. A permanent record shall be maintained of the experimental use and disposal of each animal or group of animals.

Appendix Q-II. Physical and Biological Containment Levels

Appendix Q-II-A. Biosafety Level 1 - Animals (BL1–N)

Appendix Q-II-A–1. Standard Practices (BL1–N)

Appendix Q-II-A–1-a. Animal Facility Access (BL1–N)

Appendix Q-II-A–1-a-(1). The containment area shall be locked.

Appendix Q-II-A–1-a-(2). Access to the containment area shall be limited or restricted when experimental animals are being held.

Appendix Q-II-A–1-a-(3). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q-II-A–1-b. Other (BL1–N)

Appendix Q-II-A–1-b-(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non- transgenic animals.

Appendix Q-II-A–1-b-(2) A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.

Appendix Q-II-A–1-b-(3). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q-II-A–2. Animal Facilities (BL1–N)

Appendix Q-II-A–2-(a). Animals shall be confined to securely fenced areas or be in enclosed structures (animal rooms) to minimize the possibility of theft or unintentional release.

Appendix Q-II-B. Biosafety Level 2 - Animals (BL2–N) (see Appendix Q-III-A)

Appendix Q-II-B–1. Standard Practices (BL2–N)

Appendix Q-II-B–1-a. Animal Facility Access (BL2–N)

Appendix Q-II-B–1-a-(1). The containment area shall be locked.

Appendix Q-II-B–1-a-(2). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q-II-B–1-a-(3). The containment building shall be controlled and have a locking access.

Appendix Q-II-B–1-a-(4). The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any specific entry requirements (e.g., vaccination) may enter the laboratory or animal rooms.

Appendix Q-II-B–1-a-(5). Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.

Appendix Q-II-B–1-b. Decontamination and Inactivation (BL2–N)

Appendix Q-II-B–1-b-(1). Contaminated materials that are decontaminated at a site away from the laboratory shall be placed in a closed durable leak-proof container prior to removal from the laboratory.

Appendix Q-II-B–1-b-(2). Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q-II-B–1-c. Signs (BL2–N)

Appendix Q-II-B–1-c-(1). When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) The agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director or other responsible individual, and (iv) any special requirements for entering the laboratory.

Appendix Q-II-B–1-d. Protective Clothing (BL2–N)

Appendix Q-II-B–1-d-(1). Laboratory coats, gowns, smocks, or uniforms shall be worn while in the animal area or attached laboratory. Before entering non-laboratory areas (e.g., cafeteria, library, administrative offices), protective clothing shall be removed and kept in the work entrance area.

Appendix Q-II-B–1-d-(2). Special care shall be taken to avoid skin contamination with microorganisms containing recombinant DNA. Impervious and/or protective gloves shall be worn when handling experimental animals and when skin contact with an infectious agent is unavoidable.

Appendix Q-II-B–1-e. Records (BL2–N)

Appendix Q-II-B–1-e-(1). Any incident involving spills and accidents that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant DNA molecules shall be reported immediately to the Animal Facility Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q-II-B–1-e-(2). When appropriate and giving consideration to the agent handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the agent handled and the function of the animal facility.

Appendix Q-II-B–1-f. Transfer of Materials (BL2–N)

Appendix Q-II-B–1-f-(1). Biological materials removed from the animal containment area in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container. All containers, primary and secondary, shall be disinfected before removal from the animal facility. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Packages containing viable agents may only be opened in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.

Appendix Q-II-B–1-g. Other (BL2–N)

Appendix Q-II-B–1-g-(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.

Appendix Q-II-B–1-g-(2). Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe. Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q-II-B–1-g-(3). Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as a vector is known to be transmitted by a particular route (e.g., arthropods), special attention should be given to preventing spread by that route. In the absence of specific knowledge of a particular route of transmission, all potential means of horizontal transmission (e.g., arthropods, contaminated bedding, or animal waste, etc.) should be prevented.

Appendix Q-II-B–1-g-(4). Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.

Appendix Q-II-B–1-g-(5). Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.

Appendix Q-II-B–1-g-(6). A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.

Appendix Q-II-B–1-g-(7). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q-II-B–1-g-(8). A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.

Appendix Q-II-B–2. Animal Facilities (BL2–N)

Appendix Q-II-B–2-a. Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and to avoid arthropod access. The special provision to avoid the entry or escape of arthropods from the animal areas may be waived if the agent in use is not known to be transmitted by arthropods.

Appendix Q-II-B–2-b. Surfaces shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix Q-II-B–2-c. The animal containment area shall be designed so that it can be easily cleaned.

Appendix Q-II-B–2-d. Windows that open shall be fitted with fly screens.

Appendix Q-II-B–2-e. An autoclave shall be available for decontamination of laboratory wastes.

Appendix Q-II-B–2-f. If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, interior work areas shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening of access doors or the equivalent.

Appendix Q-II-C. Biosafety Level 3—Animals (BL3–N) (See Appendix Q-III-B)

Appendix Q-II-C–1. Standard Practices (BL3–N)

Appendix Q-II-C–1-a. Animal Facility Access (BL3–N)

Appendix Q-II-C–1-a-(1). The containment area shall be locked.

Appendix Q-II-C–1-a-(2). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q-II-C–1-a-(3). The containment building shall be controlled and have a locking access.

Appendix Q-II-C–1-a-(4). The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any specific entry requirements (e.g., vaccination) shall enter the laboratory or animal rooms.

Appendix Q-II-C–1-a-(5). Animal room doors, gates, or other closures shall be kept closed when experiments are in progress.

Appendix Q-II-C–1-b. Decontamination and Inactivation (BL3–N)

Appendix Q-II-C–1-b-(1). The work surfaces of containment equipment shall be decontaminated when work with organisms containing recombinant DNA molecules is finished. Where feasible, plastic-backed paper toweling shall be used on nonporous work surfaces to facilitate clean-up.

Appendix Q-II-C–1-b-(2). All animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.

Appendix Q-II-C–1-b-(3). Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q-II-C–1-b-(4). Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL3–N animal facility to a facility with a lower containment classification.

Appendix Q-II-C–1-b-(5). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.

Appendix Q-II-C–1-c. Signs (BL3–N)

Appendix Q-II-C–1-c-(1). When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) The agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director or other responsible individual, and (iv) any special requirements for entering the laboratory.

Appendix Q-II-C–1-d. Protective Clothing (BL3–N)

Appendix Q-II-C–1-d-(1). Full protective clothing that protects the individual (e.g., scrub suits, coveralls, uniforms) shall be worn in the animal area. Clothing shall not be worn outside the animal containment area and shall be decontaminated before laundering or disposal. Personnel shall be required to shower before exiting the BL3–N area and wearing of personal clothing.

Appendix Q-II-C–1-d-(2). Special care shall be taken to avoid skin contamination with microorganisms containing recombinant DNA. Impervious and/or protective gloves shall be worn when handling experimental animals and when skin contact with an infectious agent is unavoidable.

Appendix Q-II-C–1-d-(3). Appropriate respiratory protection shall be worn in rooms containing experimental animals.

Appendix Q-II-C–1-e. Records (BL3–N)

Appendix Q-II-C–1-e-(1). Documents regarding experimental animal use and disposal shall be maintained in a permanent record book.

Appendix Q-II-C–1-e-(2). Any incident involving spills and accidents that result in environmental release or exposure of animals or laboratory workers to organisms containing recombinant DNA shall be reported immediately to the Biological Safety Office, Animal Facility Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q-II-C–1-e-(3). When appropriate and giving consideration to the agent handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the agent handled or the function of the facility.

Appendix Q-II-C–1-f. Transfer of Materials (BL3–N)

Appendix Q-II-C–1-f-(1). Biological materials removed from the animal containment laboratory in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container. All containers, primary and secondary, shall be disinfected before removal from the animal facility. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Packages containing viable agents may be opened only in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.

Appendix Q-II-C–1-f-(2). Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL3–N animal facility to a facility with a lower containment classification.

Appendix Q-II-C–1-g. Other (BL3–N)

Appendix Q-II-C–1-g-(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among nontransgenic animals.

Appendix Q-II-C–1-g-(2). Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as the vector is known to be transmitted by a particular route (e.g., arthropods), special attention should be given to preventing spread by that route. In the absence of specific knowledge of a particular route of transmission, all potential means of horizontal transmission (e.g., arthropods, contaminated bedding, or animal waste) should be prevented.

Appendix Q-II-C–1-g-(3). Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.

Appendix Q-II-C-1-g-(4). Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.

Appendix Q-II-C-1-g-(5). Experiments involving other organisms that require containment levels lower than BL3–N may be conducted in the same area concurrently with experiments requiring BL3–N containment provided that they are conducted in accordance with BL3–N practices.

Appendix Q-II-C-1-g-(6). Animal holding areas shall be cleaned at least once a day and decontaminated immediately following any spill of viable materials.

Appendix Q-II-C-1-g-(7). All procedures shall be performed carefully to minimize the creation of aerosols.

Appendix Q-II-C-1-g-(8). A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.

Appendix Q-II-C-1-g-(9). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q-II-C-1-g-(10). All animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.

Appendix Q-II-C-1-g-(11). Personnel shall be required to shower before exiting the BL3–N area and wearing personal clothing.

Appendix Q-II-C-1-g-(12). Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.

Appendix Q-II-C-1-g-(13). Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard or removed from the syringe. The needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q-II-C-1-g-(14). A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.

Appendix Q-II-C–2. Animal Facilities (BL3–N)

Appendix Q-II-C-2-a. Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and avoid arthropod access. The special provision to avoid the entry or escape of arthropods from the animal areas may be waived if the agent in use is not known to be transmitted by arthropods.

Appendix Q–II–C–2–b. The interior walls, floors, and ceilings shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat, to facilitate cleaning. Penetrations in these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix Q–II–C–2–c. Windows in the animal facility shall be closed, sealed, and breakage resistant (e.g., double-pane tempered glass or equivalent). The need to maintain negative pressure should be considered when constructing or renovating the animal facility.

Appendix Q–II–C–2–d. An autoclave, incinerator, or other effective means to decontaminate animals and waste shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.

Appendix Q–II–C–2–e. If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, the interior work area shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed, and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening, or the equivalent of access doors.

Appendix Q–II–C–2–f. Access doors to the containment area shall be self-closing.

Appendix Q–II–C–2–g. The animal area shall be separated from all other areas. Passage through two sets of doors shall be the basic requirement for entry into the animal area from access corridors or other contiguous areas. The animal containment area shall be physically separated from access corridors and other laboratories or areas by a double-door clothes change room, equipped with integral showers and airlock.

Appendix Q–II–C–2–h. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.

Appendix Q–II–C–2–i. An exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air into the animal room through the entry area. The building exhaust, or the exhaust from primary containment units, may be used for this purpose if the exhaust air is discharged to the outside and shall be dispersed away from occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the animal room) is proper.

Appendix Q–II–C–2–j. If the agent is transmitted by aerosol, then the exhaust air shall pass through a high efficiency particulate air/HEPA filter.

Appendix Q–II–C–2–k. Vacuum lines shall be protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.

Appendix Q–II–C–2–l. In lieu of open housing in the special animal room, animals held in a BL3–N area may be housed in partial-containment caging systems (e.g., Horsfall units or gnotobiotic systems, or other special containment primary barriers). Prudent judgment must be exercised to implement this ventilation system (e.g., animal species) and its discharge location.

Appendix Q–II–C–2–m. Each animal area shall contain a foot, elbow, or automatically operated sink for hand washing. The sink shall be located near the exit door.

Appendix Q–II–C–2–n. Restraining devices for animals may be required to avoid damage to the integrity of the animal containment facility.

Appendix Q–II–D. Biosafety Level 4—Animals (BL4–N) (See Appendix Q–III–C)

Appendix Q–II–D–1. Standard Practices (BL4–N)

Appendix Q–II–D–1–a. Animal Facility Access (BL4–N)

Appendix Q–II–D–1–a–(1). Individuals under 16 years of age shall not be permitted to enter the animal area.

Appendix Q–II–D–1–a–(2). The containment area shall be locked.

Appendix Q–II–D–1–a–(3). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q–II–D–1–a–(4). The containment building shall be controlled and have a locking access.

Appendix Q–II–D–1–a–(5). The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any specific entry requirements (e.g., vaccination) may enter the laboratory or animal room.

Appendix Q–II–D–1–a–(6). Individuals shall enter and exit the animal facility only through the clothing change and shower rooms.

Appendix Q–II–D–1–a–(7). Personnel shall use the airlocks to enter or exit the laboratory only in an emergency.

Appendix Q–II–D–1–a–(8). Animal room doors, gates, and other closures shall be kept closed when experiments are in progress.

Appendix Q–II–D–1–b. Decontamination and Inactivation (BL4–N)

Appendix Q–II–D–1–b–(1). All contaminated liquid or solid wastes shall be decontaminated before disposal.

Appendix Q–II–D–1–b–(2). The work surfaces and containment equipment shall be decontaminated when work with organisms containing recombinant DNA molecules is finished. Where feasible, plastic-backed paper toweling shall be used on nonporous work surfaces to facilitate clean-up.

Appendix Q–II–D–1–b–(3). All wastes from animal rooms and laboratories shall be appropriately decontaminated before disposal in an approved manner.

Appendix Q–II–D–1–b–(4). No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the maximum containment laboratory unless they have been autoclaved or decontaminated.

Equipment or material that might be damaged by high temperatures or steam shall be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

Appendix Q-II-D–1-b-(5). When ventilated suits are required, the animal personnel shower entrance/exit area shall be equipped with a chemical disinfectant shower to decontaminate the surface of the suit before exiting the area. A neutralization or water dilution device shall be integral with the chemical disinfectant discharge piping before entering the heat sterilization system. Entry to this area shall be through an airlock fitted with airtight doors.

Appendix Q-II-D–1-b-(6). Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q-II-D–1-b-(7). Supplies and materials needed in the animal facility shall be brought in by way of the double-door autoclave, fumigation chamber, or airlock that shall be appropriately decontaminated between each use.

Appendix Q-II-D–1-b-(8). An autoclave, incinerator, or other effective means to decontaminate animals and wastes shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.

Appendix Q-II-D–1-b-(9). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism. Liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Appendix Q-II-D–1-c. Signs (BL4–N)

Appendix Q-II-D–1-c-(1). When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) The agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director, or other responsible individual, and (iv) any special requirements for entering the laboratory.

Appendix Q-II-D–1-d. Protective Clothing (BL4–N)

Appendix Q-II-D–1-d-(1). Individuals shall enter and exit the animal facility only through the clothing change and shower rooms. Street clothing shall be removed and kept in the outer clothing change room. Complete laboratory clothing (may be disposable), including undergarments, pants, shirts, jump suits, and shoes shall be provided for all personnel entering the animal facility. When exiting the BL4–N area and before proceeding into the shower area, personnel shall remove their laboratory clothing in the inner change room. All laboratory clothing shall be autoclaved before laundering. Personnel shall shower each time they exit the animal facility.

Appendix Q-II-D–1-d-(2). A ventilated head-hood or a one-piece positive pressure suit, which is ventilated by a life-support system, shall be worn by all personnel entering rooms that contain experimental animals when appropriate. When ventilated suits are required, the animal personnel shower entrance/exit area shall be equipped with a chemical disinfectant shower to decontaminate the surface of the suit before exiting the area. A neutralization or water dilution device shall be integral with the chemical disinfectant discharge piping before entering the heat sterilization system. Entry to this area shall be through an airlock fitted with airtight doors.

Appendix Q-II-D–1-d-(3). Appropriate respiratory protection shall be worn in rooms containing experimental animals.

Appendix Q-II-D–1-e. Records (BL4–N)

Appendix Q-II-D–1-e-(1). Documents regarding experimental animal use and disposal shall be maintained in a permanent record book.

Appendix Q-II-D–1-e-(2). A system shall be established for: (i) Reporting laboratory accidents and exposures that are a result of overt exposures to organisms containing recombinant DNA, (ii) employee absenteeism, and (iii) medical surveillance of potential laboratory-associated illnesses. Permanent records shall be prepared and maintained. Any incident involving spills and accidents that results in environmental release or exposures of animals or laboratory workers to organisms containing recombinant DNA molecules shall be reported immediately to the Biological Safety Officer, Animal Facility Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment shall be

provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q-II-D–1-e-(3). When appropriate and giving consideration to the agents handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility.

Appendix Q-II-D–1-e-(4). A permanent record book indicating the date and time of each entry and exit shall be signed by all personnel.

Appendix Q-II-D–1-f. Transfer of Materials (BL4–N)

Appendix Q-II-D–1-f-(1). No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the maximum containment laboratory unless they have been autoclaved or decontaminated. Equipment or material that might be damaged by high temperatures or steam shall be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

Appendix Q-II-D–1-f-(2). Biological materials removed from the animal maximum containment laboratory in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container that shall be removed from the animal facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Such packages containing viable agents can only be opened in another BL4–N animal facility if the agent is biologically inactivated or incapable of reproduction. Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL4–N animal facility to one with a lower containment classification.

Appendix Q-II-D–1-f-(3). Supplies and materials needed in the animal facility shall be brought in by way of the double-door autoclave, fumigation chamber, or airlock that shall be appropriately decontaminated between each use. After securing the outer doors, personnel within the animal facility retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. These doors shall be secured after materials are brought into the animal facility.

Appendix Q-II-D–1-g. Other (BL4–N)

Appendix Q-II-D–1-g-(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.

Appendix Q-II-D–1-g-(2). Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.

Appendix Q-II-D–1-g-(3). Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.

Appendix Q-II-D–1-g-(4). Experiments involving other organisms that require containment levels lower than BL4–N may be conducted in the same area concurrently with experiments requiring BL4–N containment provided that they are conducted in accordance with BL4–N practices.

Appendix Q-II-D–1-g-(5). Animal holding areas shall be cleaned at least once a day and decontaminated immediately following any spill of viable materials.

Appendix Q-II-D–1-g-(6). All procedures shall be performed carefully to minimize the creation of aerosols.

Appendix Q-II-D–1-g-(7). A double barrier shall be provided to separate male and female animals. Animal isolation barriers shall be sturdy and accessible for cleaning. Reproductive incapacitation may be used.

Appendix Q-II-D–1-g-(8). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q-II-D–1-g-(9). The life support system for the ventilated suit or head hood is equipped with alarms and emergency back-up air tanks. The exhaust air from the suit area shall be filtered by two sets of high efficiency particulate air/HEPA filters installed in series or incinerated. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source shall be provided. The air pressure within the suit shall be greater than that of any adjacent area. Emergency lighting and communication systems shall be provided. A double-door autoclave shall be provided for decontamination of waste materials to be removed from the suit area.

Appendix Q-II-D–1-g-(10). Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe. The needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q-II-D–1-g-(11). An essential adjunct to the reporting-surveillance system is the availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory-associated illnesses.

Appendix Q-II-D–1-g-(12). A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.

Appendix Q-II-D–1-g-(13). Vacuum lines shall be protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.

Appendix Q-II-D–2. Animal Facilities (BL4–N)

Appendix Q-II-D–2-a. Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and avoid arthropod access.

Appendix Q-II-D–2-b. The interior walls, floors, and ceilings shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat, to facilitate cleaning. Penetrations in these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix Q-II-D–2-c. Windows in the animal facility shall be closed, sealed, and breakage resistant (e.g., double-pane tempered glass or equivalent).

Appendix Q-II-D–2-d. An autoclave, incinerator, or other effective means to decontaminate animals and wastes shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.

Appendix Q-II-D–2-e. Access doors to the containment area shall be self-closing.

Appendix Q-II-D–2-f. All perimeter joints and openings shall be sealed to form an arthropod-proof structure.

Appendix Q-II-D–2-g. The BL4–N laboratory provides a double barrier to prevent the release of recombinant DNA containing microorganisms into the environment. Design of the animal facility shall be such that if the barrier of the inner facility is breached, the outer barrier will prevent release into the environment. The animal area shall be separated from all other areas. Passage through two sets of doors shall be the basic requirement for entry into the animal area from access corridors or other contiguous areas. Physical separation of the animal containment area from access corridors or other laboratories or activities shall be provided by a double-door clothes change room equipped with integral showers and airlock.

Appendix Q-II-D–2-h. A necropsy room shall be provided within the BL4–N containment area.

Appendix Q-II-D–2-i. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism. Liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide.

The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Appendix Q-II-D–2-j. A ducted exhaust air ventilation system shall be provided that creates directional airflow that draws air into the laboratory through the entry area. The exhaust air, which is not recirculated to any other area of the building, shall be discharged to the outside and dispersed away from the occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the animal room) is proper.

Appendix Q-II-D–2-k. Exhaust air from BL4–N containment area shall be double high efficiency particulate air/HEPA filtered or treated by passing through a certified HEPA filter and an air incinerator before release to the atmosphere. Double HEPA filters shall be required for the supply air system in a BL4–N containment area.

Appendix Q-II-D–2-l. All high efficiency particulate air/HEPA filters' frames and housings shall be certified to have no detectable smoke [dioctylphthalate] leaks when the exit face (direction of flow) of the filter is scanned above 0.01 percent when measured by a linear or logarithmic photometer. The instrument must demonstrate a threshold sensitivity of at least 1×10^{-3} micrograms per liter for 0.3 micrometer diameter dioctylphthalate particles and a challenge concentration of 80–120 micrograms per liter. The air sampling rate should be at least 1 cfm (28.3 liters per minute).

Appendix Q-II-D–2-m. If an air incinerator is used in lieu of the second high efficiency particulate air/HEPA filter, it shall be biologically challenged to prove all viable test agents are sterilized. The biological challenge must be minimally 1×10^{8} organisms per cubic foot of airflow through the incinerator. It is universally accepted if bacterial spores are used to challenge and verify that the equipment is capable of killing spores, then assurance is provided that all other known agents are inactivated by the parameters established to operate the equipment. Test spores meeting this criterion are *Bacillus subtilis* var. *niger* or *Bacillus stearothermophilis*. The operating temperature of the incinerator shall be continuously monitored and recorded during use.

Appendix Q-II-D–2-n. All equipment and floor drains shall be equipped with deep traps (minimally 5 inches). Floor drains shall be fitted with isolation plugs or fitted with automatic water fill devices.

Appendix Q-II-D–2-o. Each animal area shall contain a foot, elbow, or automatically operated sink for hand washing. The sink shall be located near the exit door.

Appendix Q–II–D–2–p. Restraining devices for animals may be required to avoid damage to the integrity of the containment animal facility.

Appendix Q–II–D–2–q. The supply water distribution system shall be fitted with a back-flow preventer or break tank.

Appendix Q–II–D–2–r. All utilities, liquid and gas services, shall be protected with devices that avoid back-flow.

Appendix Q–II–D–2–s. Sewer and other atmospheric ventilation lines shall be equipped minimally with a single high efficiency particulate/HEPA filter. Condensate drains from these type housings shall be appropriately connected to a contaminated or sanitary drain system. The drain position in the housing dictates the appropriate system to be used.

Appendix Q–III. Footnotes and References for Appendix Q

Appendix Q–III–A. If recombinant DNA is derived from a Class 2 organism requiring BL2 containment, personnel shall be required to have specific training in handling pathogenic agents and directed by knowledgeable scientists.

Appendix Q–III–B. Personnel who handle pathogenic and potentially lethal agents shall be required to have specific training and be supervised by knowledgeable scientists who are experienced in working with these agents. BL3–N containment also minimizes escape of recombinant DNA-containing organisms from exhaust air or waste material from the containment area.

Appendix Q–III–C. Classes 4 and 5 microorganisms pose a high level of individual risk for acquiring life-threatening diseases to personnel and/or animals. To import Class 5 agents, special approval must be obtained from U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Import-Export Products, Room 756, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782.

Laboratory staff shall be required to have specific and thorough training in handling extremely hazardous infectious agents, primary and secondary containment, standard and special practices, and laboratory design characteristics. The laboratory staff shall be supervised by knowledgeable scientists who are trained and experienced in working with these agents and in the special containment facilities.

Within work areas of the animal facility, all activities shall be confined to the specially equipped animal rooms or support areas. The maximum animal containment area and support areas shall have special engineering and design features to prevent the dissemination of microorganisms into the environment via exhaust air or waste disposal.

Appendix Q–III–D. Other research with non-laboratory animals, which may not appropriately be conducted under conditions described in Appendix Q, may be conducted safely

by applying practices routinely used for controlled culture of these biota. In aquatic systems, for example, BL1 equivalent conditions could be met by utilizing growth tanks that provide adequate physical means to avoid the escape of the aquatic species, its gametes, and introduced exogenous genetic material. A mechanism shall be provided to ensure that neither the organisms nor their gametes can escape into the supply or discharge system of the rearing container (e.g., tank, aquarium, etc.) Acceptable barriers include appropriate filtration, irradiation, heat treatment, chemical treatment, etc. Moreover, the top of the rearing container shall be covered to avoid escape of the organism and its gametes. In the event of tank rupture, leakage, or overflow, the construction of the room containing these tanks should prevent the organisms and gametes from entering the building's drains before the organism and its gametes have been inactivated.

Other types of non-laboratory animals (e.g., nematodes, arthropods, and certain forms of smaller animals) may be accommodated by using the appropriate BL1 through BL4 or BL1–P through BL4–P containment practices and procedures as specified in Appendices G and P.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined to be not cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Effective Date: June 24, 1994.

Harold Varmus,

Director, National Institutes of Health.

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Part IV

Department of Health and Human Services

National Institutes of Health

Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines); Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

June 1994.

These NIH Guidelines supersede all earlier versions and shall be in effect until further notice.

Table of Contents

Section I. Scope of the NIH Guidelines

Section I–A. Purpose

The purpose of the NIH Guidelines is to specify practices for constructing and handling: (i) Recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

Section I–A–1. Any recombinant DNA experiment, which according to the NIH Guidelines requires approval by the NIH, must be submitted to the NIH or to another Federal agency that has jurisdiction for review and approval. Once approval, or other applicable clearances, has been obtained from a Federal agency other than the NIH (whether the experiment is referred to that agency by the NIH or sent directly there by the submitter), the experiment may proceed without the necessity for NIH review or approval (see exceptions in Sections I–A–2 and I–A–3).

Section I–A–2. Certain experiments that involve the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) shall be considered Major Actions (see Section IV–C–1–b–(1)), and shall require RAC review and NIH Director approval, if determined by NIH/ORDA in consultation with the RAC Chair and/or one or more RAC members, as necessary, to: (i) Represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review (see Section III–A–2).

Section I–A–3. Experiments involving the transfer of recombinant DNA to one or more human subjects that are not considered under Section III–A–2 may qualify for Accelerated Review (see Section III–B–2 and Appendix M–V) and will be considered as Minor Actions (see Section IV–C–1–b–(2)–(a)). Actions that qualify for Accelerated Review will be reviewed and approved by NIH/ORDA in consultation with the RAC Chair and/or one or more RAC members, as necessary.

Certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see Section V–U) may be considered exempt from RAC and/or NIH/ORDA review and/or NIH Director approval and only require registration with NIH/ORDA (see Section III–C–7).

Section I–B. Definition of Recombinant DNA Molecules

In the context of the NIH Guidelines, recombinant DNA molecules are defined as either: (i) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

Section I–C. General Applicability

Section I–C–1. The NIH Guidelines are applicable to:

Section I–C–1–a. All recombinant DNA research within the United States (U.S.) or its territories that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from the NIH, including research performed directly by the NIH. An individual who receives support for research involving recombinant DNA must be associated with or sponsored by an institution that assumes the responsibilities assigned in the NIH Guidelines.

Section I–C–1–b. All recombinant DNA research performed abroad: Specifically:

Section I–C–1–b–(1). Research supported by NIH funds.

Section I–C–1–b–(2). If they involve testing in humans of materials containing recombinant DNA developed with NIH funds and if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not mere provision of research materials.

Section I–C–1–b–(3). If the host country has established rules for the conduct of recombinant DNA research, then the research must be in compliance with those rules. If the host country does not have such rules, the proposed research must be reviewed and approved by an NIH-approved Institutional Biosafety Committee or equivalent review body and accepted in writing by an appropriate national governmental authority of the host country. The safety practices that are employed abroad must be reasonably consistent with the NIH Guidelines.

Section I–D. General Definitions

The following terms, which are used throughout the NIH Guidelines, are defined as follows:

Section I–D–1. An "institution" is any public or private entity (including Federal, state, and local government agencies).

Section I–D–2. An "Institutional Biosafety Committee" is a committee that: (i) Meets the requirements for membership specified in Section IV–B–2, and (ii) reviews, approves, and oversees projects in accordance with the responsibilities defined in Section IV–B–2.

Section I–D–3. The "Office of Recombinant DNA Activities (ORDA)"

is the office within the NIH that is responsible for: (i) Reviewing and coordinating all activities relating to the NIH Guidelines, and (ii) performing other duties as defined in Section IV–C–3.

Section I–D–4. The "Recombinant DNA Advisory Committee" is the public advisory committee that advises the Department of Health and Human Services (DHHS) Secretary, the DHHS Assistant Secretary for Health, and the NIH Director concerning recombinant DNA research. The RAC shall be constituted as specified in Section IV–C–2.

Section I–D–5. The "NIH Director" is the Director of the National Institutes of Health, or any other officer or employee of NIH to whom authority has been delegated.

Section I–D–6. "Deliberate release" is defined as a planned introduction of recombinant DNA-containing microorganisms, plants, or animals into the environment.

Section II. Containment

Effective biological safety programs have been operative in a variety of laboratories for many years. Considerable information already exists about the design of physical containment facilities and selection of laboratory procedures applicable to organisms carrying recombinant DNA (see section V–A). The existing programs rely upon mechanisms that can be divided into two categories: (i) A set of standard practices that are generally used in microbiological laboratories; and (ii) special procedures, equipment, and laboratory installations that provide physical barriers that are applied in varying degrees according to the estimated biohazard. Four biosafety levels are described in Appendix G. These biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and are based on the potential hazards imposed by the agents used and for the laboratory function and activity. Biosafety Level 4 provides the most stringent containment conditions, Biosafety Level 1 the least stringent.

Experiments involving recombinant DNA lend themselves to a third containment mechanism, namely, the application of highly specific biological barriers. Natural barriers exist that limit either: (i) The infectivity of a vector or vehicle (plasmid or virus) for specific hosts, or (ii) its dissemination and survival in the environment. Vectors, which provide the means for recombinant DNA and/or host cell replication, can be genetically designed to decrease, by many orders of magnitude, the probability of dissemination of recombinant DNA outside the laboratory (see Appendix I).

Since these three means of containment are complementary, different levels of containment can be established that apply various combinations of the physical and biological barriers along with a constant use of standard practices. Categories of containment are considered separately in order that such combinations can be conveniently expressed in the NIH Guidelines.

Physical containment conditions within laboratories, described in Appendix G, may not always be appropriate for all organisms because of their physical size, the number of organisms needed for an experiment, or the particular growth requirements of the organism. Likewise, biological containment for microorganisms described in Appendix I may not be appropriate for all organisms, particularly higher eukaryotic organisms. However, significant information exists about the design of research facilities and experimental procedures that are applicable to organisms containing recombinant DNA that is either integrated into the genome or into microorganisms associated with the higher organism as a symbiont, pathogen, or other relationship. This information describes facilities for physical containment of organisms used in non-traditional laboratory settings and special practices for limiting or excluding the unwanted establishment, transfer of genetic information, and dissemination of organisms beyond the intended location, based on both physical and biological containment principles. Research conducted in accordance with these conditions effectively confines the organism.

For research involving plants, four biosafety levels (BL1–P through BL4–P) are described in Appendix P. BL1–P is designed to provide a moderate level of containment for experiments for which there is convincing biological evidence that precludes the possibility of survival, transfer, or dissemination of recombinant DNA into the environment, or in which there is no recognizable and predictable risk to the environment in the event of accidental release. BL2–P is designed to provide a greater level of containment for experiments involving plants and certain associated organisms in which there is a recognized possibility of survival, transmission, or dissemination of recombinant DNA containing organisms, but the consequence of such an inadvertent release has a predictably minimal biological impact. BL3–P and BL4–P describe additional containment conditions for research with plants and certain pathogens and other organisms that require special containment because of their recognized potential for significant detrimental impact on managed or natural ecosystems. BL1–P relies upon accepted scientific practices for conducting research in most ordinary greenhouse or growth chamber facilities and incorporates accepted procedures for good pest control and cultural practices. BL1–P facilities and procedures provide a modified and protected environment for the propagation of plants and microorganisms associated with the plants and a degree of containment that adequately controls the potential for release of biologically viable plants, plant parts, and microorganisms associated with them. BL2–P and BL3–P rely upon accepted scientific practices for conducting research in greenhouses with organisms infecting or infesting plants in a manner that minimizes or prevents inadvertent contamination of plants within or surrounding the greenhouse. BL4–P describes facilities and practices known to provide containment of certain exotic plant pathogens.

For research involving animals, which are of a size or have growth requirements that preclude the use of conventional primary containment systems used for small laboratory animals, four biosafety levels (BL1–N through BL4–N) are described in Appendix Q. BL1–N describes containment for animals that have been modified by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms and is designed to eliminate the possibility of sexual transmission of the modified genome or transmission of recombinant DNA-derived viruses known to be transmitted from animal parent to offspring only by sexual reproduction. Procedures, practices, and facilities follow classical methods of avoiding genetic exchange between animals. BL2–N describes containment which is used for transgenic animals associated with recombinant DNA-derived organisms and is designed to eliminate the possibility of vertical or horizontal transmission. Procedures, practices, and facilities follow classical methods of avoiding genetic exchange between animals or controlling arthropod transmission. BL3–N and BL4–N

describe higher levels of containment for research with certain transgenic animals involving agents which pose recognized hazard.

In constructing the NIH Guidelines, it was necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. These definitions do not take into account all existing and anticipated information on special procedures that will allow particular experiments to be conducted under different conditions than indicated here without affecting risk. Individual investigators and Institutional Biosafety Committees are urged to devise simple and more effective containment procedures and to submit recommended changes in the NIH Guidelines to permit the use of these procedures.

Section III. Experiments Covered by the NIH Guidelines

This section describes five categories of experiments involving recombinant DNA: (i) Those that require RAC review and NIH and Institutional Biosafety Committee approval before initiation (see section III–A), (ii) those that require NIH/ORDA and Institutional Biosafety Committee approval before initiation (see section III–B); (iii) those that require Institutional Biosafety Committee approval before initiation (see section III–C), (iv) those that require Institutional Biosafety Committee notification simultaneous with initiation (see section III–D), and (v) those that are exempt from the NIH Guidelines (see section III–E).

Note: If an experiment falls into either section III–A or section III–B and one of the other categories, the rules pertaining to section III–A or section III–B shall be followed. If an experiment falls into section III–E and into either sections III–C or III–D categories as well, the experiment is considered exempt from the NIH Guidelines.

Any change in containment level, which is different from those specified in the NIH Guidelines, may not be initiated without the express approval of NIH/ORDA (see Minor Actions, section IV–C–1–b–(2) and its subsections).

Section III–A. Experiments that Require Institutional Biosafety Committee Approval, RAC Review, and NIH Approval Before Initiation

Experiments in this category are considered Major Actions (see section IV–C–1–b–(1)) and cannot be initiated without submission of relevant information on the proposed experiment to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838, the publication of the proposal in the **Federal Register** for 15 days of comment, reviewed by the RAC, and specific approval by the NIH (not applicable for Expedited Review single patient human gene transfer experiments considered under Appendix M–VI). The containment conditions for such experiments will be recommended by the RAC and set by the NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D which may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section III–A–1. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see section V–B), if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

Section III–A–2. Certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (see section V–U) shall be considered Major Actions (see section IV–C–1–b–(1) and Appendix M–III), and shall require RAC review and NIH Director approval, if determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, to: (i) Represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review. The requirement for RAC review shall not be considered to preempt any other required review or approval of experiments with one or more human subjects. Relevant Institutional Biosafety Committee and Institutional Review Board reviews and approvals of the proposal should be completed before submission to NIH. Certain experiments involving deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects may qualify for the Accelerated Review process (see section III–B–2). Certain categories of experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects and that are not covered by section V–U, may be considered exempt from RAC and/or NIH/ORDA review and/or NIH Director approval and only require registration with NIH/ORDA (see section III–C–7).

Section III–B. Experiments That Require NIH/ORDA and Institutional Biosafety Committee Approval Before Initiation

Section III–B–1. Experiments Involving the Cloning of Toxin Molecules with LD_{50} of Less than 100 Nanograms per Kilogram Body Weight

Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin). Specific approval has been given for the cloning in *Escherichia coli* K–12 of DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 nanograms to 100 micrograms per kilogram body weight. Specific experiments already approved under this section may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section III–B–1–(a). Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH/ORDA. The containment conditions for such experiments will be determined by NIH/ORDA in consultation with ad hoc experts. Such experiments require Institutional Biosafety Committee approval before initiation (see section IV–B–2–b–(1)).

Section III–B–2. Accelerated Review of Human Gene Transfer Experiments

As determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, certain categories of human gene transfer experiments may be considered as Minor Actions and qualify for Accelerated Review and approval (see section IV–C–1–b–(2)–(a), Appendix M–III–A, and Appendix M–V). The RAC Chair will present a report of all NIH/ORDA approved human gene transfer protocols at the next regularly scheduled RAC meeting. If NIH/ORDA determines that an experiment does not qualify for the Accelerated Review process, the Principal Investigator must submit the proposal for full RAC review ≥ 8 weeks prior to the next scheduled RAC meeting (See section III–A–2).

Section III-B–3. Minor Modifications to Human Gene Transfer Experiments

A minor modification in a human gene transfer protocol is a modification that does not significantly alter the basic design of the protocol and that does not increase risk to human subjects or the environment. After approval has been obtained by the relevant Institutional Biosafety Committee and Institutional Review Board, NIH/ORDA will consider the change in consultation with the RAC Chair and one or more RAC members, as necessary. Submit minor modifications to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. The RAC Chair will provide a report on any such approvals at the next regularly scheduled RAC meeting.

Section III-C. Experiments that Require Institutional Biosafety Committee Approval Before Initiation

Prior to the initiation of an experiment that falls into this category, the Principal Investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information: (i) The source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the NIH Guidelines. For experiments in this category, the registration document shall be dated, signed by the Principal Investigator, and filed with the Institutional Biosafety Committee. The Institutional Biosafety Committee shall review and approve all experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by NIH (see Section IV-C–1-b-(2)-(c)).

Section III-C–1. Experiments Using Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 Agents (see Section V-A) as Host-Vector Systems

Section III-C–1-a. Experiments involving the introduction of recombinant DNA into Class 2 agents shall be conducted at Biosafety Level (BL) 2 containment. Experiments with such agents shall be conducted with whole animals at BL2 or BL2–N (Animals) containment.

Section III-C–1-b. Experiments involving the introduction of recombinant DNA into Class 3 agents shall be conducted at BL3 containment. Experiments with such agents shall be conducted with whole animals at BL3 or BL3–N containment.

Section III-C–1-c. Experiments involving the introduction of recombinant DNA into Class 4 agents shall be conducted at BL4 containment. Experiments with such agents shall be conducted with whole animals at BL4 or BL4–N containment.

Section III-C–1-d. Containment conditions for experiments involving the introduction of recombinant DNA into Class 5 agents shall be set on a case-by-case basis following NIH/ORDA review. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Sections V-R and V-T). Experiments with such agents shall be conducted with whole animals at BL4 or BL4–N containment.

Section III-C–2. Experiments in Which DNA From Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 Agents (see Section V-A) is Cloned Into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems

Section III-C–2-a. Experiments in which DNA from Class 2 or Class 3 agents (see Section V-A) is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment. Experiments in which DNA from Class 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. In the absence of such a demonstration, BL4 containment shall be used. The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BL1. Many experiments in this category are exempt from the NIH Guidelines (see Section III-E). Experiments involving the formation of recombinant DNA for certain genes coding for molecules toxic for vertebrates require NIH/ORDA approval (see Section III-B–1) or shall be conducted under NIH specified conditions as described in Appendix F.

Section III-C–2-b. Containment conditions for experiments in which DNA from Class 5 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes shall be determined by NIH/ORDA following a case-by-case review. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Sections V-R and V-T).

Section III-C–3. Experiments Involving the Use of Infectious Animal or Plant DNA or RNA Viruses or Defective Animal or Plant DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems

Caution: Special care should be used in the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range (e.g., introduction of novel control elements) of viral vectors under conditions that permit a productive infection. In such cases, serious consideration should be given to increasing physical containment by at least one level.

Note: Recombinant DNA or RNA molecules derived therefrom, which contain less than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V-Q) being considered identical (see Section V-S), are considered defective and may be used in the absence of helper under the conditions specified in Section III-D–1.

Section III-C–3-a. Experiments involving the use of infectious or defective Class 2 animal viruses (see Section V-A, Appendix B-II, and Appendix B-II-E) in the presence of helper virus may be conducted at BL2.

Section III-C–3-b. Experiments involving the use of infectious or defective Class 3 animal viruses (see Section V-A and Appendix B-III-D) in the presence of helper virus may be conducted at BL3.

Section III-C–3-c. Experiments involving the use of infectious or defective Class 4 animal viruses (see Section V-A and Appendix B-IV-D) in the presence of helper virus may be conducted at BL4.

Section III-C–3-d. Experiments involving the use of infectious or defective Class 5 viruses (see Section V-A and Appendix B-V) in the presence of helper virus shall be determined on a case-by-case basis following NIH/ORDA review. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Sections V-R and V-T).

Section III-C–3-e. Experiments involving the use of infectious or defective animal or plant viruses in the presence of helper virus are not covered in Sections III-C–3-a through III-C–3-d and may be conducted at BL1.

Section III-C–4. Experiments Involving Whole Animals

This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into

the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BL1–N containment. A minimum containment of BL2 or BL2–N is required.

Caution—Special care should be used in the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions.

Section III-C–4-a. Recombinant DNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1–N and appropriate to the organism under study (see Section V-B). Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1–N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-C–4-b. For experiments involving recombinant DNA-modified Class 2, 3, 4, or 5 organisms, see Section V-A. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U.S. Department of Agriculture permit is required for work with Class 5 agents (see Section V-R and V-T).

Section III-C–4-b. For experiments involving recombinant DNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III-C–1 or III-C–4-a, the appropriate containment shall be determined by the Institutional Biosafety Committee.

Section III-C–5. Experiments Involving Whole Plants

Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA, may be conducted under the containment conditions described in Sections III-C–5-a through III-C–5-e. If experiments involving whole plants are not described in Section III-C–5 and do not fall under Sections III-A, III-B, or III-E, they are included in Section III-D.

Note: For recombinant DNA experiments falling under Sections III-C–5-a through III-C–5-d, physical containment requirements may be reduced to the next lower level by appropriate biological containment practices, such as conducting experiments on a virus with an obligate insect vector in the absence of that vector or using a genetically attenuated strain.

Section III-C–5-a. BL3–P (Plants) or BL2–P + biological containment is recommended for experiments involving most exotic (see Section V-W) infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants.

Section III-C–5-b. BL3–P or BL2–P + biological containment is recommended for experiments involving plants containing cloned genomes of readily transmissible exotic (see Section V-W) infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation *in planta*.

Section III-C–5-c. BL4–P containment is recommended for experiments with a small number of readily transmissible exotic (see Section V-W) infectious agents, such as the soybean rust fungus (*Phakospora pachyrhizi*) and maize streak or other viruses in the presence of their specific arthropod vectors, that have the potential of being serious pathogens of major U.S. crops.

Section III-C–5-d. BL3–P containment is recommended for experiments involving sequences encoding potent vertebrate toxins introduced into plants or associated organisms. Recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD_{50} of <100 nanograms per kilogram body weight fall under Section III-B–1 and require NIH/ORDA and Institutional Biosafety Committee approval before initiation.

Section III-C–5-e. BL3–P or BL2–P + biological containment is recommended for experiments with microbial pathogens of insects or small animals associated with plants if the recombinant DNA-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems.

Section III-C–6. Experiments Involving More than 10 Liters of Culture

The appropriate containment will be decided by the Institutional Biosafety Committee. Where appropriate, Appendix K, Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules, shall be used. Appendix K describes containment conditions Good Large Scale Practice through BL3–Large Scale.

Section III-C–7. Human Gene Transfer Experiments Not Covered by Sections III-A-2, III-B–2, III-B–3, and Not Considered Exempt Under Section V-U

Certain experiments involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that are not covered by Sections III-A–2, III-B–2, III-B–3, and that are not considered exempt under Section V-U must be registered with NIH/ORDA. The relevant Institutional Biosafety Committee and Institutional Review Board must review and approve all experiments in this category prior to their initiation.

Section III-D. Experiments that Require Institutional Biosafety Committee Notice Simultaneous With Initiation

Experiments not included in Sections III-A, III-B, III-C, III-E, and their subsections are considered in Section III-D. All such experiments may be conducted at BL1 containment. For experiments in this category, a registration document (see Section III-C) shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated. The Institutional Biosafety Committee reviews and approves all such proposals, but Institutional Biosafety Committee review and approval prior to initiation of the experiment is not required (see Section IV-A). For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under Section III-D and may be conducted at BL1 containment.

Section III-D–1. Experiments Involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of Any Eukaryotic Virus

Recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V-Q) being considered identical (see Section V-S)) may be propagated and maintained in cells in tissue culture using BL1 containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used. If helper virus is present, procedures specified under Section III-C–3 should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome.

Section III-D–2. Experiments Involving Whole Plants

This section covers experiments involving recombinant DNA-modified whole plants, and/or experiments involving recombinant DNA-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-C, or III-E. It should be emphasized that knowledge of the organisms and judgment based on accepted scientific practices should be used in all cases in selecting the appropriate level of containment. For example, if the genetic modification has the objective of increasing pathogenicity or converting a non-pathogenic organism into a pathogen, then a higher level of containment may be appropriate depending on the organism, its mode of dissemination, and its target organisms. By contrast, a lower level of containment may be appropriate for small animals associated with many types of recombinant DNA-modified plants.

Section III-D–2-a. BL1–P is recommended for all experiments with recombinant DNA-containing plants and plant-associated microorganisms not covered in Section III-D–2-b or other sections of the NIH Guidelines. Examples of such experiments are those involving recombinant DNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area, and experiments involving whole plants and recombinant DNA-modified non-exotic (see Section V-W) microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., *Rhizobium* spp. and *Agrobacterium* spp.).

Section III-D–2-b. BL2–P or BL1–P + biological containment is recommended for the following experiments:

Section III-D–2-b-(1). Plants modified by recombinant DNA that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.

Section III-D–2-b-(2). Plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent (see Section V-W).

Section III-D–2-b-(3). Plants associated with recombinant DNA-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems (see Section V-W).

Section III-D–2-b-(4). Plants associated with recombinant DNA-modified exotic microorganisms that have no recognized potential for serious natural ecosystems (see Section V-W).

Section III–D–2–b–(5). Experiments with recombinant DNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant DNA-modified microorganisms associated with them if the recombinant DNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems (see Section V–W).

Section III–E. Exempt Experiments

The following recombinant DNA molecules are exempt from the NIH Guidelines and registration with the Institutional Biosafety Committee is not required:

Section III–E–1. Those that are not in organisms or viruses.

Section III–E–2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

Section III–E–3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

Section III–E–4. Those that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

Section III–E–5. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV–C–1–b–(1)–(c)). See Appendices A–I through A–VI for a list of natural exchangers that are exempt from the NIH Guidelines.

Section III–E–6. Those that do not present a significant risk to health or the environment (see Section IV–C–1–b–(1)–(c)), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C for other classes of experiments which are exempt from the NIH Guidelines.

Section IV, Roles and Responsibilities

Section IV–A. Policy

The safe conduct of experiments involving recombinant DNA depends on the individual conducting such activities. The NIH Guidelines cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment. The NIH Guidelines are intended to assist the institution, Institutional Biosafety Committee, Biological Safety Officer, and Principal Investigator in determining safeguards that should be implemented. The NIH Guidelines will never be complete or final since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the NIH Guidelines as well as to their specifics. Each institution (and the Institutional Biosafety Committee acting on its behalf) is responsible for ensuring that recombinant DNA activities comply with the NIH Guidelines. General recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Further clarifications and interpretations of roles and responsibilities will be issued by the NIH as necessary.

Section IV–B. Responsibilities of the Institution

Section IV-B–1. General Information

Each institution conducting or sponsoring recombinant DNA research which is covered by the NIH Guidelines

is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH Guidelines. In order to fulfill this responsibility, the institution shall:

Section IV-B–1-a. Establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the NIH Guidelines. As part of its general responsibilities for implementing the NIH Guidelines, the institution may establish additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the NIH Guidelines. Such procedures may include: (i) Statements formulated by the institution for the general implementation of the NIH Guidelines, and (ii) any additional precautionary steps the institution deems appropriate.

Section IV-B–1-b. Establish an Institutional Biosafety Committee that meets the requirements set forth in Section IV-B–2-a and carries out the functions detailed in

Section IV-B–2-b.

Section IV-B–1-c. Appoint a Biological Safety Officer (who is also a member of the Institutional Biosafety Committee) if the institution: (i) Conducts recombinant DNA research at Biosafety Level (BL) 3 or BL4, or (ii) engages in large scale (greater than 10 liters) research. The Biological Safety Officer carries out the duties specified in Section IV-B–3.

Section IV-B–1-d. Assist and ensure compliance with the NIH Guidelines by Principal Investigators conducting research at the institution as specified in

Section IV-B–4.

Section IV-B–1-e. Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the NIH Guidelines. The Institutional Biosafety Committee Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee.

Section IV-B–1-f. Determine the necessity for health surveillance of personnel involved in connection with individual recombinant DNA projects; and if appropriate, conduct a health surveillance program for such projects. The institution shall establish and maintain a health surveillance program for personnel engaged in large scale research or production activities involving viable organisms containing recombinant DNA molecules which require BL3 containment at the laboratory scale. The institution shall establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant DNA-containing microorganisms that require BL3 or greater containment in the laboratory. The Laboratory Safety Monograph discusses various components of such a program (e.g., records of agents handled, active investigation of relevant illnesses, and the maintenance of serial serum samples for monitoring serologic changes that may result from the employees' work experience). Certain medical conditions may place a laboratory worker at increased risk in any endeavor where infectious agents are handled. Examples cited in the Laboratory Safety Monograph include gastrointestinal disorders and treatment with steroids, immunosuppressive drugs, or antibiotics. Workers with such disorders or treatment should be evaluated to determine whether they should be engaged in research with potentially hazardous organisms during their treatment or illness. Copies of the Laboratory Safety Monograph are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section IV-B–1-g. Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH/ORDA within thirty days, unless the institution determines that a report has already been filed by the Principal Investigator or Institutional Biosafety Committee. Reports shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section IV-B–2. Institutional Biosafety Committee (IBC)

The institution shall establish an Institutional Biosafety Committee whose responsibilities need not be restricted to recombinant DNA. The Institutional Biosafety Committee shall meet the following requirements:

Section IV-B–2-a. Membership and Procedures

Section IV-B–2-a-(1). The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q require Institutional Biosafety Committee prior approval. When the institution conducts recombinant DNA research at BL3 or BL4, a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B–3).

Section IV-B–2-a-(2). In order to ensure the competence necessary to review and approve recombinant DNA activities, it is recommended that the Institutional Biosafety Committee: (i) include persons with expertise in recombinant DNA technology, biological safety, and physical containment; (ii) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (iii) include at least one member representing the laboratory technical staff.

Section IV-B–2-a-(3). The institution shall file a report with NIH/ORDA which includes the names and biographical sketches of all Institutional Biosafety Committee members, including community members, in such form and at such times as required by NIH/ORDA.

Section IV-B–2-a-(4). No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in

which he/she has been or expects to be engaged or has a direct financial interest.

Section IV-B–2-a-(5). The institution, that is ultimately responsible for the effectiveness of the Institutional Biosafety Committee, may establish procedures that the Institutional Biosafety Committee shall follow in its initial and continuing review and approval of applications, proposals, and activities.

Section IV-B–2-a-(6). When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public.

Section IV-B–2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Section IV-B–2-b. Functions

On behalf of the institution, the Institutional Biosafety Committee is responsible for:

Section IV-B–2-b-(1). Reviewing recombinant DNA research conducted at or sponsored by the institution for compliance with the NIH Guidelines as specified in Section III and approving those research projects that are found to conform with the NIH Guidelines. This review shall include: (i) independent assessment of the containment levels required by the NIH Guidelines for the proposed research, and (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research.

Section IV-B–2-b-(2). Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.

Section IV-B–2-b-(3). Lowering containment levels for certain experiments as specified in Section III-C–2-a.

Section IV-B–2-b-(4). Setting containment levels as specified in Sections III-C–4-b and III-C–5.

Section IV-B–2-b-(5). Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the NIH Guidelines.

Section IV-B–2-b-(6). Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

Note: The Laboratory Safety Monograph describes basic elements for developing specific procedures dealing with major spills of potentially hazardous materials in the laboratory, including information and references about decontamination and emergency plans. The NIH and the Centers for Disease Control and Prevention are available to provide consultation and direct assistance, if necessary, as posted in the Laboratory Safety Monograph. The institution shall cooperate with the state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.

Section IV-B–2-b-(7). Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/ORDA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–9838.

Section IV-B–2-b-(8). The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the NIH Guidelines until NIH (with the advice of the RAC when required) establishes the containment requirement.

Section IV-B–2-b-(9). Performing such other functions as may be delegated to the Institutional Biosafety Committee under Section IV-B–2.

Section IV-B–3. Biological Safety Officer (BSO)

Section IV-B–3-a. The institution shall appoint a Biological Safety Officer if it engages in large scale research or production activities involving viable organisms containing recombinant DNA molecules.

Section IV-B–3-b. The institution shall appoint a Biological Safety Officer if it engages in recombinant DNA research at BL3 or BL4. The Biological Safety Officer shall be a member of the Institutional Biosafety Committee.

Section IV-B–3-c. The Biological Safety Officer's duties include, but are not be limited to:

Section IV-B–3-c-(1). Periodic inspections to ensure that laboratory standards are rigorously followed;

Section IV-B–3-c-(2). Reporting to the Institutional Biosafety Committee and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator;

Section IV-B–3-c-(3). Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research;

Section IV-B–3-c-(4). Providing advice on laboratory security;

Section IV-B–3-c-(5). Providing technical advice to Principal Investigators and the Institutional Biosafety Committee on research safety procedures.

Note: See the Laboratory Safety Monograph for additional information on the duties of the Biological Safety Officer.

Section IV–B–4. Principal Investigator (PI)

On behalf of the institution, the Principal Investigator is responsible for full compliance with the NIH Guidelines in the conduct of recombinant DNA research.

Section IV–B–4–a. General Responsibilities

As part of this general responsibility, the Principal Investigator shall:

Section IV–B–4–a–(1). Initiate or modify no recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation (see Sections III–A, III–B, and III–C) until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the NIH Guidelines;

Section IV–B–4–a–(2). Determine whether experiments are covered by Section III–D and that the appropriate procedures are followed;

Section IV–B–4–a–(3). Report any significant problems, violations of the NIH Guidelines, or any significant research–related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable) within 30 days (reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838);

Section IV–B–4–a–(4). Report any new information bearing on the NIH Guidelines to the Institutional Biosafety Committee and to NIH/ORDA (reports to NIH/ORDA shall be sent to the Office of

Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838);

Section IV–B–4–a–(5). Be adequately trained in good microbiological techniques;

Section IV–B–4–a–(6). Adhere to Institutional Biosafety Committee–approved emergency plans for handling accidental spills and personnel contamination; and

Section IV–B–4–a–(7). Comply with shipping requirements for recombinant DNA molecules (see Appendix H for shipping requirements and the Laboratory Safety Monograph for technical recommendations).

Section IV–B–4–b. Submissions by the Principal Investigator to the NIH/ORDA

The Principal Investigator shall:

Section IV–B–4–b–(1). Submit information to NIH/ORDA for certification of new host–vector systems;

Section IV–B–4–b–(2). Petition NIH/ORDA, with notice to the Institutional Biosafety Committee, for proposed exemptions to the NIH Guidelines;

Section IV–B–4–b–(3). Petition NIH/ORDA, with concurrence of the Institutional Biosafety Committee, for approval to conduct experiments specified in Sections III–A and III–B of the NIH Guidelines;

Section IV–B–4–b–(4). Petition NIH/ORDA for determination of containment for experiments requiring case–by–case review; and

Section IV–B–4–b–(5). Petition NIH/ORDA for determination of containment for experiments not covered by the NIH Guidelines.

Section IV–B–4–c. Submissions by the Principal Investigator to the Institutional Biosafety Committee

The Principal Investigator shall:

Section IV–B–4–c–(1). Make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines;

Section IV–B–4–c–(2). Select appropriate microbiological practices and laboratory techniques to be used for the research;

Section IV–B–4–c–(3). Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host–vector system), if covered under

Sections III–A, III–B, III–C, or III–D, to the Institutional Biosafety Committee for review and approval or disapproval; and

Section IV–B–4–c–(4). Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

Section IV–B–4–d. Responsibilities of the Principal Investigator Prior to Initiating Research

The Principal Investigator shall:

Section IV–B–4–d–(1). Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;

Section IV–B–4–d–(2). Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and

Section IV–B–4–d–(3). Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

Section IV–B–4–e. Responsibilities of the Principal Investigator During the Conduct of the Research

The Principal Investigator shall:

Section IV–B–4–e–(1). Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

Section IV–B–4–e–(2). Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), the Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable) (reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838);

Section IV–B–4–e–(3). Correct work errors and conditions that may result in the release of recombinant DNA materials; and

Section IV–B–4–e–(4). Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

Section IV–C. Responsibilities of the National Institutes of Health (NIH)

Section IV–C–1. NIH Director

The NIH Director is responsible for: (i) establishing the NIH Guidelines, (ii) overseeing their implementation, and (iii) their final interpretation. The NIH Director has responsibilities under the NIH Guidelines that involve ORDA and the RAC. ORDA's responsibilities under the NIH Guidelines are administrative. Advice from the RAC is primarily scientific, technical, and ethical. In certain circumstances, there is specific opportunity for public comment with published response prior to final action.

Section IV–C–1–a. General Responsibilities

The NIH Director is responsible for:

Section IV–C–1–a–(1). Promulgating requirements as necessary to implement the NIH Guidelines;

Section IV–C–1–a–(2). Establishing and maintaining the RAC to carry out the responsibilities set forth in Section IV–C–2 (RAC membership is specified in its charter and in Section IV–C–2); and

Section IV–C–1–a–(3). Establishing and maintaining ORDA to carry out the responsibilities defined in Section IV–C–3.

Section IV–C–1–b. Specific Responsibilities

In carrying out the responsibilities set forth in this section, the NIH Director, or a designee shall weigh each proposed action through appropriate analysis and consultation to determine whether it complies with the NIH Guidelines and presents no significant risk to health or the environment.

Section IV–C–1–b–(1). Major Actions

To execute Major Actions, the NIH Director shall seek the advice of the RAC and provide an opportunity for public and Federal agency comment. Specifically, the Notice of Meeting and Proposed Actions to the NIH Guidelines shall be published in the **Federal Register** at least 15 days before the RAC meeting (not applicable for Expedited Review single patient human gene transfer experiments considered under Appendix M–VI). The NIH Director's decision, at his/her discretion, may be published in the **Federal Register** for 15 days of comment before final action is taken. The NIH Director's final decision, along with responses to public comments, shall be published in the **Federal Register**. The RAC and Institutional Biosafety Committee Chairs shall be notified of the following decisions:

Section IV–C–1–b–(1)–(a). Changing containment levels for types of experiments that are specified in the NIH Guidelines when a Major Action is involved;

Section IV–C–1–b–(1)–(b). Assigning containment levels for types of experiments that are not explicitly considered in the NIH Guidelines when a Major Action is involved;

Section IV–C–1–b–(1)–(c). Promulgating and amending a list of classes of recombinant DNA molecules

to be exempt from the NIH Guidelines because they consist entirely of DNA segments from species that exchange DNA by known physiological processes or otherwise do not present a significant risk to health or the environment;

Section IV–C–1–b–(1)–(d). Permitting experiments specified by Section III–A;

Section IV–C–1–b–(1)–(e). Certifying new host-vector systems with the exception of minor modifications of already certified systems (the standards and procedures for certification are described in Appendix I–II). Minor modifications constitute (e.g., those of minimal or no consequence to the properties relevant to containment); and

Section IV–C–1–b–(1)–(f). Adopting other changes in the NIH Guidelines.

Section IV–C–1–b–(2). Minor Actions

NIH/ORDA shall carry out certain functions as delegated to it by the NIH Director (see Section IV–C–3). Minor Actions (as determined by NIH/ORDA in consultation with the RAC Chair and one or more RAC members, as necessary) will be transmitted to the RAC and Institutional Biosafety Committee Chairs:

Section IV–C–1–b–(2)–(a). Reviewing and approving certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that qualify for the Accelerated Review process (see Section III–B–2);

Section IV–C–1–b–(2)–(b). Reviewing and approving minor changes to human gene transfer protocols under Section III–A–2 and III–B–2;

Section IV–C–1–b–(2)–(c). Changing containment levels for experiments that are specified in Section III;

Section IV–C–1–b–(2)–(d). Assigning containment levels for experiments not explicitly considered in the NIH Guidelines; and

Section IV–C–1–b–(2)–(e). Revising the Classification of Etiologic Agents for the purpose of these NIH Guidelines (see Section V–A).

Section IV–C–1–b–(2)–(f). Interpreting the NIH Guidelines for experiments to which the NIH Guidelines do not specifically assign containment levels;

Section IV–C–1–b–(2)–(g). Setting containment under Sections III–C–1–d and III–C–2– b;

Section IV–C–1–b–(2)–(h). Approving minor modifications of already certified host-vector systems (the standards and procedures for such modifications are described in Appendix I–II);

Section IV–C–1–b–(2)–(i). Decertifying already certified host-vector systems;

Section IV-C–1-b-(2)-(j). Adding new entries to the list of molecules toxic for vertebrates (see Appendix F); and

Section IV-C–1-b-(2)-(k). Determining appropriate containment conditions for experiments according to case precedents developed under Section IV-C–1-b-(2)-(c).

Section IV-C–1-b-(3). The NIH Director shall conduct, support, and assist training programs in laboratory safety for Institutional Biosafety Committee members, Biological Safety Officers, Principal Investigators, and laboratory staff.

Section IV-C–2. Recombinant DNA Advisory Committee (RAC)

The RAC is responsible for carrying out specified functions cited below as well as others assigned under its charter or by the DHHS Secretary, the DHHS Assistant Secretary for Health, and the NIH Director. The RAC consists of 25 members including the Chair, appointed by the DHHS Secretary or his/her designee, at least fourteen of whom are selected from authorities knowledgeable in the fields of molecular genetics, molecular biology, recombinant DNA research, or other scientific fields. At least six members of the RAC shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Representatives from Federal agencies shall serve as non-voting members.

Nominations for the RAC may be submitted to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

All meetings of the RAC shall be announced in the **Federal Register**, including tentative agenda items, 15 days before the meeting. Final agendas, if modified, shall be available at least 72 hours before the meeting. No item defined as a Major Action under Section IV-C–1-b-(1) may be added to an agenda following **Federal Register** publication.

The RAC shall be responsible for advising the NIH Director on the actions listed in Sections IV-C–1-b-(1).

Section IV-C–3. Office of Recombinant DNA Activities (ORDA)

ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH including institutions, Biological Safety Officers, Principal Investigators, Federal agencies, state and local governments, and institutions in the private sector. ORDA shall carry out such other functions as may be delegated to it by the NIH Director, including those authorities described in Section IV-C–1-b-(2). ORDA's responsibilities include, but are not limited to the following:

Section IV-C–3-a. Reviewing and approving experiments in conjunction with ad hoc experts involving the cloning of genes encoding for toxin molecules that are lethal for vertebrates at an LD_{50} ≤100 nanograms per kilogram body weight in organisms other than Escherichia coli K–12 (see Section III-B–1 and Appendices F-I and F-II);

Section IV-C–3-b. Reviewing and approving certain experiments involving the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects, in consultation with the RAC Chair and one or more RAC members, as necessary, that qualify for the Accelerated Review process (see Section III-B–2);

Section IV-C–3-c. Reviewing and approving minor changes to human gene transfer protocols approved under Sections III-A–2 and III-B–2, in consultation with the RAC Chair and one or more RAC members, as necessary;

Section IV-C–3-d. Reviewing and approving the membership of an institution's Institutional Biosafety Committee, and where it finds the Institutional Biosafety Committee meets the requirements set forth in Section IV-B–2 will give its approval to the Institutional Biosafety Committee membership;

Section IV-C–3-e. Publishing in the **Federal Register**:

Section IV–C–3–e–(1). Announcements of RAC meetings and agendas at least 15 days in advance (NOTE—If the agenda for a RAC meeting is modified, ORDA shall make the revised agenda available to anyone upon request at least 72 hours in advance of the meeting);

Section IV–C–3–e–(2). Proposed Major Actions to the NIH Guidelines (see Section IV–C–1–b–(1)) at least 15 days prior to the RAC meeting;

Section IV–C–3–f. Serve as the focal point for data management of NIH-approved human gene transfer protocols approved under Sections III–A–2 and III–B–2 and registered with NIH/ORDA as required under Section III–C–7;

Section IV–C–3–g. Serve as the executive secretary of the RAC; and

Section IV–C–3–h. Maintain a list of Major and Minor Actions approved under Section III–A–2 and III–B–3 and a list of experiments registered with NIH/ORDA as described in Section III–C–7.

Section IV–C–4. Other NIH Components

Other NIH components shall be responsible for certifying maximum containment (BL4) facilities, inspecting them periodically, and inspecting other recombinant DNA facilities as deemed necessary.

Section IV–D. Compliance with the NIH Guidelines

As a condition for NIH funding of recombinant DNA research, institutions shall ensure that such research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the NIH Guidelines. The policies on noncompliance are as follows:

All NIH-funded projects involving recombinant DNA techniques must comply with the NIH Guidelines. Non-compliance may result in: (i) suspension, limitation, or termination of financial assistance for such projects and of NIH funds for other recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution.

All non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques must comply with the NIH Guidelines. Noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for recombinant DNA research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the institution.

Information concerning noncompliance with the NIH Guidelines may be brought forward by any person. It should be delivered to both NIH/ORDA and the relevant institution. The institution, generally through the Institutional Biosafety Committee, shall take appropriate action. The institution shall forward a complete report of the incident recommending any further action to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

In cases where NIH proposes to suspend, limit, or terminate financial assistance because of noncompliance with the NIH Guidelines, applicable DHHS and Public Health Service procedures shall govern.

Section IV–E. Voluntary Compliance

Section IV–E–1. Basic Policy

Individuals, corporations, and institutions not otherwise covered by the NIH Guidelines are encouraged to do so by following the standards and procedures set forth in Sections I through IV. In order to simplify discussion, references hereafter to "institutions" are intended to encompass corporations and individuals who have no organizational affiliation. For purposes of complying with the NIH Guidelines, an individual intending to carry out research involving recombinant DNA is encouraged to affiliate with an institution that has an Institutional Biosafety Committee approved under the NIH Guidelines.

Since commercial organizations have special concerns, such as protection of proprietary data, some modifications and explanations of the procedures are provided in Sections IV–E–2 through IV–E–5–b in order to address these concerns.

Section IV–E–2. Institutional Biosafety Committee Approval

It should be emphasized that employment of an Institutional Biosafety Committee member solely for purposes of membership on the Institutional Biosafety Committee does not itself make the member an institutionally affiliated member. Except for the unaffiliated members, a member of an Institutional Biosafety Committee for an institution not otherwise covered by the NIH Guidelines may participate in the review and approval of a project in which the member has a direct financial interest so long as the member has not been, and does not expect to be, engaged in the project. Section IV–B–2–a–(4) is modified to that extent for purposes of these institutions.

Section IV–E–3. Certification of Host-Vector Systems

A host-vector system may be proposed for certification by the NIH Director in accordance with the procedures set forth in Appendix I-II. In order to ensure protection for proprietary data, any public notice regarding a host-vector system which is designated by the institution as proprietary under Section IV–E–5-a will be issued only after consultation with the institution as to the content of the notice.

Section IV–E–4. Requests for Exemptions and Approvals

Requests for exemptions or other approvals as required by the NIH Guidelines should be submitted based on the procedures set forth in Sections I through IV. In order to ensure protection for proprietary data, any public notice regarding a request for an exemption or other approval which is designated by the institution as proprietary under Section IV–E–5-a will be issued only after consultation with the institution as to the content of the notice.

Section IV–E–5. Protection of Proprietary Data

Section IV–E–5-a. General

In general, the Freedom of Information Act requires Federal agencies to make their records available to the public upon request. However, this requirement does not apply to, among other things, "trade secrets and commercial or financial information that is obtained from a person and that is privileged or confidential." Under 18 U.S.C. 1905, it is a criminal offense for an officer or employee of the U.S. or any Federal department or agency to publish, divulge, disclose, or make known "in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, (or) processes—of any person, firm, partnership, corporation, or association." This provision applies to all employees of the Federal Government, including special Government employees. Members of the RAC are "special Government employees."

In submitting to NIH for purposes of voluntary compliance with the NIH Guidelines, an institution may designate those items of information which the institution believes constitute trade secrets, privileged, confidential, commercial, or financial information. If NIH receives a request under the Freedom of Information Act for information so designated, NIH will promptly contact the institution to secure its views as to whether the information (or some portion) should be released. If the NIH decides to release this information (or some portion) in response to a Freedom of Information request or otherwise, the institution will be advised; and the actual release will not be made until the expiration of 15 days after the institution is so advised except to the extent that earlier release in the judgment of the NIH Director is necessary to protect against an imminent hazard to the public or the environment.

Section IV–E–5-b. Presubmission Review

Any institution not otherwise covered by the NIH Guidelines, which is considering submission of data or information voluntarily to NIH, may request presubmission review of the records involved to determine if NIH will make all or part of the records available upon request under the Freedom of Information Act.

A request for presubmission review should be submitted to NIH/ORDA along with the records involved to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. These records shall be clearly marked as being the property of the institution on loan to NIH solely for the purpose of making a determination under the Freedom of Information Act. NIH/ORDA will seek a determination from the responsible official under DHHS regulations (45 Code of Federal Regulations, Part 5) as to whether the records involved, (or some portion) will be made available to members of the public under the Freedom of Information Act. Pending such a determination, the records will be kept separate from NIH/ORDA files, will be considered records of the institution and not NIH/ORDA, and will not be received as part of NIH/ORDA files. No copies will be made of such records.

NIH/ORDA will inform the institution of the DHHS Freedom of Information Officer's determination and follow the institution's instructions as to whether some or all of the records involved are to be returned to the institution or to become a part of NIH/ORDA files. If the institution instructs NIH/ORDA to return the records, no copies or summaries of the records will be made or retained by DHHS, NIH, or ORDA. The DHHS Freedom of Information Officer's determination will represent that official's judgment at the time of the determination as to whether the records involved (or some portion) would be exempt from disclosure under the Freedom of Information Act if at the time of the determination the records were in NIH/ORDA files and a request was received for such files under the Freedom of Information Act.

Section V. Footnotes and References of Sections I Through IV

Section V–A. The original reference to organisms as Class 1, 2, 3, 4, or 5 refers to the classification in the publication Classification of Etiologic Agents on the Basis of Hazard, 4th Edition, July 1974, U.S. Department of Health, Education, and Welfare, Public Health Services, Centers for Disease Control and Prevention, Office of Biosafety, Atlanta, Georgia 30333. The NIH Director, with advice of the RAC, may revise the classification for the purposes of the NIH Guidelines (see Section IV–C–1-b-(2)-(e)). The revised list of organisms in each class is reprinted in Appendix B.

Section V–B. Section III describes a number of places where judgments are to be made. In all these cases, the Principal Investigator shall make the judgment on these matters as part of his/her responsibility to "make the initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines" (see Section IV–B–4-c-(1)). For cases falling under Sections III–A through III–D, this judgment is to be reviewed and approved by the Institutional Biosafety Committee as part of its responsibility to make an "independent assessment of the containment levels required by the NIH Guidelines for the proposed research" (see Section IV–B–2-b-(1)). The Institutional Biosafety Committee may refer specific cases to NIH/ORDA as part of NIH/ORDA's functions to "provide advice to all within and outside NIH" (see Section IV–C–3). NIH/ORDA may request advice from the RAC as part of the RAC's responsibility for "interpreting the NIH Guidelines for experiments to which the NIH Guidelines do not specifically assign containment levels" (see Section IV–C–1-b-(2)-(f)).

Section V–C. Laboratory Safety at the Centers for Disease Control, September 1974, U.S. Department of Health, Education, and Welfare Publication No. CDC 75–8118.

Section V–D. Classification of Etiologic Agents on the Basis of Hazard, 4th Edition, July 1974, U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, Office of Biosafety, Atlanta, Georgia 30333.

Section V–E. National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses, October 1974, U.S. Department of Health, Education, and Welfare, Publication No. (NIH) 75–790.

Section V–F. National Institutes of Health Biohazards Safety Guide, 1974, U.S. Department of Health, Education, and Welfare, Public Health Service, NIH, U.S. Government Printing Office, Stock No. 1740–00383.

Section V–G. A. Hellman, M. N. Oxman, and R. Pollack (eds.), 1973, Biohazards in Biological Research, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY.

Section V–H. Furr, A. K., Handbook of Laboratory Safety, 2nd ed, The Chemical Rubber Co., Boca Raton, Florida, 1990.

Section V–I. American Public Health Association, Bodily, J. L., General Administration of the Laboratory, 6th ed., "Diagnostic Procedures for Bacterial, Mycotic, and Parasitic Infections," New York, 1981.

Section V–J. H. M. Darlow, Safety in the Microbiological Laboratory, in J. R. Norris and D. W. Robbins (eds.), Methods in Microbiology, Academic Press, Inc, New York, New York, 1969, pp. 169–204.

Section V–K. C. M. Collins, E. G. Hartley, and R. Pilsworth, The Prevention of Laboratory Acquired Infection, Public Health Laboratory Service, Monograph Series No. 6, 1974.

Section V–L. Chatigny, M. A, "Protection Against Infection in the Microbiological Laboratory: Devices and Procedures," in W.W. Umbreit (ed.), Advances in Applied Microbiology, Academic Press, New York, New York, 1961, 3:131–192.

Section V–M. Design Criteria for Viral Oncology Research Facilities, U.S. Department of Health, Education, and Welfare, Public Health Service, NIH, DHEW Publication No. (NIH) 75–891, 1975.

Section V–N. Kuehne, R. W., Biological Containment Facility for Studying Infectious Disease, Appl. Microbiol. 26:239–243, 1973.

Section V–O. Runkle, R. B., and G. B. Phillips, Microbial Containment Control Facilities, Van Nostrand Reinhold, New York, 1969.

Section V–P. Chatigny, M. A., and D. I. Clinger, "Contamination Control in Aerobiology," in R. L. Dimmick and A. B. Akers (eds.), An Introduction to Experimental Aerobiology, John Wiley & Sons, New York, 1969, pp. 194–263.

Section V–Q. As classified in the Third Report of the International Committee on Taxonomy of Viruses: Classification and Nomenclature of Viruses, R. E. F. Matthews (ed.), Intervirology 12 (129–296), 1979.

Section V–R. A U.S. Department of Agriculture permit is required for the importation, interstate movement, and release into the environment of certain organisms that are plant or animal pathogens, whether genetically engineered or not. Permits are required for veterinary biologics and for certain plants or microorganisms derived through genetic engineering using genetic sequences from plant pests (pathogens). Specific information about regulated organisms and procedures for obtaining a permit for regulated organisms may be obtained from the Director, Biotechnology, Biologics, and Environmental Protection, Animal and

Plant Health Inspection Service, U.S. Department of Agriculture, 6505 Belcrest Road, Room 850, Hyattsville, Maryland 20782, (301) 436–7601.

Section V–S. i.e., the total of all genomes within a family shall not exceed two-thirds of the genome.

Section V–T. All activities, including storage of variola and whitepox, are restricted to the single national facility (World Health Organization Collaborating Center for Smallpox Research, Centers for Disease Control and Prevention, Atlanta, Georgia).

Section V–U. Human studies in which the induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected, are not covered under Sections III–A–2, III–B–2, or III–B–3. Such studies may be initiated without RAC review and NIH approval if approved by another Federal agency.

Section V–V. For recombinant DNA experiments in which the intent is to modify stably the genome of cells of one or more human subjects (see Sections III–A–2, III–B–2, and III–B–3).

Section V–W. In accordance with accepted scientific and regulatory practices of the discipline of plant pathology, an exotic plant pathogen (e.g., virus, bacteria, or fungus) is one that is unknown to occur within the U.S. (see Section V–R). Determination of whether a pathogen has a potential for serious detrimental impact on managed (agricultural, forest, grassland) or natural ecosystems should be made by the Principal Investigator and the Institutional Biosafety Committee, in consultation with scientists knowledgeable of plant diseases, crops, and ecosystems in the geographic area of the research.

Appendix A. Exemptions Under Section III–E–5—Sublists of Natural Exchangers

Certain specified recombinant DNA molecules that "consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent are exempt from these NIH Guidelines (see Section III–E–5). Institutional Biosafety Committee registration is not required for these exempt experiments. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice from the RAC after appropriate notice and opportunity for public comment (see Section IV–C–1–b–(1)–(c)). See Appendices A–I through A–VI for a list of natural exchangers that are exempt from the NIH Guidelines." Section III–E–5 describes recombinant DNA molecules that are: (1) composed entirely of DNA segments from one or more of the organisms within a sublist, and (2) to be propagated in any of the organisms within a sublist (see Classification of Bergey's Manual of Determinative Bacteriology; 8th edition, R. E. Buchanan and N. E. Gibbons, editors, Williams and Wilkins Company; Baltimore, Maryland 1984). Although these experiments are exempt, it is recommended that they be performed at the appropriate biosafety level for the host or recombinant organism (see Biosafety in Microbiological and Biomedical Laboratories, 3rd edition, May 1993, U.S. DHHS, Public Health Service, Centers for Disease Control, Atlanta, Georgia, and NIH Office of Biosafety, Bethesda, Maryland).

Appendix A–I. Sublist A

Genus *Escherichia*
Genus *Shigella*
Genus *Salmonella*—including Arizona
Genus *Enterobacter*
Genus *Citrobacter*—including *Levinea*
Genus *Klebsiella*—including *oxytoca*
Genus *Erwinia*
Pseudomonas aeruginosa, Pseudomonas putida, Pseudomonas fluorescens, and Pseudomonas mendocina
Serratia marcescens
Yersinia enterocolitica

Appendix A–II. Sublist B

Bacillus subtilis
Bacillus licheniformis
Bacillus pumilus
Bacillus globigii
Bacillus niger
Bacillus nato
Bacillus amyloliquefaciens
Bacillus aterrimus

Appendix A–III. Sublist C

Streptomyces aureofaciens
Streptomyces rimosus
Streptomyces coelicolor

Appendix A–IV. Sublist D

Streptomyces griseus
Streptomyces cyaneus
Streptomyces venezuelae

Appendix A–V. Sublist E

One way transfer of *Streptococcus mutans* or *Streptococcus lactis* DNA into *Streptococcus sanguis*

Appendix A–VI. Sublist F

Streptococcus sanguis
Streptococcus pneumoniae
Streptococcus faecalis
Streptococcus pyogenes
Streptococcus mutans

Appendix B. Classification of Etiologic Agents and Oncogenic Viruses on the Basis of Hazard (See Appendix B–VI–A).

Appendix B–I. Class 1 Agents

All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes shall be considered Class 1 agents.

Appendix B–II. Class 2 Agents

Appendix B–II–A. Class 2 Bacterial Agents

Acinetobacter calcoaceticus
Actinobacillus—all species
Aeromonas hydrophila
Amycolata autotrophica
Arizona hinshawii—all serotypes
Bacillus anthracis
Bordetella—all species
Borrelia recurrentis, B. vincenti
Campylobacter fetus
Campylobacter jejuni
Chlamydia psittaci
Chlamydia trachomatis
Clostridium botulinum, Cl. chauvoei; Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani
Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale
Dermatophilus congolensis
Edwardsiella tarda
Erysipelothrix insidiosa
Escherichia coli—all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen
Haemophilus ducreyi, H. influenzae
Klebsiella—all species except oxytoca
Legionella pneumophila
Leptospira interrogans—all serotypes
Listeria—all species
Moraxella—all species
Mycobacteria—all species except those listed in Class 3
Mycobacterium avium
Mycoplasma—all species except *Mycoplasma mycoides* and *Mycoplasma agalactiae*, which are in Class 5
Neisseria gonorrhoea, N. meningitides
Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis
Pasteurella—all species except those listed in Class 3
Rhodococcus equi
Salmonella—all species and all serotypes
Shigella-all species and all serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pneumoniae, S. pyogenes
Treponema carateum, T. pallidum, and T. pertenue

Vibrio cholerae, V. parahemolyticus
Yersinia enterocolitica

Appendix B-II-B. Class 2 Fungal Agents

Blastomyces dermatitidis
Cryptococcus neoformans
Paracoccidioides braziliensis

Appendix B-II-C. Class 2 Parasitic Agents

Endamoeba histolytica
Leishmania sp.
Naegleria gruberi
Schistosoma mansoni
Toxocara canis
Toxoplasma gondii
Trichinella spiralis
Trypanosoma cruzi

Appendix B–II–D. Class 2 Viral, Rickettsial, and Chlamydial Agents

Adenoviruses—human—all types
Cache Valley virus
Coronaviruses
Coxsackie A and B viruses
Cytomegaloviruses
Echoviruses—all types
Encephalomyocarditis virus (EMC)
Flanders virus
Hart Park virus
Hepatitis viruses—associated antigen material
Herpesviruses—except *Herpesvirus simiae* (Monkey B virus) which is in Class 4
Influenza viruses—all types except A/PR8/34, which is in Class 1
Langat virus
Lymphogranuloma venereum agent
Measles virus
Mumps virus
Parainfluenza virus—all types except Parainfluenza virus 3, SF4 strain, which is in Class 1
Polioviruses —all types, wild and attenuated
Poxviruses—all types except Alastrim, Smallpox, and Whitepox which are Class 5 and Monkey pox which depending on experiments is in Class 3 or Class 4
Rabies virus—all strains except Rabies street virus which should be classified in Class 3
Reoviruses—all types
Respiratory syncytial virus
Rhinoviruses—all types
Rubella virus
Simian viruses—all types except *Herpesvirus simiae* (Monkey B virus) and Marburg virus which are in Class 4
Sindbis virus
Tensaw virus
Turlock virus
Vaccinia virus
Varicella virus
Vesicular stomatitis virus (see Appendix B-VI-B)
Vole rickettsia
Yellow fever virus, 17D vaccine strain

Appendix B-II-E. Class 2 Oncogenic Viruses (See Appendix B-VI-C)

Appendix B-II-E–1. Low-Risk Oncogenic Viruses

Adenovirus 7–Simian virus 40 (Ad7–SV40)
Adenovirus
Avian leukosis virus
Bovine leukemia virus
Bovine papilloma virus
Chick-embryo-lethal orphan (CELO) virus or fowl adenovirus 1
Dog sarcoma virus
Guinea pig herpes virus
Lucke (Frog) virus
Hamster leukemia virus
Marek's disease virus
Mason-Pfizer monkey virus
Mouse mammary tumor virus
Murine leukemia virus
Murine sarcoma virus
Polyoma virus
Rat leukemia virus
Rous sarcoma virus
Shope fibroma virus
Shope papilloma virus
Simian virus 40 (SV–40)

Appendix B-II-E–2. Moderate-Risk Oncogenic Viruses

Adenovirus 2–Simian virus 40 (Ad2–SV40)
Epstein-Barr virus (EBV)
Feline leukemia virus (FeLV)
Feline sarcoma virus (FeSV)
Gibbon leukemia virus (GaLV)
Herpesvirus (HV) *ateles*
Herpesvirus (HV) *saimiri*
Simian sarcoma virus (SSV)–1
Yaba

Appendix B–III. Class 3 Agents

Appendix B–III–A. Class 3 Bacterial Agents

Bartonella—all species
Brucella—all species
Francisella tularensis
Mycobacterium bovis, M. tuberculosis
Pasteurella multocide type—"buffalo" and other foreign virulent strains (see Appendix B–VI–B)
Pseudomonas mallei (see Appendix B–VI–B)
Pseudomonas pseudomallei (see Appendix B–VI–B)
Yersinia pestis

Appendix B–III–B. Class 3 Fungal Agents

Coccidioides immitis
Histoplasma capsulatum
Histoplasma capsulatum var. *duboisii*

Appendix B–III–C. Class 3 Parasitic Agents

None

Appendix B–III–D. Class 3 Viral, Rickettsial, and Chlamydial Agents

Monkey pox virus—when used *in vitro* (see Appendix B–VI–D)
Arboviruses—all strains except those in Class 2 and 4. (Arboviruses indigenous to the United States are in Class 3 except those listed in Class 2. West Nile and Semliki Forest viruses may be classified up or down depending on the conditions of use and geographical location of the laboratory).
Dengue virus—when used for transmission or animal inoculation experiments
Lymphocytic choriomeningitis virus (LCM)
Rickettsia—all species except *Vole rickettsia* when used for transmission or animal inoculation experiments
Yellow fever virus—wild, when used *in vitro*

Appendix B–IV. Class 4 Agents

Appendix B–IV–A. Class 4 Bacterial Agents

None

Appendix B–IV–B. Class 4 Fungal Agents

None

Appendix B–IV–C. Class 4 Parasitic Agents

None

Appendix B–IV–D. Class 4 Viral, Rickettsial, and Chlamydial Agents

Ebola fever virus
Monkey pox virus—when used for transmission or animal inoculation experiments (see Appendix B–VI–D)
Hemorrhagic fever agents—including Crimean hemorrhagic fever, (Congo), Junin, and Machupo viruses, and others as yet undefined
Herpesvirus simiae (Monkey B virus)
Lassa virus
Marburg virus
Tick-borne encephalitis virus complex—including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses
Venezuelan equine encephalitis virus, epidemic strains—when used for transmission or animal inoculation experiments
Yellow fever virus-wild—when used for transmission or animal inoculation experiments

Appendix B–V. Class 5 Agents (see Appendix B–VI–E)

Appendix B–V–A. Animal Disease Organisms which are Forbidden Entry into the United States by Law

Foot and mouth disease virus

Appendix B–V–B. Animal Disease Organisms and Vectors which are Forbidden Entry into the United States by U.S. Department of Agriculture Policy

African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Borna disease virus
Bovine infectious petechial fever
Camel pox virus
Ephemeral fever virus
Fowl plague virus
Goat pox virus
Hog cholera virus
Louping ill virus
Lumpy skin disease virus
Mycoplasma mycoides—contagious bovine pleuropneumonia
Mycoplasma agalactiae—contagious agalactia of sheep
Nairobi sheep disease virus
Newcastle disease virus—Asiatic strains
Rhinderpest virus
Rickettsia ruminatium—heart water
Rift valley fever virus
Sheep pox virus
Swine vesicular disease virus
Teschen disease virus
Theileria annulata
Theileria bovis
Theileria hirci
Theileria lawrencei
Theileria parva—East Coast fever
Trypanosoma evansi
Trypanosoma vivax—Nagana
Vesicular exanthema virus
Wesselsbron disease virus
Zyonema

Appendix B–V–C. Organisms which may not be Studied in the United States Except at Specified Facilities

Alastrim (see Appendix B–VI–D)
Small pox (see Appendix B–VI–D)
White pox (see Appendix B–VI–D)

Appendix B–VI. Footnotes and References of Appendix B

Appendix B–VI–A. The original reference for this classification was the publication Classification of Etiologic Agents on the Basis of Hazard, 4th edition, July 1974, U.S. DHHS, Public Health Service, Centers for Disease Control and Prevention, Office of Biosafety, Atlanta, Georgia 30333. For the purposes of these NIH Guidelines, this list has been revised by the NIH.

Appendix B–VI–B. A U.S. Department of Agriculture permit, required for import and interstate transport of pathogens, may be obtained from the U.S. Department of Agriculture, ATTN: Animal and Plant Health Inspection Service, Import-Export Products Office, Room 756, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782.

Appendix B–VI–C. National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses, U.S. Department of Health, Education, and Welfare Publication No. (NIH) 75–790, October 1974.

Appendix B–VI–D. All activities, including storage of variola and whitepox, are restricted to the single national facility (World Health Organization Collaborating Center for Smallpox Research, Centers for Disease Control and Prevention, Atlanta, Georgia).

Appendix B–VI–E. U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

Appendix C. Exemptions Under Section III–E–6

Section III–E–6 states that exempt from these NIH Guidelines are "those that do not present a significant risk to health or the environment (see Section IV–C–1–b–(1)–(c)), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C for other classes of experiments which are exempt from the NIH Guidelines." The following classes of experiments are exempt under Section III–E–6:

Appendix C–I. Recombinant DNA in Tissue Culture

Recombinant DNA molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family (see Appendix C–VI–D) being considered identical (see Appendix C–VI–E), that are propagated and maintained in cells in tissue culture are exempt from these NIH Guidelines with the exceptions listed in Appendix C–I–A.

Appendix C–I–A. Exceptions

The following categories are not exempt from the NIH Guidelines: (i) experiments described in Section III–A which require specific RAC review and NIH and Institutional Biosafety Committee approval before initiation, (ii) experiments described in Section III–B which require NIH/ORDA and Institutional Biosafety Committee approval before initiation, (iii) experiments involving DNA from Class 3, 4, or 5 organisms (see Appendix C–VI–A) or cells known to be infected with these agents, (iv) experiments involving the deliberate introduction of genes coding for the biosynthesis of molecules that are toxic for vertebrates (see Appendix F), and (v) whole plants regenerated from plant cells and tissue cultures are covered by the exemption provided they remain axenic cultures even though they differentiate into embryonic tissue and regenerate into plantlets.

Appendix C–II. *Escherichia coli* K–12 Host-Vector Systems

Experiments which use *Escherichia coli* K–12 host-vector systems, with the exception of those experiments listed in Appendix C–II–A, are exempt from the NIH Guidelines provided that: (i) the *Escherichia coli* host does not contain conjugation proficient plasmids or generalized transducing phages; or (ii) lambda or lambdoid or Ff bacteriophages or non-conjugative plasmids (see Appendix C–VI–B) shall be used as vectors. However, experiments involving the insertion into *Escherichia coli* K–12 of DNA from prokaryotes that exchange genetic information (see Appendix C–VI–C) with Escherichia coli may be performed with any Escherichia coli K–12 vector (e.g., conjugative plasmid). When a non-conjugative vector is used, the *Escherichia coli* K–12 host may contain conjugation-proficient plasmids either autonomous or integrated, or generalized transducing phages. For these exempt laboratory experiments, Biosafety Level (BL) 1 physical containment conditions are recommended. For large scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the host organism unmodified by recombinant DNA techniques; the Institutional Biosafety Committee can specify higher containment if deemed necessary.

Appendix C–II–A. Exceptions

The following categories of experiments are not exempt from the NIH Guidelines: (i) experiments described in Section III–A which require Institutional Biosafety Committee approval, RAC review, and NIH approval before initiation, (ii) experiments described in Section III–B which require Institutional Biosafety Committee and NIH/ORDA approval before initiation, (iii) experiments involving DNA from Class 3, 4, or 5 organisms (see Appendix C–VI–A) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III–C–2 with prior Institutional Biosafety Committee review and approval, (iv) large scale experiments (e.g., more than 10 liters of culture), and (v) experiments involving the cloning of toxin molecule genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F).

Appendix C-III. Saccharomyces Host-Vector Systems

Experiments involving *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host-vector systems, with the exception of experiments listed in Appendix C-III-A, are exempt from the NIH Guidelines. For these exempt experiments, BL1 physical containment is recommended. For large scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the host organism unmodified by recombinant DNA techniques; the Institutional Biosafety Committee can specify higher containment if deemed necessary.

Appendix C-III-A. Exceptions

The following categories are not exempt from the NIH Guidelines: (i) Experiments described in Section III-A which require Institutional Biosafety Committee approval, RAC review, and NIH approval before initiation, (ii) experiments described in Section III-B which require Institutional Biosafety Committee and NIH/ORDA approval before initiation, (iii) experiments involving DNA from Class 3, 4, or 5 organisms (see Appendix C-VI-A) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-C–2 with prior Institutional Biosafety Committee review and approval, (iv) large scale experiments (e.g., more than 10 liters of culture), and (v) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F).

Appendix C-IV. Bacillus subtilis or Bacillus licheniformis Host-Vector Systems

Any asporogenic *Bacillus subtilis* or asporogenic *Bacillus licheniformis* strain which does not revert to a spore-former with a frequency greater than 10^{-7} may be used for cloning DNA with the exception of those experiments listed in Appendix C-IV-A. For these exempt laboratory experiments, BL1 physical containment conditions are recommended. For large scale fermentation experiments, the appropriate physical containment conditions need be no greater than those for the host organism unmodified by recombinant DNA techniques; the Institutional Biosafety Committee can specify higher containment if it deems necessary.

Appendix C-IV-A. Exceptions

The following categories are not exempt from the NIH Guidelines: (i) Experiments described in Section III-A which require Institutional Biosafety Committee approval, RAC review, and NIH approval before initiation, (ii) experiments described in Section III-B which require Institutional Biosafety Committee and NIH/ORDA approval before initiation, (iii) experiments involving DNA from Class 3, 4, or 5 organisms (see Appendix C-VI-A) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III-C–2 with prior Institutional Biosafety Committee review and approval, (iv) large scale experiments (e.g., more than 10 liters of culture), and (v) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F).

Appendix C-V. Extrachromosomal Elements of Gram Positive Organisms

Recombinant DNA molecules derived entirely from extrachromosomal elements of the organisms listed below (including shuttle vectors constructed from vectors described in Appendix C), propagated and maintained in organisms listed below are exempt from these NIH Guidelines.

Bacillus amyloliquefaciens
Bacillus amylosaccharitícus
Bacillus anthracis
Bacillus aterrimus
Bacillus brevis
Bacillus cereus
Bacillus globigii
Bacillus licheniformis
Bacillus megaterium
Bacillus natto
Bacillus niger
Bacillus pumilus
Bacillus sphaericus
Bacillus stearothermophilis
Bacillus subtilis
Bacillus thuringiensis
Clostridium acetobutylicum
Lactobacillus casei
Listeria grayi
Listeria monocytogenes
Listeria murrayi
Pediococcus acidilactici
Pediococcus damnosus
Pediococcus pentosaceus
Staphylococcus aureus
Staphylcoccus carnosus
Staphylococcus epidermidis
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus avium
Streptococcus cremoris
Streptococcus dorans
Streptococcus equisimilis
Streptococcus faecalis
Streptococcus ferus
Streptococcus lactis
Streptococcus ferns
Streptococcus mitior
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus salivarious
Streptococcus sanguis
Streptococcus sobrinus
Streptococcus thermophylus

Appendix C–V–A. Exceptions

The following categories of experiments are not exempt from the NIH Guidelines: (i) Experiments described in Section III–A which require Institutional Biosafety Committee, specific RAC review, and NIH approval before initiation, (ii) experiments described in Section III–B which require Institutional Biosafety Committee and NIH/ORDA approval before initiation, (iii) experiments involving DNA from Class 3, 4, or 5 organisms (see Appendix C–VI–A) or cells known to be infected with these agents may be conducted under containment conditions specified in Section III–C–2 with prior Institutional Biosafety Committee review and approval, (iv) large scale experiments (e.g., more than 10 liters of culture), and (v) experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (see Appendix F).

Appendix C–VI. Footnotes and References of Appendix C

Appendix C–VI–A. The original reference to organisms as Class 1, 2, 3, 4, or 5 refers to the classification in the publication Classification of Etiologic Agents on the Basis of Hazard, 4th Edition, July 1974, U.S. Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control and Prevention, Office of Biosafety, Atlanta, Georgia 30333.

Appendix C–VI–A–1. The NIH Director, with advice of the RAC, may revise the classification for the purposes of these NIH Guidelines (see Section IV-C–1–b–(2)–(d)). The revised list of organisms in each class is reprinted in Appendix B.

Appendix C–VI–B. A subset of non-conjugative plasmid vectors are poorly mobilizable (e.g., pBR322, pBR313). Where practical, these vectors should be employed.

Appendix C–VI–C. Defined as observable under optimal laboratory conditions by transformation, transduction, phage infection, and/or conjugation with transfer of phage, plasmid, and/or chromosomal genetic information. Note that this definition of exchange may be less stringent than that applied to exempt organisms under Section III–E–5.

Appendix C–VI–D. As classified in the Third Report of the International Committee on Taxonomy of Viruses: Classification and Nomenclature of Viruses, R.E.F. Matthews (ed.), Intervirology 12 (129–296), 1979.

Appendix C–VI–E. i.e., the total of all genomes within a Family shall not exceed one-half of the genome.

Appendix D. Major Actions Taken Under the NIH Guidelines

Under Section IV–C–1–b–(1), the NIH Director may take certain actions with regard to the NIH Guidelines after the issues have been considered by the RAC. An updated list of these actions are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix E. Certified Host-Vector Systems (see Appendix I)

While many experiments using *Escherichia coli* K–12, *Saccharomyces cerevisiae*, and *Bacillus subtilis* are currently exempt from the NIH Guidelines under Section III–E, some derivatives of these host-vector systems were previously classified as Host-Vector 1 Systems or Host-Vector 2 Systems. A listing of those systems follows:

Appendix E–I. Bacillus subtilis

Appendix E–I–A. Bacillus subtilis Host-Vector 1 Systems

The following plasmids are accepted as the vector components of certified *B. subtilis* systems: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223, and pAB124. *B. subtilis* strains RUB 331 and BGSC 1S53 have been certified as the host component of Host-Vector 1 systems based on these plasmids.

Appendix E–I–B. Bacillus Subtilis Host-Vector 2 Systems

The asporogenic mutant derivative of *Bacillus subtilis*, ASB 298, with the following plasmids as the vector component: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223, and pAB124.

Appendix E–II. Saccharomyces Cerevisiae

Appendix E–II–A. Saccharomyces Cerevisiae Host-Vector 2 Systems

The following sterile strains of *Saccharomyces cerevisiae*, all of which have the ste-VC9 mutation, SHY1, SHY2, SHY3, and SHY4. The following plasmids are certified for use: YIp1, YEp2, YEp4, YIp5, YEp6, YRp7, YEp20, YEp21, YEp24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, and YIp33.

Appendix E-III. Escherichia coli

Appendix E-III-A. *Escherichia coli* (EK2) Plasmid Systems

The *Escherichia coli* K–12 strain chi-1776. The following plasmids are certified for use: pSC101, pMB9, pBR313, pBR322, pDH24, pBR325, pBR327, pGL101, and pHB1. The following *Escherichia coli*/S. cerevisiae hybrid plasmids are certified as EK2 vectors when used in *Escherichia coli* chi-1776 or in the sterile yeast strains, SHY1, SHY2, SHY3, and SHY4: YIpI, YEp2, YEp4, YIp5, YEp6, YRp7, YEp20, YEp21, YEP24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, and YIp33.

Appendix E-III-B. *Escherichia coli* (EK2) Bacteriophage Systems

The following are certified EK2 systems based on bacteriophage lambda:

Vector	Host
λgt *WES*λB′	DP50*supF*
λgt *WES*λB*	DP50*supF*
λgt *ZJ* virλB′	*Escherichia coli* K–12
λgtALO•λB	DP50*supF*
Charon 3A	DP50 or DP50*supF*
Charon 4A	DP50 or DP50*supF*
Charon 16A	DP50 or DP50*supF*
Charon 21A	DP50*supF*
Charon 23A	DP50 or DP50*supF*
Charon 24A	DP50 or DP50*supF*

Escherichia coli K–12 strains chi-2447 and chi-2281 are certified for use with lambda vectors that are certified for use with strain DP50 or DP50*supF* provided that the su-strain not be used as a propagation host.

Appendix E-IV. Neurospora crassa

Appendix E-IV-A. Neurospora crassa Host-Vector 1 Systems

The following specified strains of *Neurospora crassa* which have been modified to prevent aerial dispersion: In1 (inositolless) strains 37102, 37401, 46316, 64001, and 89601. Csp-1 strain UCLA37 and csp-2 strains FS 590, UCLA101 (these are conidial separation mutants).

Eas strain UCLA191 (an "easily wettable" mutant).

Appendix E–V. Streptomyces

Appendix E–V–A. *Streptomyces* Host-Vector 1 Systems

The following *Streptomyces* species: *Streptomyces coelicolor, S. lividans, S. parvulus*, and *S. griseus*. The following are accepted as vector components of certified *Streptomyces* Host-Vector 1 systems: *Streptomyces* plasmids SCP2, SLP1.2, pIJ101, actinophage phi C31, and their derivatives.

Appendix E–VI. Pseudomonas Putida

Appendix E–VI–A. Pseudomonas putida Host-Vector 1 Systems

Pseudomonas putida strains KT2440 with plasmid vectors pKT262, pKT263, and pKT264.

Appendix F. Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates

Appendix F–I. General Information

Appendix F specifies the containment to be used for the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates. The cloning of genes coding for molecules toxic for vertebrates that have an LD_{50} of <100 nanograms per kilograms body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, *Shigella dysenteriae* neurotoxin) are covered under Section III–B–1 and require Institutional Biosafety Committee and NIH/ORDA approval before initiation. No specific restrictions shall apply to the cloning of genes if the protein specified by the gene has an LD_{50} ≥100 micrograms per kilograms of body weight. Experiments involving genes coding for toxin molecules with an LD_{50} of <100 micrograms per kilograms and >100 nanograms per kilograms body weight require Institutional Biosafety Committee approval and registration with NIH/ORDA prior to initiating the experiments. A list of toxin molecules classified as to LD_{50} is available from NIH/ORDA. Testing procedures for determining toxicity of toxin molecules not on the list are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. The results of such tests shall be forwarded to NIH/ORDA, which will consult with *ad hoc* experts, prior to inclusion of the molecules on the list (see Section IV–C–1–b–(2)–(e)).

Appendix F–II. Cloning of Toxin Molecule Genes in Escherichia coli K–12

Appendix F–II–A. Cloning of genes coding for molecules toxic for vertebrates that have an LD_{50} of >100 nanograms per kilograms and <1000 nanograms per kilograms body weight (e.g., abrin, *Clostridium perfringens* epsilon toxin) may proceed under Biosafety Level (BL) 2 + EK2 or BL3 + EK1 containment conditions.

Appendix F–II–B. Cloning of genes for the biosynthesis of molecules toxic for vertebrates that have an LD_{50} of >1 microgram per kilogram and <100 microgram per kilogram body weight may proceed under BL1 + EK1 containment conditions (e.g., *Staphylococcus aureus* alpha toxin, *Staphylococcus aureus* beta toxin, ricin, *Pseudomonas aeruginosa* exotoxin A, *Bordetella pertussis* toxin, the lethal factor of *Bacillus anthracis*, the *Pasteurella pestis* murine toxins, the oxygen-labile hemolysins such as streptolysin O, and certain neurotoxins present in snake venoms and other venoms).

Appendix F–II–C. Some enterotoxins are substantially more toxic when administered enterally than parenterally. The following enterotoxins shall be subject to BL1 + EK1 containment conditions: cholera toxin, the heat labile toxins of *Escherichia coli*, *Klebsiella*, and other related proteins that may be identified by neutralization with an antiserum monospecific for cholera toxin, and the heat stable toxins of *Escherichia coli* and of *Yersinia enterocolitica*.

Appendix F–III. Cloning of Toxic Molecule Genes in Organisms Other Than Escherichia coli K–12

Requests involving the cloning of genes coding for molecules toxic for vertebrates at an LD_{50} of <100 nanograms per kilogram body weight in host-vector systems other than *Escherichia coli* K–12 will be evaluated by NIH/ORDA in consultation with *ad hoc* toxin experts (see Sections III–B–1 and IV–C–1–b–(2)–(e)).

Appendix F–IV. Specific Approvals

An updated list of experiments involving the deliberate formation of recombinant DNA containing genes coding for toxins lethal for vertebrates at an LD_{50} of <100 nanograms per kilogram body weight is available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix G. Physical Containment

Appendix G specifies physical containment for standard laboratory experiments and defines Biosafety Level 1 through Biosafety Level 4. For large scale (over 10 liters) research or production, Appendix K supersedes Appendix G. Appendix K defines Good Large Scale Practice through Biosafety Level 3—Large Scale. For certain work with plants, Appendix P supersedes Appendix G. Appendix P defines Biosafety Levels 1 through 4—Plants. For certain work with animals, Appendix Q supersedes Appendix G. Appendix Q defines Biosafety Levels 1 through 4—Animals.

Appendix G–I. Standard Practices and Training

The first principle of containment is strict adherence to good microbiological practices (see Appendices G–III–A through G–III–J). Consequently, all personnel directly or indirectly involved in experiments using recombinant DNA shall receive adequate instruction (see Sections IV–B–1–e and IV–B–4–d). At a minimum, these instructions include training in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.

Any research group working with agents that are known or potential biohazards shall have an emergency plan that describes the procedures to be followed if an accident contaminates personnel or the environment. The Principal Investigator shall ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan (see Sections IV–B–4–d and IV–B–4–e). If a research group is working with a known pathogen for which there is an effective vaccine, the vaccine should be made available to all workers. Serological monitoring, when clearly appropriate, will be provided (see Section IV–B–1–f).

The Laboratory Safety Monograph (see Appendix G–III–O) and Biosafety in Microbiological and Biomedical Laboratories (see Appendix G–III–B) describe practices, equipment, and facilities in detail.

Appendix G–II. Physical Containment Levels

The objective of physical containment is to confine organisms containing recombinant DNA molecules and to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment to organisms containing recombinant DNA molecules. Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed.

Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Four levels of physical containment, which are designated as BL1, BL2, BL3, and BL4 are described. It should be emphasized that the descriptions and assignments of physical containment detailed below are based on existing approaches to containment of pathogenic organisms (see Appendix G–III–B). The National Cancer Institute describes three levels for research on oncogenic viruses which roughly correspond to our BL2, BL3, and BL4 levels (see Appendix G–III–C).

It is recognized that several different combinations of laboratory practices, containment equipment, and special laboratory design may be appropriate for containment of specific research activities. The NIH Guidelines, therefore, allow alternative selections of primary containment equipment within facilities that have been designed to provide BL3 and BL4 levels of physical containment. The selection of alternative methods of primary containment is dependent, however, on the level of biological containment provided by the host-vector system used in the experiment. Consideration will be given by the NIH Director, with the advice of the RAC to other combinations which achieve an equivalent level of containment (see Section IV-C–1-b-(2)-(c)).

Appendix G-II-A. Biosafety Level 1 (BL1) (see Appendix G-III-M)

Appendix G-II-A–1. Standard Microbiological Practices (BL1). Appendix G-II-A–1-a. Access to the laboratory is limited or restricted at the discretion of the Principal Investigator when experiments are in progress.

Appendix G-II-A–1-b. Work surfaces are decontaminated once a day and after any spill of viable material.

Appendix G-II-A–1-c. All contaminated liquid or solid wastes are decontaminated before disposal.

Appendix G-II-A–1-d. Mechanical pipetting devices are used; mouth pipetting is prohibited.

Appendix G-II-A–1-e. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.

Appendix G-II-A–1-f. Persons wash their hands: (i) After they handle materials involving organisms containing recombinant DNA molecules

and animals, and (ii) before exiting the laboratory.

Appendix G-II-A–1-g. All procedures are performed carefully to minimize the creation of aerosols.

Appendix G-II-A–1-h. In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant DNA molecules.

Appendix G-II-A–2. Special Practices (BL1). Appendix G-II-A–2-a. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

Appendix G-II-A–2-b. An insect and rodent control program is in effect.

Appendix G-II-A–3. Containment Equipment (BL1). Appendix G-II-A–3-a. Special containment equipment is generally not required for manipulations of agents assigned to BL1.

Appendix G-II-A–4. Laboratory Facilities (BL1). Appendix G-II-A–4-a. The laboratory is designed so that it can be easily cleaned.

Appendix G-II-A–4-b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix G-II-A–4-c. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.

Appendix G-II-A–4-d. Each laboratory contains a sink for hand washing.

Appendix G-II-A–4-e. If the laboratory has windows that open, they are fitted with fly screens.

Appendix G-II-B. Biosafety Level 2 (BL2) (see Appendix G-III-N)

Appendix G-II-B–1. Standard Microbiological Practices (BL2). Appendix G-II-B–1-a. Access to the laboratory is limited or restricted by the Principal Investigator when work with organisms containing recombinant DNA molecules is in progress.

Appendix G-II-B–1-b. Work surfaces are decontaminated at least once a day and after any spill of viable material.

Appendix G-II-B–1-c. All contaminated liquid or solid wastes are decontaminated before disposal.

Appendix G-II-B–1-d. Mechanical pipetting devices are used; mouth pipetting is prohibited.

Appendix G-II-B–1-e. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.

Appendix G-II-B–1-f. Persons wash their hands: (i) after handling materials involving organisms containing recombinant DNA molecules and animals, and (ii) when exiting the laboratory.

Appendix G-II-B–1-g. All procedures are performed carefully to minimize the creation of aerosols.

Appendix G-II-B–1-h. Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory.

Appendix G-II-B–2. Special Practices (BL2). Appendix G-II-B–2-a. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

Appendix G-II-B–2-b. The Principal Investigator limits access to the laboratory. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

Appendix G-II-B–2-c. The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

Appendix G-II-B–2-d. When the organisms containing recombinant DNA molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.

Appendix G-II-B–2-e. An insect and rodent control program is in effect.

Appendix G-II-B–2-f. Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.

Appendix G-II-B–2-g. Animals not involved in the work being performed are not permitted in the laboratory.

Appendix G-II-B–2-h. Special care is taken to avoid skin contamination with organisms containing recombinant DNA molecules; gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.

Appendix G-II-B–2-i. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

Appendix G-II-B–2-j. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably autoclaved, before discard or reuse.

Appendix G-II-B–2-k. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Institutional Biosafety Committee and NIH/ORDA. Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix G-II-B–2-l. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility.

Appendix G-II-B–2-m. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

Appendix G-II-B–3. Containment Equipment (BL 2). Appendix G-II-B–3-a. Biological safety cabinets (Class I or II) (see Appendix G-III-L) or other appropriate personal protective or physical containment devices are used whenever:

Appendix G-II-B–3-a-(1). Procedures with a high potential for creating aerosols are conducted (see Appendix G-III-O). These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of

materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.

Appendix G-II-B–3-a-(2). High concentrations or large volumes of organisms containing recombinant DNA molecules are used. Such materials may be centrifuged in the open laboratory if sealed beads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

Appendix G-II-B–4. Laboratory Facilities (BL 2). Appendix G-II-B–4-a. The laboratory is designed so that it can be easily cleaned.

Appendix G-II-B–4-b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix G-II-B–4-c. Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.

Appendix G-II-B–4-d. Each laboratory contains a sink for hand washing.

Appendix G-II-B–4-e. If the laboratory has windows that open, they are fitted with fly screens.

Appendix G-II-B–4-f. An autoclave for decontaminating laboratory wastes is available.

Appendix G-II-C. Biosafety Level 3 (BL3) (see Appendix G-III-P)

Appendix G-II-C–1. Standard Microbiological Practices (BL3). Appendix G-II-C–1-a. Work surfaces are decontaminated at least once a day and after any spill of viable material.

Appendix G-II-C–1-b. All contaminated liquid or solid wastes are decontaminated before disposal.

Appendix G-II-C–1-c. Mechanical pipetting devices are used; mouth pipetting is prohibited.

Appendix G-II-C–1-d. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the work area.

Appendix G-II-C–1-e. Persons wash their hands: (i) after handling materials involving organisms containing recombinant DNA molecules, and handling animals, and (ii) when exiting the laboratory.

Appendix G-II-C–1-f. All procedures are performed carefully to minimize the creation of aerosols.

Appendix G-II-C–1-g. Persons under 16 years of age shall not enter the laboratory.

Appendix G-II-C–1-h. If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

Appendix G-II-C–2. Special Practices (BL3) Appendix G-II-C–2-a. Laboratory doors are kept closed when experiments are in progress.

Appendix G-II-C–2-b. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

Appendix G-II-C–2-c. The Principal Investigator controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

Appendix G-II-C–2-d. The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures entering the laboratory or animal rooms.

Appendix G-II-C–2-e. When organisms containing recombinant DNA molecules or experimental animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biosafety symbol is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates any special requirements for entering the laboratory such as the need for immunizations, respirators, or other personal protective measures.

Appendix G-II-C–2-f. All activities involving organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.

Appendix G-II-C–2-g. The work surfaces of biological safety cabinets and other containment equipment are decontaminated when work with organisms containing recombinant DNA molecules is finished. Plastic-backed paper toweling used on non-perforated work surfaces within biological safety cabinets facilitates clean-up.

Appendix G-II-C–2-h. An insect and rodent program is in effect.

Appendix G-II-C–2-i. Laboratory clothing that protects street clothing (e.g., solid front or wrap-around gowns, scrub suits, coveralls) is worn in the laboratory. Laboratory clothing is not worn outside the laboratory, and it is decontaminated prior to laundering or disposal.

Appendix G-II-C–2-j. Special care is taken to avoid skin contamination with contaminated materials; gloves should be worn when handling infected animals and when skin contact with infectious materials is unavoidable.

Appendix G-II-C–2-k. Molded surgical masks or respirators are worn in rooms containing experimental animals.

Appendix G-II-C–2-l. Animals and plants not related to the work being conducted are not permitted in the laboratory.

Appendix G-II-C–2-m. Laboratory animals held in a BL3 area shall be housed in partial-containment caging systems, such as Horsfall units (see Appendix G-III-K), open cages placed in ventilated enclosures, solid-wall and -bottom cages covered by filter bonnets or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors.

Note: Conventional caging systems may be used provided that all personnel wear appropriate personal protective devices. These protective devices shall include at a minimum wrap-around gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.

Appendix G-II-C–2-n. All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

Appendix G-II-C–2-o. Vacuum lines are protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.

Appendix G–II–C–2–p. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix G–II–C–2–q. Spills and accidents which result in overt or potential exposures to organisms

containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and NIH/ORDA. Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

Appendix G–II–C–2–r. Baseline serum samples for all laboratory and other at-risk personnel should be collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the laboratory.

Appendix G–II–C–2–s. A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and follow the instructions on practices and procedures.

Appendix G–II–C–2–t. Alternative Selection of Containment Equipment (BL3) Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified may be conducted in the BL3 laboratory using containment equipment specified for the BL2 level of physical containment. Experimental procedures involving a host-vector system that provides a one-step lower level of biological containment than that specified may be conducted in the BL3 laboratory using containment equipment specified for the BL4 level of physical containment. Alternative combination of containment safeguards are shown in Appendix G–Table 1.

Appendix G–II–C–3. Containment Equipment (BL3). Appendix G–II–C–3–a. Biological safety cabinets (Class I, II, or III) (see Appendix G–III–L) or other appropriate combinations of personal protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) are used for all activities with organisms containing recombinant DNA molecules which pose a threat of aerosol exposure. These include: manipulation of cultures and of those clinical or environmental materials which may be a source of aerosols; the aerosol challenge of experimental animals; the harvesting of infected tissues or fluids from experimental animals and embryonate eggs; and the necropsy of experimental animals.

Appendix G–II–C–4. Laboratory Facilities (BL3) Appendix G–II–C–4–a. The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories or activities may be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the laboratory.

Appendix G–II–C–4–b. The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontaminating the area. Appendix G–II–C–4–c. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix G–II–C–4–d. Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.

Appendix G–II–C–4–e. Each laboratory contains a sink for hand washing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.

Appendix G–II–C–4–f. Windows in the laboratory are closed and sealed.

Appendix G–II–C–4–g. Access doors to the laboratory or containment module are self-closing.

Appendix G–II–C–4–h. An autoclave for decontaminating laboratory wastes is available preferably within the laboratory.

Appendix G–II–C–4–i. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry area. The exhaust air is not recirculated to any other area of the building, is discharged to the outside, and is dispersed away from the occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room may be discharged to the outside without being filtered or otherwise treated.

Appendix G–II–C–4–j. The high efficiency particulate air/HEPA filtered exhaust air from Class I or Class II biological safety cabinets is discharged directly to the outside or through the building exhaust system. Exhaust air from Class I or II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months. If the HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection (see Appendix G–III–L)) that avoids any interference with the air balance of the cabinets or building exhaust system.

Appendix G–II–D. Biosafety Level 4 (BL4)

Appendix G–II–D–1. Standard Microbiological Practices (BL4)

Appendix G–II–D–1–a. Work surfaces are decontaminated at least once a day and immediately after any spill of viable material.

Appendix G–II–D–1–b. Only mechanical pipetting devices are used.

Appendix G–II–D–1–c. Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the laboratory.

Appendix G–II–D–1–d. All procedures are performed carefully to minimize the creation of aerosols.

Appendix G–II–D–2. Special Practices (BL4). Appendix G–II–D–2–a. Biological materials to be removed from the Class III cabinets or from the maximum containment laboratory in a viable or intact state are transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container which is removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.

Appendix G–II–D–2–b. No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before exiting the facility. Equipment or material which might be damaged by high temperatures or steam is decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

Appendix G–II–D–2–c. Only persons whose presence in the facility or individual laboratory rooms is required for program or support purposes are authorized to enter. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. Access to the facility is limited by means of secure, locked doors; accessibility is managed by the Principal Investigator, Biological Safety Officer, or other persons responsible for the physical security of the facility. Before entering, persons are advised of the potential biohazards and instructed as to appropriate safeguards for ensuring their safety. Authorized persons comply with the instructions and all other applicable entry and exit procedures. A logbook signed by all personnel

indicates the date and time of each entry and exit. Practical and effective protocols for emergency situations are established.

Appendix G–II–D–2–d. Personnel enter and exit the facility only through the clothing change and shower rooms. Personnel shower each time they exit the facility. Personnel use the air locks to enter or exit the laboratory only in an emergency.

Appendix G–II–D–2–e. Street clothing is removed in the outer clothing change room and kept there. Complete laboratory clothing (may be disposable), including undergarments, pants and shirts or jump suits, shoes, and gloves, is provided and used by all personnel entering the facility. Head covers are provided for personnel who do not wash their hair during the exit shower. When exiting the laboratory and before proceeding into the shower area, personnel remove their laboratory clothing and store it in a locker or hamper in the inner change room. Protective clothing shall be decontaminated prior to laundering or disposal.

Appendix G–II–D–2–f. When materials that contain organisms containing recombinant DNA molecules or experimental animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biosafety symbol is posted on all access doors. The sign identifies the agent, lists the name of the Principal Investigator or other responsible person(s), and indicates any special requirements for entering the area (e.g., the need for immunizations or respirators).

Appendix G–II–D–2–g. Supplies and materials needed in the facility are brought in by way of the double-doored autoclave, fumigation chamber, or airlock which is appropriately decontaminated between each use. After securing the outer doors, personnel within the facility retrieve the materials by opening the interior doors or the autoclave, fumigation chamber, or airlock. These doors are secured after materials are brought into the facility.

Appendix G–II–D–2–h. An insect and rodent control program is in effect.

Appendix G–II–D–2–i. Materials (e.g., plants, animals, and clothing) not related to the experiment being conducted are not permitted in the facility.

Appendix G–II–D–2–j. Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) are used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be placed in a puncture-resistant container and decontaminated, preferably by autoclaving before discard or reuse. Whenever possible, cannulas are used instead of sharp needles (e.g., gavage).

Appendix G–II–D–2–k. A system is set up for reporting laboratory accidents, exposures, employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and NIH/ORDA. Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Written records are prepared and maintained. An essential adjunct to such a reporting-surveillance system is the availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory associated illnesses.

Appendix G–II–D–2–l. Laboratory animals involved in experiments requiring BL4 level physical containment shall be housed either in cages contained in Class III cabinets or in partial containment caging systems, such as Horsfall units (see Appendix G–III–K), open cages placed in ventilated enclosures, or solid-wall and- bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors that are located in a specially designed area in which all personnel are required to wear one-piece positive pressure suits.

Appendix G–II–D–2–m. Alternative Selection of Containment Equipment (BL4)

Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified may be conducted in the BL4 facility using containment equipment requirements specified for the BL3 level of physical containment. Alternative combinations of containment safeguards are shown in Appendix G—Table 1.

Appendix G–II–D–3. Containment Equipment (BL4). Appendix G–II–D–3–a. All procedures within the facility with agents assigned to Biosafety Level 4 are conducted in the Class III biological safety cabinet or in Class I or II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

Appendix G–II–D–4. Laboratory Facilities (BL4). Appendix G–II–D–4–a. The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and exiting the facility. A double-doored autoclave, fumigation chamber, or ventilated airlock is provided for passage of those materials, supplies, or equipment which are not brought into the facility through the change room.

Appendix G–II–D–4–b. Walls, floors, and ceilings of the facility are constructed to form a sealed internal shell which facilitates fumigation and is animal and insect proof. The internal surfaces of this shell are resistant to liquids and chemicals, thus facilitating cleaning and decontamination of the area. All penetrations in these structures and surfaces are sealed. Any drains in the floors contain traps filled with a chemical disinfectant of demonstrated efficacy against the target agent, and they are connected directly to the liquid waste decontamination system. Sewer and other ventilation lines contain high efficiency particulate air/HEPA filters.

Appendix G–II–D–4–c. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize the horizontal surface area on which dust can settle.

Appendix G–II–D–4–d. Bench tops have seamless surfaces which are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix G–II–D–4–e. Laboratory furniture is simple and of sturdy construction; and spaces between benches, cabinets, and equipment are accessible for cleaning.

Appendix G–II–D–4–f. A foot, elbow, or automatically operated hand washing sink is provided near the door of each laboratory room in the facility.

Appendix G–II–D–4–g. If there is a central vacuum system, it does not serve areas outside the facility. In-line high efficiency particulate air/HEPA filters are placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement. Other liquid and gas services to the facility are protected by devices that prevent back-flow.

Appendix G–II–D–4–h. If water fountains are provided, they are foot operated and are located in the facility

corridors outside the laboratory. The water service to the fountain is not connected to the back-flow protected distribution system supplying water to the laboratory areas.

Appendix G–II–D–4–i. Access doors to the laboratory are self-closing and locking.

Appendix G–II–D–4–j. Any windows are breakage resistant.

Appendix G–II–D–4–k. A double-doored autoclave is provided for decontaminating materials passing out of the facility. The autoclave door which opens to the area external to the facility is sealed to the outer wall and automatically controlled so that the outside door can only be opened after the autoclave "sterilization" cycle has been completed.

Appendix G–II–D–4–l. A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method is provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility.

Appendix G–II–D–4–m. Liquid effluent from laboratory sinks, biological safety cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being released from the maximum containment facility. Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes is evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower room are decontaminated with chemical disinfectants, the chemical used is of demonstrated efficacy against the target or indicator microorganisms.

Appendix G–II–D–4–n. An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials and directional airflow as required to assure flows inward from areas outside of the facility toward areas of highest potential risk within the facility. Manometers are used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers sound an alarm. The supply and exhaust airflow is interlocked to assure inward (or zero) airflow at all times.

Appendix G–II–D–4–o. The exhaust air from the facility is filtered through high efficiency particulate air/HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters are located as near the laboratories as practicable in order to reduce the length of potentially contaminated air ducts. The filter chambers are designed to allow in situ decontamination before filters are removed and to facilitate certification testing after they are replaced. Coarse filters and HEPA filters are provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the supply air system should air pressures become unbalanced in the laboratory.

Appendix G–II–D–4–p. The treated exhaust air from Class I and II biological safety cabinets may be discharged into the laboratory room environment or the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory the cabinets are tested and certified at six-month intervals. The exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of high efficiency particulate air/HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner (e.g., thimble unit connection (see Appendix G–III–L)) that avoids any interference with the air balance of the cabinets or the facility exhaust air system.

Appendix G–II–D–4–q. A specially designed suit area may be provided in the facility. Personnel who enter this area shall wear a one-piece positive pressure suit that is ventilated by a life-support system. The life-support system includes alarms and emergency backup breathing air tanks. Entry to this area is through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker exits the area. The exhaust air from the suit area is filtered by two sets of high efficiency particulate air/HEPA filters installed in series. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source are provided. The air pressure within the suit area is greater than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit are sealed. A double-doored autoclave is provided for decontaminating waste materials to be removed from the suit areas.

APPENDIX G—TABLE 1.—POSSIBLE ALTERNATIVE COMBINATIONS OF PHYSICAL AND BIOLOGICAL CONTAINMENT SAFEGUARDS

Classification of physical & biological containment	Alternate physical containment			Alternate biological containment
	Laboratory facilities	Laboratory practices	Laboratory equipment	
BL3/HV2	BL3	BL3	BL3	HV2
	BL3	BL3	BL4	HV1
BL3/HV1	BL3	BL3	BL3	HV1
	BL3	BL3	BL2	HV2
BL4/HV1	BL4	BL4	BL4	HV1
	BL4	BL4	BL3	HV2

BL—Biosafety Level.
HV—Host-Vector System.

Appendix G–III. Footnotes and References of Appendix G

Appendix G–III–A. Laboratory Safety at the Center for Disease Control, U.S. Department of Health, Education, and Welfare Publication No. CDC 75–8118, September 1974.

Appendix G–III–B. Biosafety in Microbiological and Biomedical Laboratories, 3rd edition, May 1993, U.S. DHHS, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia, and NIH, Bethesda, Maryland.

Appendix G–III–C. National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses, U.S. Department of Health, Education, and Welfare Publication No. (NIH) 75–790, October 1974.

Appendix G–III–D. National Institutes of Health Biohazards Safety Guide, U.S.

Department of Health, Education, and Welfare, Public Health Service, NIH, U.S. Government Printing Office, Stock No. 1740–00383, 1974.

Appendix G–III–E. A. Hellman, M. N. Oxman, and R. Pollack (eds.), Biohazards in Biological Research, Cold Spring Harbor Laboratory 1973.

Appendix G–III–F. N. V. Steere (ed.), Handbook of Laboratory Safety, 2nd edition, The Chemical Rubber Co., Cleveland, Ohio, 1971.

Appendix G–III–G. Bodily, J. L, "General Administration of the Laboratory," H. L. Bodily, E. L. Updyke, and J. O. Mason (eds.), Diagnostic Procedures for Bacterial, Mycotic, and Parasitic Infections, American Public Health Association, New York, 1970, pp. 11–28.

Appendix G–III–H. Darlow, H. M. (1969). "Safety in the Microbiological Laboratory," in J. R. Norris and D. W. Robbins (eds.), Methods in Microbiology, Academic Press, Inc., New York, pp. 169–204.

Appendix G–III–I. The Prevention of Laboratory Acquired Infection, C. H. Collins, E. G. Hartley, and R. Pilsworth, Public Health Laboratory Service, Monograph Series No. 6, 1974.

Appendix G–III–J. Chatigny, M. A., "Protection Against Infection in the Microbiological Laboratory: Devices and Procedures," in W. W. Umbreit (ed.), Advances in Applied Microbiology, Academic Press, New York, New York, 1961, 3:131–192.

Appendix G–III–K. Horsfall, F. L. Jr., and J. H. Baner, Individual Isolation of Infected Animals in a Single Room, J. Bact., 1940, 40, 569–580.

Appendix G–III–L. Biological safety cabinets referred to in this section are classified as Class I, Class II, or Class III cabinets. A Class I is a ventilated cabinet for personnel protection having an inward flow of air away from the operator. The exhaust air from this cabinet is filtered through a high efficiency particulate air/HEPA filter. This cabinet is used in three operational modes: (i) with a full-width open front, (ii) with an installed front closure panel (having four 6-inch diameter openings) without gloves, and (iii) with an installed front closure panel equipped with arm-length rubber gloves. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. A Class II cabinet is a ventilated cabinet for personnel and product protection having an open front with inward air flow for personnel protection, and HEPA filtered mass recirculated air flow for product protection. The cabinet exhaust air is filtered through a HEPA filter. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. Design and performance specifications for Class II cabinets have been adopted by the National Sanitation Foundation, Ann Arbor, Michigan. A Class III cabinet is a closed-front ventilated cabinet of gas tight construction which provides the highest level of personnel protection of all biosafety safety cabinets. The interior of the cabinet is protected from contaminants exterior to the cabinet. The cabinet is fitted with arm-length rubber gloves and is operated under a negative pressure of at least 0.5 inches water gauge. All supply air is filtered through HEPA filters. Exhaust air is filtered through two HEPA filters or one HEPA filter and incinerator before being discharged to the outside environment. National Sanitation Foundation Standard 49. 1976. Class II (Laminar Flow) Biohazard Cabinetry, Ann Arbor, Michigan.

Appendix G–III–M. Biosafety Level 1 is suitable for work involving agents of unknown or minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the building. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science (see Appendix G–III–B).

Appendix G–III–N. Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that: (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; and (3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment (see Appendix G–III–B).

Appendix G–III–O. Office of Research Safety, National Cancer Institute, and the Special Committee of Safety and Health Experts, Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research, NIH, Bethesda, Maryland 1978.

Appendix G–III–P. Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is conducted with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious material are conducted within biological safety cabinets or other physical containment devices or by personnel wearing appropriate personal protective clothing and devices. The laboratory has special engineering and design features. It is recognized, however, that many existing facilities may not have all the facility safeguards recommended for BL3 (e.g., access zone, sealed penetrations, and directional airflow, etc.). In these circumstances, acceptable safety may be achieved for routine or repetitive operations (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, and susceptibility testing) in laboratories where facility features satisfy BL2 recommendations provided the recommended "Standard Microbiological Practices," "Special Practices," and "Containment Equipment" for BL3 are rigorously followed. The decision to implement this modification of BL3 recommendations should be made only by the Principal Investigator.

Appendix H. Shipment

Recombinant DNA molecules contained in an organism or in a viral genome shall be shipped under the applicable regulations of the U.S. Postal Service (39 Code of Federal Regulations, Part 3); the Public Health Service (42 Code of Federal Regulations, Part 72); the U.S. Department of Agriculture (9 Code of Federal Regulations, Subchapters D and E; 7 CFR, Part 340); and/or the U.S. Department of Transportation (49 Code of Federal Regulations, Parts 171–179).

Appendix H–I. Host organisms or viruses will be shipped as etiologic agents, regardless of whether they contain recombinant DNA, if they are regulated as human pathogens by the Public Health Service (42 Code of Federal Regulations, Part 72) or as animal pathogens or plant pests under the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (Titles 9 and 7 Code of Federal Regulations, respectively).

Appendix H–II. Host organisms and viruses will be shipped as etiologic agents if they contain recombinant DNA when: (i) the recombinant DNA includes the complete genome of a host organism or virus regulated as a human or animal

pathogen or a plant pest; or (ii) the recombinant DNA codes for a toxin or other factor directly involved in eliciting human, animal, or plant disease or inhibiting plant growth, and is carried on an expression vector or within the host chromosome and/or when the host organism contains a conjugation proficient plasmid or a generalized transducing phage; or (iii) the recombinant DNA comes from a host organism or virus regulated as a human or animal pathogen or as a plant pest and has not been adequately characterized to demonstrate that it does not code for a factor involved in eliciting human, animal, or plant disease.

Appendix H–III. Footnotes and References of Appendix H

For further information on shipping etiologic agents contact: (i) The Centers for Disease Control and Prevention, ATTN: Biohazards Control Office, 1600 Clifton Road, Atlanta, Georgia 30333, (404) 639–3883, FTS 236–3883; (ii) The U.S. Department of Transportation, ATTN: Office of Hazardous Materials Transportation, 400 7th Street, S.W., Washington, DC 20590, (202) 366–4545; or (iii) U.S. Department of Agriculture, ATTN: Animal and Plant Health Inspection Service, Import-Export Products, Room 756, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782; for Animal Pathogens call (301) 436–7885; for Plant Pests (301) 436–6799.

Appendix I. Biological Containment (See Appendix E)

Appendix I–I. Levels of Biological Containment

In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which is to provide biological containment shall be chosen or constructed so that the following types of "escape" are minimized: (i) survival of the vector in its host outside the laboratory, and (ii) transmission of the vector from the propagation host to other non-laboratory hosts. The following levels of biological containment (host-vector systems) for prokaryotes are established. Appendices I–I–A through I–II–B describe levels of biological containment (host-vector systems) for prokaryotes. Specific criteria will depend on the organisms to be used.

Appendix I–I–A. Host-Vector 1 Systems

Host-Vector 1 systems provide a moderate level of containment. Specific Host-Vector 1 systems are:

Appendix I–I–A–1. Escherichia coli K–12 Host-Vector 1 Systems (EK1). The host is always *Escherichia coli* K–12 or a derivative thereof, and the vectors include non-conjugative plasmids (e.g., pSC101, Co1E1, or derivatives thereof (see Appendices I–III–A through G) and variants of bacteriophage, such as lambda (see Appendices I–III–H through O). The *Escherichia coli* K–12 hosts shall not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

Appendix I–I–A–2. Other Host-Vector 1 Systems. At a minimum, hosts and vectors shall be comparable in containment to *Escherichia coli* K–12 with a non-conjugative plasmid or bacteriophage vector. Appendix I–II describes the data to be considered and mechanism for approval of Host-Vector 1 systems.

Appendix I–I–B. Host-Vector 2 Systems

Host-Vector 2 Systems provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be $<1/10^8$ under specified conditions. Specific Host-Vector 2 systems are:

Appendix I–I–B–1. For *Escherichia coli* K–12 Host-Vector 2 systems (EK2) in which the vector is a plasmid, no more than $1/10^8$ host cells shall perpetuate a cloned DNA fragment under the specified non-permissive laboratory conditions designed to represent the natural environment, either by survival of the original host or as a consequence of transmission of the cloned DNA fragment.

Appendix I–I–B–2. For Escherichia coli K–12 Host-Vector 2 systems (EK2) in which the vector is a phage, no more than $1/10^8$ phage particles shall perpetuate a cloned DNA fragment under the specified non-permissive laboratory conditions designed to represent the natural environment, either as a prophage (in the inserted or plasmid form) in the laboratory host used for phage propagation, or survival in natural environments and transferring a cloned DNA fragment to other hosts (or their resident prophages).

Appendix I–II. Certification of Host-Vector Systems

Appendix I–II–A. Responsibility. Host-Vector 1 systems (other than Escherichia coli K–12) and Host-Vector 2 systems may not be designated as such until they have been certified by the NIH Director. Requests for certification of host-vector systems may be submitted to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Proposed host-vector systems will be reviewed by the RAC (see section IV-C-1-b-(1)-(e)). Initial review will based on the construction, properties, and testing of the proposed host-vector system by a subcommittee composed of one or more RAC members and/or *ad hoc* experts. The RAC will evaluate the subcommittee's report and any other available information at the next scheduled RAC meeting. The NIH Director is responsible for certification of host-vector systems, following advice of the RAC. Minor modifications to existing host-vector systems (i.e., those that are of minimal or no consequence to the properties relevant to containment), may be certified by the NIH Director without prior RAC review (see section IV-C-1-b-(2)-(h)). Once a host-vector system has been certified by the NIH Director, a notice of certification will be sent by NIH/ORDA to the applicant and to the Institutional Biosafety Committee Chairs. A list of all currently certified host-vector systems is available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838. The NIH Director may rescind the certification of a host-vector system (see section IV-C-1-b-(2)-(i)). If certification is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher level of physical containment level, unless NIH determines that the already constructed clones incorporate adequate biological containment. Certification of an host-vector system does not extend to modifications of either the host or vector component of that system. Such modified systems shall be independently certified by the NIH Director. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications to a certified host-vector system requires submission of complete testing data.

Appendix I–II–B. Data To Be Submitted for Certification

Appendix I–II–B–1. Host-Vector 1 Systems Other than Escherichia coli K–12. The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) a description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction, survival, and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and the type of information is exchanged; and any relevant information about its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an Host-Vector 1 system.

Appendix I–II–B–2. Host-Vector 2 Systems. Investigators planning to request Host-Vector 2 systems certification may obtain instructions from NIH/ORDA concerning data to be submitted (see Appendices I–III–N and O). In general, the following types of data are required: (i) description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals or one or more human subjects. Such in vivo data may be required to confirm the validity of predicting in vivo survival on the basis of in vitro experiments. Data shall be submitted 12 weeks prior to the RAC meeting at which such data will be considered by the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Investigators are encouraged to publish their data on the construction, properties, and testing of proposed Host Vector 2 systems prior to consideration of the system by the RAC and its subcommittee. Specific instructions concerning the submission of data for proposed *Escherichia coli* K–12 Host-Vector 2 system (EK2) involving either plasmids or bacteriophage in *Escherichia coli* K–12, are available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix I–III. Footnotes and References of Appendix I

Appendix I–III–A. Hersfield, V., H.W. Boyer, C. Yanofsky, M.A. Lovett, and D.R. Helinski, Plasmid Co1E1 as a Molecular Vehicle for Cloning and Amplification of DNA. Proc. Nat. Acad. Sci., 1974, 71, pp. 3455–3459.

Appendix I–III–B. Wensink, P.C., D.J. Finnegan, J.E. Donelson, and D.S. Hogness, A System for Mapping DNA Sequences in the Chromosomes of Drosophila Melanogaster. Cell, 1974, 3, pp. 315–335.

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Appendix I–III–E. Bolivar, F., R.L. Rodriguez, M.C. Betlack, and H.W. Boyer, Construction and Characterization of New Cloning Vehicles: I. Ampicillin-Resistant Derivative of PMB9, Gene, 1977, 2, pp. 75–93.

Appendix I–III–F. Cohen, S.N., A.C.W. Chang, H. Boyer, and R. Helling. Construction of Biologically Functional Bacterial Plasmids in Vitro. Proc. Natl. Acad, Sci., 1973, 70, pp. 3240–3244.

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Appendix I–III–H. Thomas, M., J.R. Cameron, and R.W. Davis (1974). Viable Molecular Hybrids of Bacteriophage Lambda and Eukaryotic DNA. Proc. Nat. Acad. Sci., 1974, 71, pp. 4579–4583.

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Appendix I–III–J. Ramback, A., and P. Tiollais (1974). Bacteriophage Having EcoRI Endonuclease Sites Only in the Non-Essential Region of the Genome. Proc. Nat. Acad. Sci., 1974, 71, pp. 3927–3820.

Appendix I–III–K. Blattner, F.R., B.G. Williams, A.E. Bleche, K. Denniston-Thompson, H.E. Faber, L.A. Furlong, D.J. Gunwald, D.O. Kiefer, D.D. Moore, J.W. Shumm, E.L. Sheldon, and O. Smithies, Charon Phages: Safer Derivatives of Bacteriophage Lambda for DNA Cloning, Science 1977, 196, pp. 163–169.

Appendix I–III–L. Donoghue, D.J., and P.A. Sharp, An Improved Lambda Vector: Construction of Model Recombinants Coding for Kanamycin Resistance, Gene, 1977, 1, pp. 209–227.

Appendix I–III–M. Leder, P., D. Tiemeier and L. Enquist (1977), EK2 Derivatives of Bacteriophage Lambda Useful in the Cloning of DNA from Higher Organisms: The λgt WES System, Science, 1977, 196, pp. 175–177.

Appendix I–III–N. Skalka, A., Current Status of Coliphage AEK2 Vectors, Gene, 1978, 3, pp. 29–35.

Appendix I–III–O. Szybalski, W., A. Skalka, S. Gottesman, A. Campbell, and D. Botstein, Standardized Laboratory Tests for EK2 Certification, Gene, 1978, 3, pp. 36–38.

Appendix J. Biotechnology Research Subcommittee

The National Science and Technology Council's Committee on Fundamental Science determined that a subcommittee should be continued to identify and coordinate Federal research efforts, identify research needs, stimulating international cooperation, and assess national and international policy issues concerning biotechnology sciences. The primary emphasis will be on scientific issues to increase the overall effectiveness and productivity of the Federal investment in biotechnology sciences, especially regarding issues which cut across agency boundaries. This subcommittee is called the Biotechnology Research Subcommittee.

Membership of the Biotechnology Research Subcommittee will include Federal agencies that support biotechnology research. Agencies represented are: U.S. Department of Agriculture, Department of Commerce, Department of Defense, Department of Energy, Department of Health and Human Services, Department of Interior,

Department of Justice, Department of State, Department of Veterans Affairs, Agency for International Development, Environmental Protection Agency, National Aeronautics and Space Administration, and National Science Foundation. The Biotechnology Research Subcommittee will function in an advisory capacity to the Committee on Fundamental Science, the Director of the Office of Science and Technology Policy, and the Executive Office of the President. The Biotechnology Research Subcommittee will review the scientific aspects of proposed regulations and guidelines as they are developed.

The primary responsibilities of the Biotechnology Research Subcommittee are to: (i) Describe and review current Federal efforts in biotechnology research; (ii) identify and define the priority areas for future Federal biotechnology research, including areas needing greater emphasis, describing the role of each agency in those areas, and delineate where interagency cooperation would enhance progress in the biotechnology sciences, with an emphasis on integrated research efforts, where appropriate; (iii) assess major international efforts in the biotechnology sciences and develop mechanisms for international collaboration. For example, activities of the U.S.-European Community Task Force on Biotechnology have been coordinated through the Biotechnology Research Subcommittee; (iv) identify and review national and international policy issues (such as public education) associated with biotechnology; and (v) provide reviews, analyses, and recommendations to the Chairs of the Committee on Fundamental Science on scientific issues related to regulations and the applications of biotechnology research and biotechnology policies and issues.

In 1990, the Biotechnology Research Subcommittee replaced the Biotechnology Sciences Coordinating Committee. Both the Biotechnology Research Subcommittee and the Biotechnology Sciences Coordinating Committee previously functioned under the Federal Coordinating Council on Science, Engineering, and Technology (FCCSET). While regulatory issues became the primary focus of the Biotechnology Sciences Coordinating Committee, the Biotechnology Research Subcommittee focuses on scientific issues, although it will still provide scientific support for regulatory responsibilities.

Appendix K. Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules

Appendix K specifies physical containment guidelines for large scale (greater than 10 liters of culture) research or production involving viable organisms containing recombinant DNA molecules. It shall apply to large scale research or production activities as specified in Section III-C–6. It is important to note that this appendix addresses only the biological hazard associated with organisms containing recombinant DNA. Other hazards accompanying the large scale cultivation of such organisms (e.g., toxic properties of products; physical, mechanical, and chemical aspects of downstream processing) are not addressed and shall be considered separately, albeit in conjunction with this appendix.

All provisions shall apply to large scale research or production activities with the following modifications: (i) Appendix K shall supersede Appendix G when quantities in excess of 10 liters of culture are involved in research or production. Appendix K-II applies to Good Large Scale Practice; (ii) the institution shall appoint a Biological Safety Officer if it engages in large scale research or production activities involving viable organisms containing recombinant DNA molecules. The duties of the Biological Safety Officer shall include those specified in Section IV-B–3; (iii) the institution shall establish and maintain a health surveillance program for personnel engaged in large scale research or production activities involving viable organisms containing recombinant DNA molecules which require Biosafety Level (BL) 3 containment at the laboratory scale. The program shall include: preassignment and periodic physical and medical examinations; collection, maintenance, and analysis of serum specimens for monitoring serologic changes that may result from the employee's work experience; and provisions for the investigation of any serious, unusual, or extended illnesses of employees to determine possible occupational origin.

Appendix K–I. Selection of Physical Containment Levels

The selection of the physical containment level required for recombinant DNA research or production involving more than 10 liters of culture is based on the containment guidelines established in Section III. For purposes of large scale research or production, four physical containment levels are established. The four levels set containment conditions at those appropriate for the degree of hazard to health or the environment posed by the organism, judged by experience with similar organisms unmodified by recombinant DNA techniques and consistent with Good Large Scale Practice. The four biosafety levels of large scale physical containment are referred to as Good Large Scale Practice, BL1–Large Scale, BL2–Large Scale, and BL3–Large Scale. Good Large Scale Practice is recommended for large scale research or production involving viable, non-pathogenic, and non-toxigenic recombinant strains derived from host organisms that have an extended history of safe large scale use. Good Large Scale Practice is recommended for organisms such as those included in Appendix C which have built-in environmental limitations that permit optimum growth in the large scale setting but limited survival without adverse consequences in the environment. BL1–Large Scale is recommended for large scale research or production of viable organisms containing recombinant DNA molecules that require BL1 containment at the laboratory scale and that do not qualify for Good Large Scale Practice. BL2–Large Scale is recommended for large scale research or production of viable organisms containing recombinant DNA molecules that require BL2 containment at the laboratory scale. BL3–Large Scale is recommended for large scale research or production of viable organisms containing recombinant DNA molecules that require BL3 containment at the laboratory scale. No provisions are made for large scale research or production of viable organisms containing recombinant DNA molecules that require BL4 containment at the laboratory scale. If necessary, these requirements will be established by NIH on an individual basis.

Appendix K–II. Good Large Scale Practice (GLSP)

Appendix K–II–A. Institutional codes of practice shall be formulated and implemented to assure adequate control of health and safety matters.

Appendix K–II–B. Written instructions and training of personnel shall be provided to assure that cultures of viable organisms containing recombinant DNA molecules are handled prudently and that the workplace is kept clean and orderly.

Appendix K–II–C. In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g.,

uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant DNA molecules. Eating, drinking, smoking, applying cosmetics, and mouth pipetting shall be prohibited in the work area.

Appendix K–II–D. Cultures of viable organisms containing recombinant DNA molecules shall be handled in facilities intended to safeguard health during work with microorganisms that do not require containment.

Appendix K–II–E. Discharges containing viable recombinant organisms shall be handled in accordance with applicable governmental environmental regulations.

Appendix K–II–F. Addition of materials to a system, sample collection, transfer of culture fluids within/between systems, and processing of culture fluids shall be conducted in a manner that maintains employee's exposure to viable organisms containing recombinant DNA molecules at a level that does not adversely affect the health and safety of employees.

Appendix K–II–G. The facility's emergency response plan shall include provisions for handling spills. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix K–III. Biosafety Level 1 (BL1)—Large Scale

Appendix K–III–A. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix K–III–B. Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessel used for the propagation and growth of cultures) or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to reduce the potential for escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in Appendix G–II–A are met.

Appendix K–III–C. Culture fluids (except as allowed in Appendix K–III–D) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.

Appendix K–III–D. Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which minimizes the release of aerosols or contamination of exposed surfaces.

Appendix K–III–E. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air/HEPA filters or by other equivalent procedures (e.g., incineration) to minimize the release of viable organisms containing recombinant DNA molecules to the environment.

Appendix K–III–F. A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.

Appendix K–III–G. Emergency plans required by Sections IV–B–2–b–(6) and IV–B–3–c–(3) shall include methods and procedures for handling large losses of culture on an emergency basis.

Appendix K–IV. Biosafety Level 2 (BL2)—Large Scale

Appendix K–IV–A. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix K–IV–B. Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessel used for the propagation and growth of cultures) or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to prevent the escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in Appendix G–II–B are met.

Appendix K–IV–C. Culture fluids (except as allowed in Appendix K–IV–D) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.

Appendix K–IV–D. Sample collection from a closed system, the addition of materials to a closed system, and the transfer of cultures fluids from one closed system to another shall be conducted in a manner which prevents the release of aerosols or contamination of exposed surfaces.

Appendix K–IV–E. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air/HEPA filters or by other equivalent procedures (e.g., incineration) to prevent the release of viable organisms containing recombinant DNA molecules to the environment.

Appendix K–IV–F. A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the

organisms that will serve as the host for propagating the recombinant DNA molecules.

Appendix K–IV–G. Rotating seals and other mechanical devices directly associated with a closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to high efficiency particulate air/HEPA filters or through other equivalent treatment devices.

Appendix K–IV–H. A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules and other primary containment equipment used to contain operations involving viable organisms containing sensing devices that monitor the integrity of containment during operations.

Appendix K–IV–I. A closed system used for the propagation and growth of viable organisms containing the recombinant DNA molecules shall be tested for integrity of the containment features using the organism that will serve as the host for propagating recombinant DNA molecules. Testing shall be accomplished prior to the introduction of viable organisms containing recombinant DNA molecules and following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

Appendix K–IV–J. A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to use of this equipment for research or production activities involving viable organisms containing recombinant DNA molecules.

Appendix K–IV–K. The universal biosafety sign shall be posted on each closed system and primary containment equipment when used to contain viable organisms containing recombinant DNA molecules.

Appendix K–IV–L. Emergency plans required by Sections IV–B–2–b–(6) and IV–B–3–c–(3) shall include methods and procedures for handling large losses of culture on an emergency basis.

Appendix K–V. Biosafety Level 3 (BL3)—Large Scale

Appendix K–V–A. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix K–V–B. Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessels used for the propagation and growth of cultures) or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to prevent the escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system provided all physical containment requirements specified in Appendix G–II–C are met.

Appendix K–V–C. Culture fluids (except as allowed in Appendix K–V–D) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the recombinant DNA molecules.

Appendix K–V–D. Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which prevents the release of aerosols or contamination of exposed surfaces.

Appendix K–V–E. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air/HEPA filters or by other equivalent procedures (e.g., incineration) to prevent the release of viable organisms containing recombinant DNA molecules to the environment.

Appendix K–V–F. A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the recombinant DNA molecules.

Appendix K–V–G. A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be operated so that the space above the culture level will be maintained at a pressure as low as possible, consistent with equipment design, in order to maintain the integrity of containment features.

Appendix K–V–H. Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms containing recombinant DNA molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to high efficiency particulate air/HEPA filters or through other equivalent treatment devices.

Appendix K–V–I. A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules and other primary containment equipment used to contain operations involving viable organisms containing recombinant DNA molecules shall include monitoring or sensing devices that monitor the integrity of containment during operations.

Appendix K–V–J. A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be tested for integrity of the containment features using the organisms that will serve as the host for propagating the recombinant DNA molecules. Testing shall be accomplished prior to the introduction of viable organisms containing recombinant DNA molecules and following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

Appendix K–V–K. A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, maintenance, and use of this equipment for research production activities

involving viable organisms containing recombinant DNA molecules.

Appendix K–V–L. The universal biosafety sign shall be posted on each closed system and primary containment equipment when used to contain viable organisms containing recombinant DNA molecules.

Appendix K–V–M. Emergency plans required by Sections IV–B–2–b–(6) and IV–B–3–c–(3) shall include methods and procedures for handling large losses of culture on an emergency basis.

Appendix K–V–N. Closed systems and other primary containment equipment used in handling cultures of viable organisms containing recombinant DNA molecules shall be located within a controlled area which meets the following requirements:

Appendix K–V–N–1. The controlled area shall have a separate entry area. The entry area shall be a double-doored space such as an air lock, anteroom, or change room that separates the controlled area from the balance of the facility.

Appendix K–V–N–2. The surfaces of walls, ceilings, and floors in the controlled area shall be such as to permit ready cleaning and decontamination.

Appendix K–V–N–3. Penetrations into the controlled area shall be sealed to permit liquid or vapor phase space decontamination.

Appendix K–V–N–4. All utilities and service or process piping and wiring entering the controlled area shall be protected against contamination.

Appendix K–V–N–5. Hand washing facilities equipped with foot, elbow, or automatically operated valves shall be located at each major work area and near each primary exit.

Appendix K–V–N–6. A shower facility shall be provided. This facility shall be located in close proximity to the controlled area.

Appendix K–V–N–7. The controlled area shall be designed to preclude release of culture fluids outside the controlled area in the event of an accidental spill or release from the closed systems or other primary containment equipment.

Appendix K–V–N–8. The controlled area shall have a ventilation system that is capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure supply air, the system shall operate in a manner that prevents the reversal of the direction of air movement or shall be equipped with an alarm that would be actuated in the event that reversal in the direction of air movement were to occur. The exhaust air from the controlled area shall not be recirculated to other areas of the facility. The exhaust air from the controlled area may not be discharged to the outdoors without being high efficiency particulate air/HEPA filtered, subjected to thermal oxidation, or otherwise treated to prevent the release of viable organisms.

Appendix K–V–O. The following personnel and operational practices shall be required:

Appendix K–V–O–1. Personnel entry into the controlled area shall be through the entry area specified in Appendix K–V–N–1.

Appendix K–V–O–2. Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jump suits, laboratory coats, pants and shirts, head cover, and shoes or shoe covers. On exit from the controlled area the work clothing may be stored in a locker separate from that used for personal clothing or discarded for laundering. Clothing shall be decontaminated before laundering.

Appendix K–V–O–3. Entry into the controlled area during periods when work is in progress shall be restricted to those persons required to meet program or support needs. Prior to entry, all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted.

Appendix K-V-O–4. Persons under 18 years of age shall not be permitted to enter the controlled area.

Appendix K-V-O–5. The universal biosafety sign shall be posted on entry doors to the controlled area and all internal doors when any work involving the organism is in progress. This includes periods when decontamination procedures are in progress. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter the controlled area.

Appendix K-V-O–6. The controlled area shall be kept neat and clean.

Appendix K-V-O–7. Eating, drinking, smoking, and storage of food are prohibited in the controlled area.

Appendix K-V-O–8. Animals and plants shall be excluded from the controlled area.

Appendix K-V-O–9. An effective insect and rodent control program shall be maintained.

Appendix K-V-O–10. Access doors to the controlled area shall be kept closed, except as necessary for access, while work is in progress. Serve doors leading directly outdoors shall be sealed and locked while work is in progress.

Appendix K-V–0–11. Persons shall wash their hands when exiting the controlled area.

Appendix K-V-O–12. Persons working in the controlled area shall be trained in emergency procedures.

Appendix K-V-O–13. Equipment and materials required for the management of accidents involving viable organisms containing recombinant DNA molecules shall be available in the controlled area.

Appendix K-V-O–14. The controlled area shall be decontaminated in accordance with established procedures following spills or other accidental release of viable organisms containing recombinant DNA molecules.

Appendix K—Table 1. Comparison of Good Large Scale Practice (GLSP) and Biosafety Level (BL)—Large Scale (LS) Practice (see Appendix K–VI–A)

Criterion [See Appendix K–VI–B]	GLSP	BL1–LS	BL2–LS	BL3–LS
1. Formulate and implement institutional codes of practice for safety of personnel and adequate control of hygiene and safety measures.	K–II–A	G–I	G–I	G–I
2. Provide adequate written instructions and training of personnel to keep work place clean and tidy and to keep exposure to biological, chemical or physical agents at a level that does not adversely affect health and safety of employees.	K–II–B	G–I ¶ 1	G–I ¶ 1	G–I ¶ 1
3. Provide changing and hand washing facilities as well as protective clothing, appropriate to the risk, to be worn during work.	K–II–C	G–II–A–1–h	G–II–B–2–f	G–II–C–2–i
4. Prohibit eating, drinking, smoking, mouth pipetting, and applying cosmetics in the work place.	K–II–C	G–II–A–1–d G–II–A–1–e	G–II–B–1–d G–II–B–1–e	G–II–C–1–c G–II–C–1–d
5. Internal accident reporting	K–II–G	K–III–A	K–IV–A	K–IV–A

Criterion [See Appendix K–VI–B]	GLSP	BL1–LS	BL2–LS	BL3–LS
6. Medical surveillance	NR	NR	K–IV–A	K–V–A
7. Viable organisms should be handled in a system that physically separates the process from the external environment (closed system or other primary containment).	NR	K–III–B	K–IV–B	K–V–B
8. Culture fluids not removed from a system until organisms are inactivated.	NR	K–III–C	K–IV–C	K–V–C
9. Inactivation of waste solutions and materials with respect to their biohazard potential.	K–II–E	K–III–C	K–V–C	K–V–C
10. Control of aerosols by engineering or procedural controls to prevent or minimize release of organisms during sampling from a system, addition of materials to a system, transfer of cultivated cells, and removal of material, products, and effluent from a system.	Minimize Procedure K–II–F	Minimize Engineer K–III–B K–III–D	Prevent Engineer K–IV–B K–IV–D	Prevent Engineer K–V–B K–V–D
11. Treatment of exhaust gases from a closed system to minimize or prevent release of viable organisms.	NR	Minimize K–III–E	Prevent K–IV–E	Prevent K–V–E
12. Closed system that has contained viable organisms not to be opened until sterilized by a validated procedure.	NR	K–III–F	K–IV–F	K–V–F
13. Closed system to be maintained at as a low pressure as possible to maintain integrity of containment features.	NR	NR	NR	K–V–G
14. Rotating seals and other penetrations into closed system designed to prevent or minimize leakage.	NR	NR	Prevent K–IV–G	Prevent K–V–H
15. Closed system shall incorporate monitoring or sensing devices to monitor the integrity of containment.	NR	NR	K–IV–H	K–V–I
16. Validated integrity testing of closed containment system	NR	NR	K–IV–I	K–V–J
17. Closed system to be permanently identified for record keeping purposes.	NR	NR	K–IV–J	K–V–K
18. Universal biosafety sign to be posted on each closed system	NR	NR	K–IV–K	K–V–L
19. Emergency plans required for handling large losses of cultures	K–II–G	K–III–G	K–IV–L	K–V–M
20. Access to the work place	NR	G–II–A–1–a	G–II–B–1–a	K–V–N
21. Requirements for controlled access area	NR	NR	NR	K–V–N&O

NR=not required.

Appendix K–VI. Footnotes of Appendix K

Appendix K–VI–A. This table is derived from the text in Appendices G and K and is not to be used in lieu of Appendices G and K.

Appendix K–VI–B. The criteria in this grid address only the biological hazards associated with organisms containing recombinant DNA. Other hazards accompanying the large scale cultivation of such organisms (e.g., toxic properties of products; physical, mechanical, and chemical aspects of downstream processing) are not addressed and shall be considered separately, albeit in conjunction with this grid.

Appendix K–VII. Definitions to Accompany Containment Grid and Appendix K

Appendix K–VII–A. Accidental Release. An accidental release is the unintentional discharge of a microbiological agent (i.e., microorganism or virus) or eukaryotic cell due to a failure in the containment system.

Appendix K–VII–B. Biological Barrier. A biological barrier is an impediment (naturally occurring or introduced) to the infectivity and/or survival of a microbiological agent or eukaryotic cell once it has been released into the environment.

Appendix K–VII–C. Closed System. A closed system is one in which by its design and proper operation, prevents release of a microbiological agent or eukaryotic cell contained therein.

Appendix K–VII–D. Containment. Containment is the confinement of a microbiological agent or eukaryotic cell that is being cultured, stored, manipulated, transported, or destroyed in order to prevent or limit its contact with people and/or the environment. Methods used to achieve this include: physical and biological barriers and inactivation using physical or chemical means.

Appendix K–VII–E. De minimis Release. *De minimis* release is the release of: (i) viable microbiological agents or eukaryotic cells that does not result in the establishment of disease in healthy people, plants, or animals; or (ii) in uncontrolled proliferation of any microbiological agents or eukaryotic cells.

Appendix K–VII–F. Disinfection. Disinfection is a process by which viable microbiological agents or eukaryotic cells are reduced to a level unlikely to produce disease in healthy people, plants, or animals.

Appendix K–VII–G. Good Large Scale Practice Organism. For an organism to qualify for Good Large Scale Practice consideration, it must meet the following criteria [Reference: Organization for Economic Cooperation and Development, Recombinant DNA Safety Considerations, 1987, p. 34–35]: (i) the host organism should be non-pathogenic, should not contain adventitious agents and should have an extended history of safe large scale use or have built-in environmental limitations that permit optimum growth in the large scale setting but limited survival without adverse consequences in the environment; (ii) the recombinant DNA-engineered organism should be non-pathogenic, should be as safe in the large scale setting as the host organism, and without adverse consequences in the environment; and (iii) the vector/insert should be well characterized and free from known harmful sequences; should be limited in size as much as possible to the DNA required to perform the intended function; should not increase the stability of the construct in the environment unless that is a requirement of the intended function; should be poorly mobilizable; and should not transfer any resistance markers to microorganisms unknown to acquire them naturally if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture.

Appendix K–VII–H. Inactivation. Inactivation is any process that destroys

the ability of a specific microbiological agent or eukaryotic cell to self-replicate.

Appendix K–VII–I. Incidental Release. An incidental release is the discharge of a microbiological agent or eukaryotic cell from a containment system that is expected when the system is appropriately designed and properly operated and maintained.

Appendix K–VII–J. Minimization. Minimization is the design and operation of containment systems in order that any incidental release is a de minimis release.

Appendix K–VII–K. Pathogen. A pathogen is any microbiological agent or eukaryotic cell containing sufficient genetic information, which upon expression of such information, is capable of producing disease in healthy people, plants, or animals.

Appendix K–VII–L. Physical Barrier. A physical barrier is considered any equipment, facilities, or devices (e.g., fermentors, factories, filters, thermal oxidizers) which are designed to achieve containment.

Appendix K–VII–M. Release. Release is the discharge of a microbiological agent or eukaryotic cell from a containment system. Discharges can be incidental or accidental. Incidental releases are de minimis in nature; accidental releases may be de minimis in nature.

Appendix L. Release into the Environment of Certain Plants

Appendix L–I. General Information

Appendix L specifies conditions under which certain plants as specified below, may be approved for release into the environment. Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH, review by the RAC Plant Subcommittee, and specific approval by the NIH Director. Such experiments also require the approval of the Institutional Biosafety Committee before initiation.

Appendix L–II. Criteria Allowing Review by the RAC Plant Subcommittee Without the Requirement for Full RAC Review

In consultation with the RAC Plant Subcommittee and without the requirement for full RAC review (Institutional Biosafety Committee review and approval is necessary), NIH/ORDA may approve the growing of plants containing recombinant DNA in the field under the following conditions: (i) The plant species is a cultivated crop of a genus that has no species known to be a noxious weed; (ii) the introduced DNA consists of well-characterized genes containing no sequences harmful to humans, animals, or plants; (iii) the vector consists of DNA from exempt host-vector systems (see Appendix C), from plants of the same or closely related species, from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants, from plants pathogens only if sequences resulting in production of disease symptoms have been deleted, or chimeric vectors constructed from sequences of exempt host-vector systems (see Appendix C) or from sequences from plant pathogens in which the disease symptoms have been deleted. The DNA may be introduced by any suitable method. If sequences resulting in production of disease symptoms are retained for purposes of introducing the DNA into the plant, greenhouse-grown plants must be shown to be free of such sequences before such plants, their derivatives, or seed can be used in field tests; (iv) plants are grown in controlled access fields under specified conditions appropriate for the plant under study and the geographical location. Such conditions should include provisions for using good cultural and pest control practices, for physical isolation from plants of the same species outside of the experimental plot in accordance with pollination characteristics of the species, and the prevention of plants containing recombinant DNA from becoming established in the environment. Review by the Institutional Biosafety Committee should include an appraisal by scientists knowledgeable of the crop, its production practices, and the local geographical conditions. Procedures for assessing alterations in and the spread of organisms containing recombinant DNA must be developed. The results of the outlined tests must be submitted for review and approval by the Institutional Biosafety Committee. Copies of such results must be submitted to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix M. Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules Into the Genome of One or More Human Subjects

Appendix M applies to research conducted at or sponsored by an institution that receives any support for recombinant DNA research from the NIH. Researchers not covered by the NIH Guidelines are encouraged to use Appendix M. Experiments in which recombinant DNA or DNA or RNA derived from recombinant DNA is introduced into one or more human subjects with the intent of stably modifying his/her genome are covered by Sections III–A–2, III–B–2, and III–B–3 (see Section V–U). Experiments in which recombinant DNA or DNA or RNA derived from recombinant DNA and that are not covered by Sections III–A–2, III–B–2, or III–B–3 and that are not considered exempt under Section V–U, are covered under Section III–C–7.

This document is intended to provide guidance in preparing proposals for NIH consideration under Sections III–A–2 and III–B–2. Section III–A–2 addresses Major Actions involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that have been determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, to: (i) Represent novel characteristics (e.g., target disease or vector), (ii) represent an uncertain degree of risk to human health or the environment, or (iii) contain information determined to require further public review. Proposals considered under Section III–A–2 will be reviewed by the RAC and approved by the NIH Director. RAC review of experiments considered under Section III–A–2 will follow publication of a precis of the proposal in the **Federal Register** and an opportunity for public comment. Section III–B–2 addresses Minor Actions involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects that have been determined by NIH/ORDA, in consultation with the RAC Chair and one or more RAC members, as necessary, to qualify for the Accelerated Review process. Proposals considered under Sections III–A–2 and III–B–2 will be on a case-by-case basis. A list of actions approved under Sections III–A–2 and III–B–2 involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects is available from the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. The list of actions to the NIH Guidelines involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects does not include experiments considered to be exempt from RAC and NIH/ORDA review under Section III–C–7.

Since the recombinant DNA or DNA or RNA derived from recombinant DNA is expected to be confined following transfer to one or more human subjects,

no risk to public health or to the environment is expected. Nevertheless, Appendix M–I–B–4–b specifically asks the researchers to address this point.

This appendix will be considered for revision as experience in evaluating proposals accumulates and as new scientific developments occur. This review will be carried out periodically as needed.

A proposal involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects will be considered by the RAC and/or NIH/ORDA only after the protocol has been approved by the local Institutional Biosafety Committee and Institutional Review Board in accordance with DHHS Regulations for the Federal Regulations for the Protection of Human Subjects (45 Code of Federal Regulations, Part 46). If a proposal involves children, special attention should be paid to subpart D of these DHHS regulations. The Institutional Review Board and Institutional Biosafety Committee may, at their discretion, condition their approval on further specific deliberation by the RAC and/or NIH/ORDA. Consideration of human gene transfer proposals by the RAC and/or NIH/ORDA may proceed simultaneously with review by other involved Federal agencies (see Appendix M–VII–A) provided that NIH/ORDA is notified of the simultaneous review. Meetings of the full RAC and its subcommittee will be open to the public except where trade secrets or proprietary information would be disclosed. The committee prefers that proposals submitted for RAC review contain no proprietary information or trade secrets, enabling all aspects of the review to be open to the public. Public review of these protocols will serve to inform the public about the technical aspects of the proposals as well as the meaning and significance of the research.

The clinical application of recombinant DNA techniques raises two general kinds of questions: (i) the questions usually discussed by Institutional Review Boards in their review of any proposed research involving one or more human subjects; and (ii) broader issues. The first type of question is addressed principally in Appendix M-I of this document. Several broader issues are discussed throughout Appendix M.

Appendix M-I requests a description of the protocol with special attention to the short-term risks and benefits of the proposed research to the patient and to other people, the selection of patients, informed consent, privacy, and confidentiality. Appendix M-II addresses special issues pertaining to the free flow of information about the clinical trials. These issues lie outside the usual purview of Institutional Review Boards and reflect general public concerns about biomedical research. Appendix M-III summarizes guidelines for submission of human gene transfer protocols for RAC review. Appendix M-IV specifies reporting requirements. Appendix M-V describes the procedures for Accelerated Review of human gene transfer experiments. Appendix M-VI describes the procedures to be followed for Expedited Review of single patient human gene transfer experiments. Appendix M-VII contains the footnotes to Appendix M.

The RAC will not at present entertain proposals for germ-line alterations but will consider for approval protocols involving somatic cell gene transfer. The purpose of somatic cell gene therapy is to treat an individual patient, e.g., by inserting a properly functioning gene into a patient's somatic cells. In germ-line alterations, a specific attempt is made to introduce genetic changes into the germ (reproductive) cells of an individual, with the aim of changing the set of genes passed on to the individual's offspring.

The acceptability of human somatic cell gene therapy has been addressed in several public documents as well as in numerous academic studies. In November 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published a report, Splicing Life, which resulted from a two-year process of public deliberations and hearing. Upon release of that report, a U.S. House of Representatives subcommittee held three days of public hearings with witnesses from a wide range of fields from the biomedical and social sciences to theology, philosophy, and law. In December 1984, the Office of Technology Assessment released a background paper, Human Gene Therapy, which concluded: civic, religious, scientific, and medical groups have all accepted, in principle, the appropriateness of gene therapy of somatic cells in humans for specific genetic diseases. Somatic cell gene therapy is seen as an extension of present methods of therapy that might be preferable to other technologies. In light of this public support, the RAC is prepared to consider proposals for somatic cell gene therapy.

In its evaluation of proposals involving the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects, the RAC will consider whether the design of such experiments offers adequate assurance that their consequences will not go beyond their purpose, which is the same as the traditional purpose of clinical investigations, namely, to protect the health and well-being of one or more human subjects being treated while at the same time gathering generalizable knowledge. Two possible undesirable consequences of the transfer of recombinant DNA would be unintentional: (i) vertical transmission of genetic changes from an individual to his/her offspring, or (ii) horizontal transmission of viral infection to other persons with whom the individual comes in contact. Accordingly, this document requests information that will enable the RAC and/or NIH/ORDA to assess the possibility that the proposed experiments will inadvertently affect reproductive cells or lead to infection of other people (e.g., medical personnel or relatives).

In recognition of the social concern that surrounds the subject of gene transfer, the RAC and NIH/ORDA will cooperate with other groups in assessing the possible long-term consequences of the transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects and related laboratory and animal experiments in order to define appropriate human applications of this emerging technology.

Responses to Appendix M should be provided in the form of either written answers or references to specific sections of the protocol or its appendices. Principal Investigators should indicate points which are not applicable with a brief explanation. Principal Investigators submitting proposals that employ essentially the same vector systems (or with minor variations), and/or that are based on the same preclinical testing as proposals previously reviewed by the RAC, may refer to preceding documents without having to rewrite such material.

Appendix M–I. Description of Proposal

Appendix M–I–A. Objectives and Rationale of the Proposed Research

State concisely the overall objectives and rationale of the proposed study. Provide information on the specific points that relate to whichever type of research is being proposed.

Appendix M–I–A–1. Use of Recombinant DNA for Therapeutic Purposes. For research in which recombinant DNA is transferred in order to treat a disease or disorder (e.g., genetic diseases, cancer, and metabolic

diseases), the following questions should be addressed:

Appendix M–I–A–1–a. Why is the disease selected for treatment by means of gene therapy a good candidate for such treatment?

Appendix M–I–A–1–b. Describe the natural history and range of expression of the disease selected for treatment. What objective and/or quantitative measures of disease activity are available? In your view, are the usual effects of the disease predictable enough to allow for meaningful assessment of the results of gene therapy?

Appendix M–I–A–1–c. Is the protocol designed to prevent all manifestations of the disease, to halt the progression of the disease after symptoms have begun to appear, or to reverse manifestations of the disease in seriously ill victims?

Appendix M–I–A–1–d. What alternative therapies exist? In what groups of patients are these therapies effective? What are their relative advantages and disadvantages as compared with the proposed gene therapy?

Appendix M–I–A–2. Transfer of DNA for Other Purposes. Appendix M–I–A–2–a. Into what cells will the recombinant DNA be transferred?

Why is the transfer of recombinant DNA necessary for the proposed research? What questions can be answered by using recombinant DNA?

Appendix M–I–A–2–b. What alternative methodologies exist? What are their relative advantages and disadvantages as compared to the use of recombinant DNA?

Appendix M–I–B. Research Design, Anticipated Risks and Benefits

Appendix M–I–B–1. Structure and Characteristics of the Biological System. Provide a full description of the methods and reagents to be employed for gene delivery and the rationale for their use. The following are specific points to be addressed:

Appendix M–I–B–1–a. What is the structure of the cloned DNA that will be used?

Appendix M–I–B–1–a–(1). Describe the gene (genomic or cDNA), the bacterial plasmid or phage vector, and the delivery vector (if any). Provide complete nucleotide sequence analysis or a detailed restriction enzyme map of the total construct.

Appendix M–I–B–1–a–(2). What regulatory elements does the construct contain (e.g., promoters, enhancers, polyadenylation sites, replication origins, etc.)? From what source are these elements derived? Summarize what is currently known about the regulatory character of each element.

Appendix M–I–B–1–a–(3). Describe the steps used to derive the DNA construct.

Appendix M–I–B–1–b. What is the structure of the material that will be administered to the patient?

Appendix M–I–B–1–b–(1). Describe the preparation, structure, and composition of the materials that will be given to the patient or used to treat the patient's cells: (i) If DNA, what is the purity (both in terms of being a single DNA species and in terms of other contaminants)? What tests have been used and what is the sensitivity of the tests? (ii) If a virus, how is it prepared from the DNA construct? In what cell is the virus grown (any special features)? What medium and serum are used? How is the virus purified? What is its structure and purity? What steps are being taken (and assays used with their sensitivity) to detect and eliminate any contaminating materials (for example, VL30 RNA, other nucleic acids, or proteins) or contaminating viruses (both replication-competent or replication-defective) or other organisms in the cells or serum used for preparation of the virus stock including any contaminants that may have biological effects? (iii) If co-cultivation is employed, what kinds of cells are being used for co-cultivation? What steps are being taken (and assays used with their sensitivity) to detect and eliminate any contaminating materials? Specifically, what tests are being conducted to assess the material to be returned to the patient for the presence of live or killed donor cells or other non-vector materials (for example, VL30 sequences) originating from those cells? (iv) If methods other than those covered by Appendices M–I–B–1–b-(1)-(i) through (iii) are used to introduce new genetic information into target cells, what steps are being taken to detect and eliminate any contaminating materials? What are possible sources of contamination? What is the sensitivity of tests used to monitor contamination?

Appendix M–I–B–1–b-(2). Describe any other material to be used in preparation of the material to be administered to the patient. For example, if a viral vector is proposed, what is the nature of the helper virus or cell line? If carrier particles are to be used, what is the nature of these?

Appendix M–I–B–2. Preclinical Studies, Including Risk-Assessment Studies. Provide results that demonstrate the safety, efficacy, and feasibility of the proposed procedures using animal and/or cell culture model systems, and explain why the model(s) chosen is/are most appropriate.

Appendix M–I–B–2–a. Delivery System. Appendix M–I–B–2–a–(1). What cells are the intended target cells of recombinant DNA? What target cells are to be treated ex vivo and returned to the patient, how will the cells be characterized before and after treatment? What is the theoretical and practical basis for assuming that only the target cells will incorporate the DNA?

Appendix M–I–B–2–a–(2). Is the delivery system efficient? What percentage of the target cells contain the added DNA?

Appendix M–I–B–2–a–(3). How is the structure of the added DNA sequences monitored and what is the sensitivity of the analysis? Is the added DNA extrachromosomal or integrated? Is the added DNA unrearranged?

Appendix M–I–B–2–a–(4). How many copies are present per cell? How stable is the added DNA both in terms of its continued presence and its structural stability?

Appendix M–I–B–2–b. Gene Transfer and Expression. Appendix M–I–B–2–b–(1). What animal and cultured cell models were used in laboratory studies to assess the in vivo and in vitro efficacy of the gene transfer system? In what ways are these models similar to and different from the proposed human treatment?

Appendix M–I–B–2–b–(2). What is the minimal level of gene transfer and/or expression that is estimated to be necessary for the gene transfer protocol to be successful in humans? How was this level determined?

Appendix M–I–B–2–b–(3). Explain in detail all results from animal and cultured cell model experiments which assess the effectiveness of the delivery system (see Appendix M–I–B–2–a) in achieving the minimally required level of gene transfer and expression (see Appendix M–I–B–2–b–(2)).

Appendix M–I–B–2–b–(4). To what extent is expression only from the desired gene (and not from the surrounding DNA)? To what extent does the insertion modify the expression of other genes?

Appendix M–I–B–2–b–(5). In what percentage of cells does expression from the added DNA occur? Is the product biologically active? What percentage of normal activity results from the inserted gene?

Appendix M–I–B–2–b–(6). Is the gene expressed in cells other than the target cells? If so, to what extent?

Appendix M–I–B–2–c. Retrovirus Delivery Systems. Appendix M–I–B–2–c–(1). What cell types have been infected with the retroviral vector

preparation? Which cells, if any, produce infectious particles?

Appendix M–I–B–2–c–(2). How stable are the retroviral vector and the resulting provirus against loss, rearrangement, recombination, or mutation? What information is available on how much rearrangement of recombination with endogenous or other viral sequences is likely to occur in the patient's cells? What steps have been taken in designing the vector to minimize instability or variation? What laboratory studies have been performed to check for stability, and what is the sensitivity of the analyses?

Appendix M–I–B–2–c–(3). What laboratory evidence is available concerning potential harmful effects of the transfer (e.g., development of neoplasia, harmful mutations, regeneration of infectious particles, or immune responses)? What steps will be taken in designing the vector to minimize pathogenicity? What laboratory studies have been performed to check for pathogenicity, and what is the sensitivity of the analyses?

Appendix M–I–B–2–c–(4). Is there evidence from animal studies that vector DNA has entered untreated cells, particularly germ-line cells? What is the sensitivity of the analyses?

Appendix M–I–B–2–c–(5). Has a protocol similar to the one proposed for a clinical trial been conducted in non-human primates and/or other animals? What were the results? Specifically, is there any evidence that the retroviral vector has recombined with any endogenous or other viral sequences in the animals?

Appendix M–I–B–2–d. Non-Retrovirus Delivery/Expression Systems. If a non-retroviral delivery system is used, what animal studies have been conducted to determine if there are pathological or other undesirable consequences of the protocol (including insertion of DNA into cells other than those treated, particularly germ-line cells)? How long have the animals been studied after treatment? What safety studies have been conducted? (Include data about the level of sensitivity of such assays.)

Appendix M–I–B–3. Clinical Procedures, Including Patient Monitoring. Describe the treatment that will be administered to patients and the diagnostic methods that will be used to monitor the success or failure of the treatment. If previous clinical studies using similar methods have been performed by yourself or others, indicate their relevance to the proposed study. Specifically:

Appendix M–I–B–3–a. Will cells (e.g., bone marrow cells) be removed from patients and treated ex vivo? If so, describe the type, number, and intervals at which these cells will be removed.

Appendix M–I–B–3–b. Will patients be treated to eliminate or reduce the number of cells containing malfunctioning genes (e.g., through radiation or chemotherapy)?

Appendix M–I–B–3–c. What treated cells (or vector/DNA combination) will be given to patients? How will the treated cells be administered? What volume of cells will be used? Will there be single or multiple treatments? If so, over what period of time?

Appendix M–I–B–3–d. How will it be determined that new gene sequences have been inserted into the patient's cells and if these sequences are being expressed? Are these cells limited to the intended target cell populations? How sensitive are these analyses?

Appendix M–I–B–3–e. What studies will be conducted to assess the presence and effects of the contaminants?

Appendix M–I–B–3–f. What are the clinical endpoints of the study? Are there objections and quantitative measurements to assess the natural history of the disease? Will such measurements be used in patient follow-up? How will patients be monitored to assess specific effects of the treatment on the disease? What is the sensitivity of the analyses? How frequently will follow-up studies be conducted? How long will patient follow-up continue?

Appendix M–I–B–3–g. What are the major beneficial and adverse effects of treatment that you anticipate? What measures will be taken in an attempt to control or reverse these adverse effects if they occur? Compare the probability and magnitude of deleterious consequences from the disease if recombinant DNA transfer is not used.

Appendix M–I–B–3–h. If a treated patient dies, what special post-mortem studies will be performed?

Appendix M–I–B–4. Public Health Considerations. Describe any potential benefits and hazards of the proposed therapy to persons other than the patients being treated. Specifically:

Appendix M–I–B–4–a. On what basis are potential public health benefits or hazards postulated?

Appendix M–I–B–4–b. Is there a significant possibility that the added DNA will spread from the patient to other persons or to the environment?

Appendix M–I–B–4–c. What precautions will be taken against such spread (e.g., patients sharing a room, health-care workers, or family members)?

Appendix M–I–B–4–d. What measures will be undertaken to mitigate the risks, if any, to public health?

Appendix M–I–B–4–e. In light of possible risks to offspring, including vertical transmission, will birth control measures be recommended to patients? Are such concerns applicable to health care personnel?

Appendix M–I–B–5. Qualifications of Investigators and Adequacy of Laboratory and Clinical Facilities. Indicate the relevant training and experience of the personnel who will be involved in the preclinical studies and clinical administration of recombinant DNA. Describe the laboratory and clinical facilities where the proposed study will be performed. Specifically:

Appendix M–I–B–5–a. What professional personnel (medical and nonmedical) will be involved in the proposed study and what is their relevant expertise? Provide a two-page curriculum vitae for each key professional person in biographical sketch format (see Appendix M–III–E).

Appendix M–I–B–5–b. At what hospital or clinic will the treatment be given? Which facilities of the hospital or clinic will be especially important for the proposed study? Will patients occupy regular hospital beds or clinical research center beds? Where will patients reside during the follow-up period? What special arrangements will be made for the comfort and consideration of the patients. Will the research institution designate an ombudsman, patient care representative, or other individual to help protect the rights and welfare of the patient?

Appendix M–I–C. Selection of the Patients

Estimate the number of patients to be involved in the proposed study. Describe recruitment procedures and patient eligibility requirements, paying particular attention to whether these procedures and requirements are fair and equitable. Specifically:

Appendix M–I–C–1. How many patients do you plan to involve in the proposed study?

Appendix M–I–C–2. How many eligible patients do you anticipate being able to identify each year?

Appendix M–I–C–3. What recruitment procedures do you plan to use?

Appendix M–I–C–4. What selection criteria do you plan to employ? What are the exclusion and inclusion criteria for the study?

Appendix M–I–C–5. How will patients be selected if it is not possible to include all who desire to participate?

Appendix M–I–D. Informed Consent

Indicate how patients will be informed about the proposed study and

how their consent will be solicited. The consent procedure should adhere to the requirements of DHHS regulations for the protection of human subjects (45 Code of Federal Regulations, Part 46). If the study involves pediatric or mentally handicapped patients, describe procedures for seeking the permission of parents or guardians and, where applicable, the assent of each patient. Areas of special concern include potential adverse effects, financial costs, privacy, long-term follow-up and post-mortem examination. When gene transfer is a procedure separate from a clinical protocol, Informed Consent documents shall be submitted for both the gene transfer and clinical protocols.

Appendix M–I–D–1. How will the major points covered in Appendices M–I–A through M–I–C be disclosed to potential participants in this study and/or parents or guardians in language that is understandable to them?

Appendix M–I–D–2. How will the innovative character and the theoretically possible adverse effects of the experiment be discussed with patients and/or parents or guardians? How will the potential adverse effects be compared with the consequences of the disease?

Appendix M–I–D–3. What explanation of the financial costs of the experiment, follow-up care, and any available alternatives will be provided to patients and/or parents or guardians?

Appendix M–I–D–4. How will patients and/or their parents or guardians be informed that the innovative character of the experiment may lead to great interest by the media in the research and in the treated patients?

Appendix M–I–D–5. How will the patients and/or their parents or guardians be informed about: (i) the irreversible consequences of some of the procedures performed? (ii) any adverse medical consequences that may occur if the subject(s) withdraws from the study once it has begun? (iii) expectations of willingness to cooperate in long-term follow-up? and (iv) expectations that permission to perform an autopsy will be granted in the event of a patient's death as a precondition for a patient's participation in the study? This stipulation is included because an accurate determination of the precise cause of a patient's death would be of vital importance to all future patients.

Appendix M–I–E. Privacy and Confidentiality

Indicate what measure will be taken to protect the privacy of patients and their families as well as to maintain the confidentiality of research data.

Appendix M–I–E–1. What provisions will be made to honor the wishes of individual patients (and the parents or guardians of pediatric or mentally handicapped patients) as to whether, when, or how the identity of patients is publicly disclosed.

Appendix M–I–E–2. What provision will be made to maintain the confidentiality of research data, at least in cases where data could be linked to individual patients?

Appendix M–II. Special Issues

Although the following issues are beyond the normal purview of local Institutional Review Boards, the RAC requests that Principal Investigators respond to Appendices M–II–A and M–II–B below:

Appendix M–II–A. What steps will be taken, consistent with Appendix M–I–E, to ensure that accurate and appropriate information is made available to the public with respect to such public concerns as may arise from the proposed study?

Appendix M–II–B. Do you or your funding sources intend to protect under patent or trade secret laws either the products or the procedures developed in the proposed study? If so, what steps will be taken to permit as full communication as possible among Principal Investigators and clinicians concerning research methods and results?

Appendix M–III. Guidelines for the Submission of Human Gene Transfer Protocols

Appendices M–III–A through M–III–D and M–IV apply to human gene transfer protocols considered under Section III–A–2 and III–B–2. Appendices M–III–A, M– IV, and M–V apply to human gene transfer protocols considered under Section III– B–2.

Appendix M–III–A. Principal Investigator-Submitted Material

Principal Investigators should submit the following materials to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix M–III–A–1. Written proposals shall be submitted in the following order:

(1) Scientific abstract—1 page; (2) non-technical abstract—1 page; (3) Institutional Biosafety Committee and Institutional Review Board approvals and their deliberations pertaining to your protocol; (4) Response to Points to Consider—5 pages (see Appendix M through M–III); (6) protocol—20 pages excluding appendices—approved by the local Institutional Biosafety Committee and Institutional Review Board); (7) Informed Consent document—approved by the Institutional Review Board; (8) appendices including tables, figures, and manuscripts; (9) curricula vitae—2 pages for each key professional person in biographical sketch format; and (10) an indication of other Federal agencies to which the protocol is being submitted for review.

Appendix M–III–A–2. When a proposal has been submitted previously, there should be a short section (≤ 200 words) immediately following the abstracts that summarizes the major revisions since the last review.

Appendix M–III–A–3. Data provided shall include: (i) A description of the elements in the vector, (ii) the source of that information, (iii) the method by which sequence data were compiled, and (iv) three 3½ inch diskettes with the vector sequence in ASCII format.

Appendix M–III–B. Time Frame for Submissions

Note: Time frames are applicable only to protocols that are determined by NIH/ORDA to require full RAC review and NIH Director approval. Time frames do not apply to *Accelerated* Review human gene transfer experiments (see Section III–B–2 or those that only require registration with NIH/ORDA (see Section III–C– 7).

Appendix M–III–B–1. Written material from Principal Investigator shall be submitted ≤ 8 weeks before the RAC meeting at which it will be reviewed.

Appendix M–III–B–2. Written comments from the primary reviewers to the Principal Investigator shall be submitted ≤ 4 weeks before the RAC meeting at which it will be reviewed.

Appendix M–III–B–3. Written responses (including critical data in response to the primary reviewers' comments) shall be submitted by the Principal Investigator to NIH/ORDA ≤ 2 weeks before the RAC meeting.

Appendix M–III–C. Oral Responses to the RAC

Principal Investigators shall limit their oral responses to the RAC only to those questions that are raised during the meeting. Oral presentations of previously submitted material and/or critical data that was not submitted ≤ 2 weeks prior to the RAC meeting are prohibited.

Appendix M–III–D. Primary Reviewers' Responses

Appendix M–III–D–1. Primary Reviewers' Written Comments. The primary reviewers' written comments on a proposal should include the following:

Appendix M–III–D–1–a. Emphasize the issues related to gene marking, gene transfer, or gene therapy.

Appendix M–III–D–1–b. State explicitly whether the Points to Consider have been addressed satisfactorily.

Appendix M–III–D–1–c. Examine the scientific rationale, scientific context (relative to other proposals reviewed by the RAC), whether the preliminary in vitro and in vivo data were obtained in appropriate models and are sufficient, and whether questions related to safety, efficacy, and social/ethical context have been resolved.

Appendix M–III–D–1–d. Whenever possible, criticisms of Informed Consent documents should include written alternatives for suggested revisions for the RAC to consider.

Appendix M–III–D–1–e. Primary reviews should state whether the proposal is: (i) acceptable as written, (ii) expected to be acceptable with specific revisions or after satisfactory responses to specific questions raised on review, or (iii) unacceptable in its present form.

Appendix M–III–D–2. Oral Discussions by Primary Reviewers at the RAC Meeting. Appendix M–III–D–2–a. It should be possible for most primary reviewers to present their oral reviews in ≤ 5 minutes.

Appendix M–IV. Reporting Requirements

Appendix M–IV–A. Serious adverse effects of treatment should be reported immediately to the local Institutional Review Board, the NIH Office for Protection from Research Risks, and NIH/ORDA followed by the submission of a written report filed with each group. Reports submitted to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix M–IV–B. Reports regarding the general progress of patients should be filed with both the local Institutional Review Board and NIH/ORDA within six months of the commencement of the experiment and at six-month intervals thereafter. These twice-yearly reports should continue for a sufficient period of time to allow observation of all major effects. In the event of a patient's death, a summary of the special post-mortem studies and statement of the cause of death should be submitted to the Institutional Review Board and NIH/ORDA, if available.

Appendix M–V. Procedures to the Followed for Accelerated Review of Human Gene Transfer Experiments by NIH/ORDA under Section III–B–2

Requests for Accelerated Review should be submitted to the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–9838.

Appendix M–V–A. Human gene transfer experiments in this category must be in accordance with the provisions of Section III–B–2. If the human gene transfer protocol does not qualify for Accelerated Review (see Section III–B–2) as determined by NIH/ORDA, then the Principal Investigator must submit the experiment for full RAC review and NIH approval in accordance with Section III–A–2.

Appendix M–V–B. No protocol shall be considered without Institutional Biosafety Committee and Institutional Review Board approval.

Appendix M–V–C. At this time, all gene transfer protocols must be considered experimental.

Appendix M–V–D. Principal Investigators requesting Accelerated Review (see Section III–B–2), must submit the relevant documentation in accordance with Appendix M–III. NIH/ORDA will notify the Principal Investigator whether the proposed study qualifies for the Accelerated Review process. If NIH/ORDA determines that an experiment does not qualify for Accelerated Review process, the Principal Investigator must submit the proposal for full RAC review ≤ 8 weeks prior to the next scheduled RAC meeting.

Appendix M–V–E. It is expected that NIH/ORDA will consult with the RAC Chair and one or more RAC members, as necessary, when considering Accelerated Review human gene transfer protocols (see Section III–B–2).

Appendix M–V–F. The RAC Chair will provide a report on all human gene transfer protocols that have been approved by NIH/ORDA at the next regularly scheduled RAC meeting.

Appendix M–V–F–1. In accordance with Reporting Requirements (See Appendix M– IV), any adverse effects of the treatment should be reported immediately to the local Institutional Review Board, the NIH Office for Protection from Research Risks, and NIH/ORDA followed by the submission of a written report filed with each group. Reports submitted to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838.

Appendix M–V–F–2. In accordance with Reporting Requirements (see Appendix M– IV), reports regarding the general progress of patients should be filed with both the local Institutional Review Board and NIH/ORDA within six months of the commencement of the experiment and at six-month intervals thereafter. In the event of a patient's death, a summary of the special post-mortem studies and statement of the cause of death should be submitted to the Institutional Review Board and NIH/ORDA, if available.

Appendix M–VI. Procedures to be Followed for Expedited Review of Single Patient Human Gene Transfer Experiments by NIH Director Under Section III–A–2 Requests for Expedited Review should be submitted to the Office of Recombinant DNA Activities, National Insitutes of Health, Bethesda, Maryland 20892, (301) 496–9838.

Appendix M–VI–A. A Principal Investigator submitting a request to the NIH/ORDA for Expedited Review of a single patient gene transfer protocol shall provide detailed information regarding the necessity of Expedited Review.

Appendix M–VI–B. No protocol shall be considered without relevant Institutional Biosafety Committee and Institutional Review Board approvals.

Appendix M–VI–C. At this time, all gene transfer protocols are considered experimental.

Appendix M–VI–D. Regardless of the method of review, the Points to Consider is the standard of review for all gene transfer protocols.

Appendix M–VI–E. Review of such protocols may include intramural NIH experts but must include extramural experts.

Appendix M–VI–F. The reviewers shall consider similarity of the new protocol to previously approved protocols.

Appendix M–VI–G. The NIH/ORDA shall report to the RAC following Expedited Review and include all of the materials on which the decision was based. The RAC shall formally review the protocol at its next scheduled meeting. Patient privacy shall be maintained.

Appendix M–VI–H. Protocols that are deferred or not approved by the RAC in its normal review process are not eligible for Expedited Review. No protocol shall have more than one patient approved under Expedited Review.

Appendix M–VI–I. As requested in the context of non-expedited review, none of the costs of the experimental protocol shall be borne by the patient or the patient's family.

Appendix M–VI–J. Data on all patients undergoing gene transfer shall be provided to the RAC within six months of the procedure.

Appendix M–VII. Footnotes of Appendix M

Appendix M–VII–A. The Food and Drug Administration has jurisdiction over products intended for use in human gene transfer clinical trials. For general information on the Food and Drug Administration's policies and regulatory requirements, see the Federal Register, Volume 51, pages 23309–23313, 1986.

Appendix M–VII–B. The term "patient" and its variants are used in the text as a shorthand designation for "patient-subject."

Appendix P. Physical and Biological Containment for Recombinant DNA Research Involving Plants

Appendix P specifies physical and biological containment conditions and practices suitable to the greenhouse conduct of experiments involving recombinant DNA-containing plants, plant-associated microorganisms, and small animals. All provisions of the NIH Guidelines apply to plant research activities with the following modifications:

Appendix P shall supersede Appendix G when the research plants are of a size, number, or have growth requirements that preclude the use of containment conditions described in Appendix G. The plants covered in Appendix P include but are not limited to mosses, liverworts, macroscopic algae, and vascular plants including terrestrial crops, forest, and ornamental species.

Plant-associated microorganisms include viroids, virusoids, viruses, bacteria, fungi, protozoans, certain small algae, and microorganisms that have a benign or beneficial association with plants, such as certain Rhizobium species and microorganisms known to cause plant diseases. The appendix applies to microorganisms which are being modified with the objective of fostering an association with plants.

Plant-associated small animals include those arthropods that: (i) Are in obligate association with plants, (ii) are plant pests, (iii) are plant pollinators, or (iv) transmit plant disease agents, as well as other small animals such as nematodes for which tests of biological properties necessitate the use of plants. Microorganisms associated with such small animals (e.g., pathogens or symbionts) are included.

The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P require prior approval by the Institutional Biosafety Committee.

Appendix P–I. General Plant Biosafety Levels

Appendix P–I–A. The principal purpose of plant containment is to avoid the unintentional transmission of a recombinant DNA-containing plant genome, including nuclear or organelle hereditary material or release of recombinant DNA-derived organisms associated with plants.

Appendix P–I–B. The containment principles are based on the recognition that the organisms that are used pose no health threat to humans or higher animals (unless deliberately modified for that purpose), and that the containment conditions minimize the possibility of an unanticipated deleterious effect on organisms and ecosystems outside of the experimental facility, e.g., the inadvertent spread of a serious pathogen from a greenhouse to a local agricultural crop or the unintentional introduction and establishment of an organism in a new ecosystem.

Appendix P–I–C. Four biosafety levels, referred to as Biosafety Level (BL) 1—Plants (P), BL2–P, BL3–P, and BL4–P, are established in Section II. The selection of containment levels required for research involving recombinant DNA molecules in plants or associated with plants is specified in Section III. These biosafety levels are described in Appendix P–II. This appendix describes greenhouse practices and special greenhouse facilities for physical containment.

Appendix P–I–D. BL1–P through BL4–P are designed to provide differential levels of biosafety for plants in the absence or presence of other experimental organisms that contain recombinant DNA. These biosafety levels, in conjunction with biological containment conditions described in Appendix P–III, provide flexible approaches to ensure the safe conduct of research.

Appendix P–I–E. For experiments in which plants are grown at the BL1 through BL4 laboratory settings, containment practices shall be followed as described in Appendix G. These containment practices include the use of plant tissue culture rooms, growth chambers within laboratory facilities, or experiments performed on open benches. Additional biological containment practices should be added by the Greenhouse Director or Institutional Biosafety Committee as necessary (see Appendix P–III), if botanical reproductive structures are produced that have the potential of being released.

Appendix P–II. Physical Containment Levels

Appendix P–II–A. Biosafety Level 1—Plants (BL1–P)

Appendix P–II–A–1. Standard Practices (BL1–P)

Appendix P–II–A–1–a. Greenhouse Access (BL1–P)

Appendix P–II–A–1–a–(1). Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Director, when experiments are in progress.

Appendix P–II–A–1–a–(2). Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL1–P greenhouse practices and procedures. All procedures shall be performed in accordance with accepted greenhouse practices that are appropriate to the experimental organism.

Appendix P–II–A–1–b. Records (BL1–P)

Appendix P–II–A–1–b–(1). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P–II–A–1–c. Decontamination and Inactivation (BL1–P)

Appendix P–II–A–1–c–(1). Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Appendix P–II–A–1–d. Control of Undesired Species and Motile Macroorganisms (BL1–P)

Appendix P–II–A–1–d–(1). A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens), by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Appendix P–II–A–1–d–(2). Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Appendix P–II–A–1–e. Concurrent Experiments Conducted in the Greenhouse (BL1–P)

Appendix P–II–A–1–e–(1). Experiments involving other organisms that require a containment level lower than BL1–P may be conducted in the greenhouse concurrently with

experiments that require BL1–P containment, provided that all work is conducted in accordance with BL1–P greenhouse practices.

Appendix P–II–A–2. Facilities (BL1–P)

Appendix P–II–A–2–a. Definitions (BL1–P)

Appendix P–II–A–2–a–(1). The term "greenhouse" refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

Appendix P–II–A–2–a–(2). The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area.

Appendix P–II–A–2–b. Greenhouse Design (BL1–P)

Appendix P–II–A–2–b–(1). The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended.

Appendix P–II–A–2–b–(2). Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

Appendix P–II–B. Biosafety Level 2—Plants (BL2–P)

Appendix P–II–B–1. Standard Practices (BL2–P)

Appendix P–II–B–1–a. Greenhouse Access (BL2–P)

Appendix P–II–B–1–a–(1). Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Director, to individuals directly involved with the experiments when they are in progress.

Appendix P–II–B–1–a–(2). Personnel shall be required to read and follow instructions on BL2–P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms.

Appendix P–II–B–1–b. Records (BL2–P)

Appendix P–II–B–1–b–(1). A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.

Appendix P–II–B–1–b–(2). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P–II–B–1–b–(3). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Greenhouse Director, Institutional Biosafety Committee, NIH/ORDA and other appropriate authorities immediately (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Documentation of any such accident shall be prepared and maintained.

Appendix P–II–B–1–c. Decontamination and Inactivation (BL2–P)

Appendix P–II–B–1–c–(1). Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Appendix P–II–B–1–c–(2). Decontamination of run-off water is not necessarily required. If part of the greenhouse is composed of gravel or similar material, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel.

Appendix P–II–B–1–d. Control of Undesired Species and Motile Macroorganisms (BL2–P)

Appendix P–II–B–1–d–(1). A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Appendix P–II–B–1–d–(2). Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Appendix P–II–B–1–e. Concurrent Experiments Conducted in the Greenhouse (BL2–P)

Appendix P–II–B–1–e–(1). Experiments involving other organisms that require a containment level lower than BL2–P may be conducted in the greenhouse concurrently with experiments that require BL2–P containment provided that all work is conducted in accordance with BL2–P greenhouse practices.

Appendix P–II–B–1–f. Signs (BL2–P)

Appendix P–II–B–1–f–(1). A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

Appendix P–II–B–1–f–(2). If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors.

Appendix P–II–B–1–f–(3). If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Appendix P–II–B–1–g. Transfer of Materials (BL2–P)

Appendix P–II–B–1–g–(1). Materials containing experimental microorganisms, which are brought into or removed from the greenhouse facility in a viable or intact state, shall be transferred in a closed non–breakable container.

Appendix P–II–B–1–h. Greenhouse Practices Manual (BL2–P)

Appendix P–II–B–1–h–(1). A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms.

Appendix P–II–B–2. Facilities (BL2–P)

Appendix P–II–B–2–a. Definitions (BL2–P)

Appendix P–II–B–2–a–(1). The term "greenhouse" refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

Appendix P–II–B–2–a–(2). The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas and is considered part of the confinement area.

Appendix P–II–B–2–b. Greenhouse Design (BL2–P)

Appendix P–II–B–2–b–(1). A greenhouse floor composed of an impervious material. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through soil. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil.

Appendix P–II–B–2–b–(2). Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds).

Appendix P–II–B–2–c. Autoclaves (BL2–P)

Appendix P–II–B–2–c–(1). An autoclave shall be available for the treatment of contaminated greenhouse materials.

Appendix P–II–B–2–d. Supply and Exhaust Air Ventilation Systems (BL2–P)

Appendix P–II–B–2–d–(1). If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.

Appendix P–II–B–2–e. Other (BL2–P)

Appendix P–II–B–2–e–(1). BL2–P greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macroorganisms in a manner that satisfies the intent of the foregoing clauses.

Appendix P–II–C. Biosafety Level 3—Plants (BL3–P)

Appendix P–II–C–1. Standard Practices (BL3–P)

Appendix P–II–C–1–a. Greenhouse Access (BL3–P)

Appendix P–II–C–1–a–(1). Authorized entry into the greenhouse shall be restricted to individuals who are required for program or support purposes. The Greenhouse Director shall be responsible for assessing each circumstance and determining those individuals who are authorized to enter the greenhouse facility.

Appendix P–II–C–1–a–(2). Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL3–P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms.

Appendix P–II–C–1–b. Records (BL3–P)

Appendix P–II–C–1–b–(1). A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.

Appendix P–II–C–1–b–(2). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P–II–C–1–b–(3). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, Greenhouse Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities immediately (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Documentation of any such accident shall be prepared and maintained.

Appendix P–II–C–1–c. Decontamination and Inactivation (BL3–P)

Appendix P–II–C–1–c–(1). All experimental materials shall be sterilized in an autoclave or rendered biologically inactive by appropriate methods before disposal, except those that are to remain in a viable or intact state for experimental purposes; including water that comes in contact with experimental microorganisms or with material exposed to such microorganisms, and contaminated equipment and supplies.

Appendix P–II–C–1–d. Control of Undesired Species and Motile Macroorganisms (BL3–P)

Appendix P–II–C–1–d–(1). A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Appendix P–II–C–1–d–(2). Arthropods and other motile macroorganisms shall be housed in appropriate cages. When appropriate to the organism, experiments shall be conducted within cages designed to contain the motile organisms.

Appendix P–II–C–1–e. Concurrent Experiments Conducted in the Greenhouse (BL3–P)

Appendix P–II–C–1–e–(1). Experiments involving organisms that require a containment level lower than BL3–P may be conducted in the greenhouse concurrently with experiments that require BL3–P containment provided that all work is conducted in accordance with BL3–P greenhouse practices.

Appendix P–II–C–1–f. Signs (BL3–P)

Appendix P–II–C–1–f–(1). A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) The name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

Appendix P–II–C–1–f–(2). If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence should be indicated on a sign posted on the greenhouse access doors.

Appendix P–II–C–1–f–(3). If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Appendix P–II–C–1–g. Transfer of Materials (BL3–P)

Appendix P–II–C–1–g–(1). Experimental materials that are brought into or removed from the greenhouse facility in a viable or intact state shall be transferred to a non-breakable sealed secondary container. At the time of transfer, if the same plant species, host, or vector are present within the effective dissemination distance of propagules of the experimental organism, the surface of the secondary container shall be decontaminated. Decontamination may be accomplished by passage through a chemical disinfectant or fumigation chamber or by an alternative procedure that has demonstrated effective inactivation of the experimental organism.

Appendix P–II–C–1–h. Greenhouse Practices Manual (BL3–P)

Appendix P–II–C–1–h–(1). A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) Advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms with recognized potential for serious detrimental impact.

Appendix P–II–C–1–i. Protective Clothing (BL3–P)

Appendix P–II–C–1–i–(1). Disposable clothing (e.g., solid front or wrap-around gowns, scrub suits, or other appropriate clothing) shall be worn in the greenhouse if deemed necessary by the Greenhouse Director because of potential dissemination of the experimental microorganisms.

Appendix P–II–C–1–i–(2). Protective clothing shall be removed before exiting the greenhouse and decontaminated prior to laundering or disposal.

Appendix P–II–C–1–j. Other (BL3–P)

Appendix P–II–C–1–j–(1). Personnel are required to thoroughly wash their hands upon exiting the greenhouse.

Appendix P–II–C–1–j–(2). All procedures shall be performed carefully to minimize the creation of aerosols and excessive splashing of potting material/soil during watering, transplanting, and all experimental manipulations.

Appendix P–II–C–2. Facilities (BL3–P)

Appendix P–II–C–2–a. Definitions (BL3–P)

Appendix P–II–C–2–a–(1). The term "greenhouse" refers to a structure with walls, roof, and floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

Appendix P–II–C–2–a–(2). The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area. The need to maintain negative pressure should be considered when constructing or renovating the greenhouse.

Appendix P–II–C–2–b. Greenhouse Design (BL3–P)

Appendix P–II–C–2–b–(1). The greenhouse floor shall be composed of concrete or other impervious material with provision for collection and decontamination of liquid run-off.

Appendix P–II–C–2–b–(2). Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent).

Appendix P–II–C–2–b–(3). The greenhouse shall be a closed self-contained structure with a continuous covering that is separated from areas that are open to unrestricted traffic flow. The minimum requirement for greenhouse entry shall be passage through two sets of self-closing locking doors.

Appendix P–II–C–2–b–(4). The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures.

Appendix P–II–C–2–b–(5). Internal walls, ceilings, and floors shall be resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix P–II–C–2–b–(6). Bench tops and other work surfaces should have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix P–II–C–2–b–(7). The greenhouse contains a foot, elbow, or automatically operated sink, which is located near the exit door for hand washing.

Appendix P–II–C–2–c. Autoclaves (BL3–P)

Appendix P–II–C–2–c–(1). An autoclave shall be available for decontaminating materials within the greenhouse facility. A double-door autoclave is recommended (not required) for the decontamination of materials passing out of the greenhouse facility.

Appendix P–II–C–2–d. Supply and Exhaust Air Ventilation Systems (BL3–P)

Appendix P–II–C–2–d–(1). An individual supply and exhaust air ventilation system shall be provided. The system maintains pressure differentials and directional airflow, as required, to assure inward (or zero) airflow from areas outside of the greenhouse.

Appendix P–II–C–2–d–(2). The exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air-HEPA filters and discharged to the outside. The filter chambers shall be designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. Air filters shall be 80–85% average efficiency by the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 52–68 test method using atmosphere dust. Air supply fans shall be equipped with a back-flow damper that closes when the air supply fan is off. Alternatively, a HEPA filter may be used on the air supply system instead of the filters and damper. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times.

Appendix P–II–C–2–e. Other (BL3–P)

Appendix P–II–C–2–e–(1). BL3–P greenhouse containment requirements may be satisfied using a growth chamber or growth room within a building provided that the location, access, airflow patterns, and provisions for decontamination of experimental materials and supplies meet the intent of the foregoing clauses.

Appendix P–II–C–2–e–(2). Vacuum lines shall be protected with high efficiency particulate air/HEPA or equivalent filters and liquid disinfectant traps.

Appendix P–II–D. Biosafety Level 4—Plants (BL4–P)

Appendix P–II–D–1. Standard Practices (BL4–P)

Appendix P–II–D–1–a. Greenhouse Access (BL4–P)

Appendix P–II–D–1–a–(1). Authorized entry into the greenhouse shall be restricted to individuals who are required for program or support purposes. The Greenhouse Director shall be responsible for assessing each circumstance and determining those individuals who are authorized to enter the greenhouse facility or work in the greenhouse during experiments.

Appendix P–II–D–1–a–(2). Access shall be managed by the Greenhouse Director, Biological Safety Officer, or other individual responsible for physical security of the greenhouse facility; and access limited by means of secure, locked doors.

Appendix P–II–D–1–a–(3). Prior to entering, individuals shall be advised of the potential environmental hazards and instructed on appropriate safeguards for ensuring environmental safety. Individuals authorized to enter the greenhouse facility shall comply with the instructions and all other applicable entry/exit procedures.

Appendix P–II–D–1–a–(4). Personnel shall enter and exit the greenhouse facility only through the clothing change and shower rooms and shall shower each time they exit the greenhouse facility. Personnel shall use the airlocks to enter or exit the laboratory only in an emergency. In the event of an emergency, every reasonable effort should be made to prevent the possible transport of viable propagules from containment.

Appendix P–II–D–1–a–(5). Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL4–P practices and procedures.

Appendix P–II–D–1–b. Records (BL4–P)

Appendix P–II–D–1–b–(1). A record shall be kept of all experimental materials brought into or removed from the greenhouse.

Appendix P–II–D–1–b–(2). A record shall be kept of experiments currently in progress in the greenhouse facility.

Appendix P–II–D–1–b–(3). A record shall be kept of all personnel entering and exiting the greenhouse facility, including the date and time of each entry.

Appendix P–II–D–1–b–(4). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, Greenhouse Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities immediately (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Documentation of any such accident shall be prepared and maintained.

Appendix P–II–D–1–c. Decontamination and Inactivation (BL4–P)

Appendix P–II–D–1–c–(1). All materials, except for those that are to remain in a viable or intact state for experimental purposes, shall be autoclaved prior to removal from the maximum containment greenhouse. Equipment or material that could be damaged by high temperatures or steam shall be decontaminated by alternative methods (e.g., gas or vapor sterilization) in an airlock or chamber designed for this purpose.

Appendix P–II–D–1–c–(2). Water that comes in contact with experimental microorganisms or with material exposed to such microorganisms (e.g., run-off from watering plants) shall be collected and decontaminated before disposal.

Appendix P–II–D–1–c–(3). Standard microbiological procedures shall be followed for decontamination of equipment and materials. Spray or liquid waste or rinse water from containers used to apply the experimental microorganisms shall be decontaminated before disposal.

Appendix P–II–D–1–d. Control of Undesired Species and Motile Macroorganisms (BL4–P)

Appendix P–II–D–1–d–(1). A chemical control program shall be implemented to eliminate undesired pests and pathogens in accordance with applicable state and Federal laws.

Appendix P–II–D–1–d–(2). Arthropods and other motile macroorganisms used in conjunction with experiments requiring BL4–P level physical containment shall be housed in appropriate cages. When appropriate to the organism, experiments shall be conducted within cages designed to contain the motile organisms.

Appendix P–II–D–1–e. Concurrent Experiments Conducted in the Greenhouse (BL4–P)

Appendix P–II–D–1–e–(1). Experiments involving organisms that require a containment level lower than BL4–P may be conducted in the greenhouse concurrently with experiments that require BL4–P containment provided that all work is conducted in accordance with BL4–P greenhouse practices. When the experimental microorganisms in use require a containment level lower than BL4–P, greenhouse practices reflect the level of containment required by the highest containment level microorganisms being tested.

Appendix P–II–D–1–f. Signs (BL4–P)

Appendix P–II–D–1–f–(1). A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) The name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

Appendix P–II–D–1–f–(2). If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated by a sign posted on the greenhouse access doors.

Appendix P–II–D–1–f–(3). If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Appendix P–II–D–1–g. Transfer of Materials (BL4–P)

Appendix P–II–D–1–g–(1). Experimental materials that are brought into or removed from the greenhouse in a viable or intact state shall be transferred to a non- breakable, sealed, primary container then enclosed in a non-breakable, sealed secondary container. These containers shall be removed from the greenhouse facility through a chemical disinfectant, fumigation chamber, or an airlock designed for this purpose.

Appendix P–II–D–g–(2). Supplies and materials shall be brought into the greenhouse facility through a double-door autoclave, fumigation chamber, or airlock that is appropriately decontaminated between each use. After securing the outer doors, personnel within the greenhouse facility shall retrieve the materials by opening the interior door of the autoclave, fumigation chamber, or airlock. These doors shall be secured after the materials are brought into the greenhouse facility.

Appendix P–II–D–1–h. Greenhouse Practices Manual (BL4–P)

Appendix P–II–D–1–h–(1). A greenhouse practices manual shall be prepared or adopted. This manual shall include contingency plans to be implemented in the event of the unintentional release of experimental organisms.

Appendix P–II–D–1–i. Protective Clothing (BL4–P)

Appendix P–II–D–1–i–(1). Street clothing shall be removed in the outer clothing change room. Complete laboratory clothing (may be disposable) including undergarments, pants, and shirts, jump suits, shoes, and hats shall be provided and worn by all personnel entering the greenhouse facility.

Appendix P–II–D–1–i–(2). Personnel shall remove laboratory clothing when exiting the greenhouse facility and before entering the shower area. This clothing shall be stored in a locker or hamper in the inner change room.

Appendix P–II–D–1–i–(3). All laboratory clothing shall be autoclaved before laundering.

Appendix P–II–D–2. Facilities (BL4–P)

Appendix P–II–D–2–a. Greenhouse Design (BL4–P)

Appendix P–II–D–2–a–(1). The maximum containment greenhouse facility shall consist of a separate building or a clearly demarcated and isolated area within a building. The need to maintain negative pressure should be considered when constructing or renovating the greenhouse facility.

Appendix P–II–D–2–a–(2). Outer and inner change rooms, separated by a shower, shall be provided for personnel entering and exiting the greenhouse facility.

Appendix P–II–D–2–a–(3). Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent).

Appendix P–II–D–2–a–(4). Access doors to the greenhouse shall be self-closing and locking.

Appendix P–II–D–2–a–(5). The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures.

Appendix P–II–D–2–a–(6). The walls, floors, and ceilings of the greenhouse

shall be constructed to form a sealed internal shell that facilitates fumigation and is animal and arthropod-proof. These internal surfaces shall be resistant to penetration and degradation by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix P–II–D–2–a–(7). Bench tops and other work surfaces shall have seamless surfaces impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix P–II–D–2–a–(8). A double-door autoclave, fumigation chamber, or ventilated airlock shall be provided for passage of all materials, supplies, or equipment that are not brought into the greenhouse facility through the change room.

Appendix P–II–D–2–b. Autoclaves (BL4–P)

Appendix P–II–D–2–b–(1). A double-door autoclave shall be provided for the decontamination of materials removed from the greenhouse facility. The autoclave door, which opens to the area external to the greenhouse facility, shall be sealed to the outer wall and automatically controlled so that it can only be opened upon completion of the sterilization cycle.

Appendix P–II–D–2–c. Supply and Exhaust Air Ventilation Systems (BL4–P)

Appendix P–II–D–2–c–(1). An individual supply and exhaust air ventilation system shall be provided. The system shall maintain pressure differentials and directional airflow as required to assure inward (or zero) airflow from areas outside of the greenhouse. Differential pressure transducers shall be used to sense pressure levels. If a system malfunctions, the transducers shall sound an alarm. A backup source of power should be considered. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times. The integrity of the greenhouse shall have an air leak rate (decay rate) not to exceed 7 percent per minute (logarithm of pressure against time) over a 20-minute period at 2 inches of water gauge pressure. Nominally, this is 0.05 inches of water gauge pressure loss in 1 minute at 2 inches water gauge pressure.

Appendix P–II–D–2–c–(2). Exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air/HEPA filters and discharged to the outside and dispersed away from occupied buildings and air intakes. Filter chambers shall be designed to allow in situ decontamination before filters are removed and to facilitate certification testing after they are replaced. HEPA filters shall be provided to treat air supplied to the greenhouse facility. HEPA filters shall be certified annually.

Appendix P–II–D–2–d. Other (BL4–P)

Appendix P–II–D–2–d–(1). Sewer vents and other ventilation lines contain high efficiency particulate air/HEPA filters. HEPA filters shall be certified annually.

Appendix P–II–D–2–d–(2). A pass-through dunk tank, fumigation chamber, or an equivalent method of decontamination shall be provided to ensure decontamination of materials and equipment that cannot be decontaminated in the autoclave.

Appendix P–II–D–2–d–(3). Liquid effluent from sinks, floors, and autoclave chambers shall be decontaminated by heat or chemical treatment before being released from the maximum containment greenhouse facility. Liquid wastes from shower rooms and toilets may be decontaminated by heat or chemical treatment. Autoclave and chemical decontamination of liquid wastes shall be evaluated by appropriate standard procedures for autoclaved wastes. Decontamination shall be evaluated mechanically and biologically using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes are decontaminated with chemical disinfectants, the chemicals used must have demonstrated efficacy against the target or indicator microorganisms.

Appendix P–II–D–2–d–(4). If there is a central vacuum system, it shall not serve areas outside of the greenhouse facility. In-line high efficiency particulate air/HEPA filters shall be placed as near as practicable to each use point or vacuum service cock. Other liquid and gas services to the greenhouse facility shall be protected by devices that prevent back-flow. HEPA filters shall be certified annually.

Appendix P–III. Biological Containment Practices

Appropriate selection of the following biological containment practices may be used to meet the containment requirements for a given organism. The present list is not exhaustive; there may be other ways of preventing effective dissemination that could possibly lead to the establishment of the organism or its genetic material in the environment resulting in deleterious consequences to managed or natural ecosystems.

Appendix P–III–A. Biological Containment Practices (Plants)

Appendix P–III–A–1. Effective dissemination of plants by pollen or seed can be prevented by one or more of the following procedures: (i) Cover the reproductive structures to prevent pollen dissemination at flowering and seed dissemination at maturity; (ii) remove reproductive structures by employing male sterile strains, or harvest the plant material prior to the reproductive stage; (iii) ensure that experimental plants flower at a time of year when cross-fertile plants are not flowering within the normal pollen dispersal range of the experimental plant; or (iv) ensure that cross-fertile plants are not growing within the known pollen dispersal range of the experimental plant.

Appendix P–III–B. Biological Containment Practices (Microorganisms)

Appendix P–III–B–1. Effective dissemination of microorganisms beyond the confines of the greenhouse can be prevented by one or more of the following procedures: (i) Confine all operations to injections of microorganisms or other biological procedures (including genetic manipulation) that limit replication or reproduction of viruses and microorganisms or sequences derived from microorganisms, and confine these injections to internal plant parts or adherent plant surfaces; (ii) ensure that organisms, which can serve as hosts or promote the transmission of the virus or microorganism, are not present within the farthest distance that the airborne virus or microorganism may be expected to be effectively disseminated; (iii) conduct experiments at a time of year when plants that can serve as hosts are either not growing or are not susceptible to productive infection; (iv) use viruses and other microorganisms or their genomes that have known arthropod or animal vectors, in the absence of such vectors; (v) use microorganisms that have an obligate association with the plant; or (vi) use microorganisms that are genetically disabled to minimize survival outside of the research facility and whose natural mode of transmission requires injury of the target organism, or assures that inadvertent release is unlikely to initiate productive infection of organisms outside of the experimental facility.

Appendix P–III–C. Biological Containment Practices (Macroorganisms)

Appendix P–III–C–1. Effective dissemination of arthropods and other small animals can be prevented by using one or more of the following procedures: (i) Use non-flying, flight-impaired, or sterile arthropods; (ii) use non-motile or sterile strains of small animals; (iii) conduct experiments at a time of year that precludes the survival of escaping organisms; (iv) use animals that have an obligate association with a plant that is not present within the dispersal range of the organism; or (v) prevent the escape of organisms present in run-off water by chemical treatment or evaporation of run-off water.

Appendix Q. Physical and Biological Containment for Recombinant DNA Research Involving Animals

Appendix Q specifies containment and confinement practices for research involving whole animals, both those in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. The appendix applies to animal research activities with the following modifications:

Appendix Q shall supersede Appendix G when research animals are of a size or have growth requirements that preclude the use of containment for laboratory animals. Some animals may require other types of containment (see Appendix Q– III–D). The animals covered in Appendix Q are those species normally categorized as animals including but not limited to cattle, swine, sheep, goats, horses, and poultry.

The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q require Institutional Biosafety Committee prior approval.

The institution shall establish and maintain a health surveillance program for personnel engaged in animal research involving viable recombinant DNA-containing microorganisms that require Biosafety Level (BL) 3 or greater containment in the laboratory.

Appendix Q–I. General Considerations

Appendix Q–I–A. Containment Levels

The containment levels required for research involving recombinant DNA associated with or in animals is based on classification of experiments in Section III. For the purpose of animal research, four levels of containment are established. These are referred to as BL1-Animals (N), BL2–N, BL3–N, and BL4–N and are described in the following sections of Appendix Q. The descriptions include: (i) standard practices for physical and biological containment, and (ii) animal facilities.

Appendix Q–I–B. Disposal of Animals (BL1–N through BL4–N)

Appendix Q–I–B–1. When an animal covered by Appendix Q containing recombinant DNA or a recombinant DNA-derived organism is euthanized or dies, the carcass shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an appropriate Federal agency.

Appendix Q–I–B–2. A permanent record shall be maintained of the experimental use and disposal of each animal or group of animals.

Appendix Q–II. Physical and Biological Containment Levels

Appendix Q–II–A. Biosafety Level 1—Animals (BL1–N)

Appendix Q–II–A–1. Standard Practices (BL1–N)

Appendix Q–II–A–1–a. Animal Facility Access (BL1–N)

Appendix Q–II–A–1–a–(1). The containment area shall be locked.

Appendix Q–II–A–1–a–(2). Access to the containment area shall be limited or restricted when experimental animals are being held.

Appendix Q–II–A–1–a–(3). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q–II–A–1–b. Other (BL1–N)

Appendix Q–II–A–1–b–(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.

Appendix Q–II–A–1–b–(2). A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.

Appendix Q–II–A–1–b–(3). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q–II–A–2. Animal Facilities (BL1–N)

Appendix Q–II–A–2–(a). Animals shall be confined to securely fenced areas or be in enclosed structures (animal rooms) to minimize the possibility of theft or unintentional release.

Appendix Q–II–B. Biosafety Level 2—Animals (BL2–N) (see Appendix Q–III–A)

Appendix Q–II–B–1. Standard Practices (BL2–N)

Appendix Q–II–B–1–a. Animal Facility Access (BL2–N)

Appendix Q–II–B–1–a–(1). The containment area shall be locked.

Appendix Q–II–B–1–a–(2). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q–II–B–1–a–(3). The containment building shall be controlled and have a locking access.

Appendix Q–II–B–1–a–(4). The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any specific entry requirements (e.g., vaccination) may enter the laboratory or animal rooms.

Appendix Q–II–B–1–a–(5). Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.

Appendix Q–II–B–1–b. Decontamination and Inactivation (BL2–N)

Appendix Q–II–B–1–b–(1). Contaminated materials that are decontaminated at a site away from the laboratory shall be placed in a closed durable leak-proof container prior to removal from the laboratory.

Appendix Q–II–B–1–b–(2). Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q–II–B–1–c. Signs (BL2–N)

Appendix Q–II–B–1–c–(1). When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) the agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director or other responsible individual, and (iv) any special requirements for entering the laboratory.

Appendix Q–II–B–1–d. Protective Clothing (BL2–N)

Appendix Q–II–B–1–d–(1). Laboratory coats, gowns, smocks, or uniforms shall be worn while in the animal area or attached laboratory. Before entering non-laboratory areas (e.g., cafeteria, library, administrative offices), protective clothing shall be removed and kept in the work entrance area.

Appendix Q–II–B–1–d–(2). Special care shall be taken to avoid skin contamination with microorganisms containing recombinant DNA. Impervious and/or protective gloves shall be worn when handling experimental animals and when skin contact with an infectious agent is unavoidable.

Appendix Q–II–B–1–e. Records (BL2–N)

Appendix Q–II–B–1–e–(1). Any incident involving spills and accidents that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant DNA molecules shall be reported immediately to the Animal Facility Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q–II–B–1–e–(2). When appropriate and giving consideration to the agent handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the agent handled and the function of the animal facility.

Appendix Q–II–B–1–f. Transfer of Materials (BL2–N)

Appendix Q–II–B–1–f–(1). Biological materials removed from the animal containment area in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container. All containers, primary and secondary, shall be disinfected before removal from the animal facility. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Packages containing viable agents may only be opened in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.

Appendix Q–II–B–1–g. Other (BL2–N)

Appendix Q–II–B–1–g–(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.

Appendix Q–II–B–1–g–(2). Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe. Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q–II–B–1–g–(3). Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as a vector is known to be transmitted by a particular route (e.g., arthropods), special attention should be given to preventing spread by that route. In the absence of specific knowledge of a particular route of transmission, all potential means of horizontal transmission (e.g., arthropods, contaminated bedding, or animal waste, etc.) should be prevented.

Appendix Q–II–B–1–g–(4). Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.

Appendix Q–II–B–1–g–(5). Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.

Appendix Q–II–B–1–g–(6). A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.

Appendix Q–II–B–1–g–(7). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q–II–B–1–g–(8). A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.

Appendix Q–II–B–2. Animal Facilities (BL2–N)

Appendix Q–II–B–2–a. Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and to avoid arthropod access. The special provision to avoid the entry or escape of arthropods from the animal areas may be waived if the agent in use is not known to be transmitted by arthropods.

Appendix Q–II–B–2–b. Surfaces shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

Appendix Q–II–B–2–c. The animal containment area shall be designed so that it can be easily cleaned.

Appendix Q–II–B–2–d. Windows that open shall be fitted with fly screens.

Appendix Q–II–B–2–e. An autoclave shall be available for decontamination of laboratory wastes.

Appendix Q–II–B–2–f. If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, interior work areas shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening of access doors or the equivalent.

Appendix Q–II–C. Biosafety Level 3—Animals (BL3–N) (see Appendix Q–III–B)

Appendix Q–II–C–1. Standard Practices (BL3–N)

Appendix Q–II–C–1–a. Animal Facility Access (BL3–N)

Appendix Q–II–C–1–a–(1). The containment area shall be locked.

Appendix Q–II–C–1–a–(2). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q–II–C–1–a–(3). The containment building shall be controlled and have a locking access.

Appendix Q–II–C–1–a–(4). The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the

potential hazard and who meet any specific entry requirements (e.g., vaccination) shall enter the laboratory or animal rooms.

Appendix Q–II–C–1–a–(5). Animal room doors, gates, or other closures shall be kept closed when experiments are in progress.

Appendix Q–II–C–1–b. Decontamination and Inactivation (BL3–N)

Appendix Q–II–C–1–b–(1). The work surfaces of containment equipment shall be decontaminated when work with organisms containing recombinant DNA molecules is finished. Where feasible, plastic-backed paper toweling shall be used on nonporous work surfaces to facilitate clean-up.

Appendix Q–II–C–1–b–(2). All animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.

Appendix Q–II–C–1–b–(3). Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q–II–C–1–b–(4). Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL3–N animal facility to a facility with a lower containment classification.

Appendix Q–II–C–1–b–(5). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.

Appendix Q–II–C–1–c. Signs (BL3–N)

Appendix Q–II–C–1–c–(1). When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) the agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director or other responsible individual, and (iv) any special requirements for entering the laboratory.

Appendix Q–II–C–1–d. Protective Clothing (BL3–N)

Appendix Q–II–C–1–d–(1). Full protective clothing that protects the individual (e.g., scrub suits, coveralls, uniforms) shall be worn in the animal area. Clothing shall not be worn outside the animal containment area and shall be decontaminated before laundering or disposal. Personnel shall be required to shower before exiting the BL3–N area and wearing of personal clothing.

Appendix Q–II–C–1–d–(2). Special care shall be taken to avoid skin contamination with microorganisms containing recombinant DNA. Impervious and/or protective gloves shall be worn when handling experimental animals and when skin contact with an infectious agent is unavoidable.

Appendix Q–II–C–1–d–(3). Appropriate respiratory protection shall be worn in rooms containing experimental animals.

Appendix Q–II–C–1–e. Records (BL3–N)

Appendix Q–II–C–1–e–(1). Documents regarding experimental animal use and disposal shall be maintained in a permanent record book.

Appendix Q–II–C–1–e–(2). Any incident involving spills and accidents that result in environmental release or exposure of animals or laboratory workers to organisms containing recombinant DNA shall be reported immediately to the Biological Safety Office, Animal Facility Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q–II–C–1–e–(3). When appropriate and giving consideration to the agent handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the agent handled or the function of the facility.

Appendix Q–II–C–1–f. Transfer of Materials (BL3–N)

Appendix Q–II–C–1–f–(1). Biological materials removed from the animal containment laboratory in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container. All containers, primary and secondary, shall be disinfected before removal from the animal facility. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Packages containing viable agents may be opened only in a facility having an equivalent or higher level of physical containment unless the agent is biologically inactivated or incapable of reproduction.

Appendix Q–II–C–1–f–(2). Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL3–N animal facility to a facility with a lower containment classification.

Appendix Q–II–C–1–g. Other (BL3–N)

Appendix Q–II–C–1–g–(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.

Appendix Q–II–C–1–g–(2). Appropriate steps should be taken to prevent horizontal transmission or exposure of laboratory personnel. If the agent used as the vector is known to be transmitted by a particular route (e.g., arthropods), special attention should be given to preventing spread by that route. In the absence of specific knowledge of a particular route of transmission, all potential means of horizontal transmission (e.g., arthropods, contaminated bedding, or animal waste) should be prevented.

Appendix Q–II–C–1–g–(3). Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.

Appendix Q–II–C–1–g–(4). Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.

Appendix Q–II–C–1–g–(5). Experiments involving other organisms that require containment levels lower than BL3–N may be conducted in the same area concurrently with experiments requiring BL3–N containment provided that they are conducted in accordance with BL3–N practices.

Appendix Q–II–C–1–g–(6). Animal holding areas shall be cleaned at least once a day and decontaminated immediately following any spill of viable materials.

Appendix Q–II–C–1–g–(7). All procedures shall be performed carefully to minimize the creation of aerosols.

Appendix Q–II–C–1–g–(8). A double barrier shall be provided to separate male and female animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission. Reproductive incapacitation may be used.

Appendix Q–II–C–1–g–(9). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q–II–C–1–g–(10). All animals shall be euthanized at the end of their experimental usefulness and the carcasses decontaminated before disposal in an approved manner.

Appendix Q–II–C–1–g–(11). Personnel shall be required to shower before exiting the BL3–N area and wearing personal clothing.

Appendix Q–II–C–1–g–(12). Animals of the same or different species, which are not involved in the work being performed, shall not be permitted in the animal area.

Appendix Q–II–C–1–g–(13). Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard or removed from the syringe. The needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q–II–C–1–g–(14). A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.

Appendix Q–II–C–2. Animal Facilities (BL3–N)

Appendix Q–II–C–2–a. Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and avoid arthropod access. The special provision to avoid the entry or escape of arthropods from the animal areas may be waived if the agent in use is not known to be transmitted by arthropods.

Appendix Q–II–C–2–b. The interior walls, floors, and ceilings shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat, to facilitate cleaning. Penetrations in these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix Q–II–C–2–c. Windows in the animal facility shall be closed, sealed, and breakage resistant (e.g., double-pane tempered glass or equivalent). The need to maintain negative pressure should be considered when constructing or renovating the animal facility.

Appendix Q–II–C–2–d. An autoclave, incinerator, or other effective means to decontaminate animals and waste shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.

Appendix Q–II–C–2–e. If arthropods are used in the experiment or the agent under study can be transmitted by an arthropod, the interior work area shall be appropriately screened (52 mesh). All perimeter joints and openings shall be sealed, and additional arthropod control mechanisms used to minimize arthropod entry and propagation, including appropriate screening, or the equivalent of access doors.

Appendix Q–II–C–2–f. Access doors to the containment area shall be self-closing.

Appendix Q–II–C–2–g. The animal area shall be separated from all other areas.

Passage through two sets of doors shall be the basic requirement for entry into the animal area from access corridors or other contiguous areas. The animal containment area shall be physically separated from access corridors and other laboratories or areas by a double-door clothes change room, equipped with integral showers and airlock.

Appendix Q–II–C–2–h. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.

Appendix Q–II–C–2–i. An exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air into the animal room through the entry area. The building exhaust, or the exhaust from primary containment units, may be used for this purpose if the exhaust air is discharged to the outside and shall be dispersed away from occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the animal room) is proper.

Appendix Q–II–C–2–j. If the agent is transmitted by aerosol, then the exhaust air shall pass through a high efficiency particulate air/HEPA filter.

Appendix Q–II–C–2–k. Vacuum lines shall be protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.

Appendix Q–II–C–2–l. In lieu of open housing in the special animal room, animals held in a BL3–N area may be housed in partial-containment caging systems (e.g., Horsfall units or gnotobiotic systems, or other special containment primary barriers). Prudent judgment must be exercised to implement this ventilation system (e.g., animal species) and its discharge location.

Appendix Q–II–C–2–m. Each animal area shall contain a foot, elbow, or automatically operated sink for hand washing. The sink shall be located near the exit door.

Appendix Q–II–C–2–n. Restraining devices for animals may be required to avoid damage to the integrity of the animal containment facility.

Appendix Q–II–D. Biosafety Level 4—Animals (BL4–N) (see Appendix Q–III–C)

Appendix Q–II–D–1. Standard Practices (BL4–N)

Appendix Q–II–D–1–a. Animal Facility Access (BL4–N)

Appendix Q–II–D–1–a–(1). Individuals under 16 years of age shall not be permitted to enter the animal area.

Appendix Q–II–D–1–a–(2). The containment area shall be locked.

Appendix Q–II–D–1–a–(3). The containment area shall be patrolled or monitored at frequent intervals.

Appendix Q–II–D–1–a–(4). The containment building shall be controlled and have a locking access.

Appendix Q–II–D–1–a–(5). The Animal Facility Director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any

specific entry requirements (e.g., vaccination) may enter the laboratory or animal room.

Appendix Q–II–D–1–a–(6). Individuals shall enter and exit the animal facility only through the clothing change and shower rooms.

Appendix Q–II–D–1–a–(7). Personnel shall use the airlocks to enter or exit the laboratory only in an emergency.

Appendix Q–II–D–1–a–(8). Animal room doors, gates, and other closures shall be kept closed when experiments are in progress.

Appendix Q–II–D–1–b. Decontamination and Inactivation (BL4–N)

Appendix Q–II–D–1–b–(1). All contaminated liquid or solid wastes shall be decontaminated before disposal.

Appendix Q–II–D–1–b–(2). The work surfaces and containment equipment shall be decontaminated when work with organisms containing recombinant DNA molecules is finished. Where feasible, plastic-backed paper toweling shall be used on nonporous work surfaces to facilitate clean-up.

Appendix Q–II–D–1–b–(3). All wastes from animal rooms and laboratories shall be appropriately decontaminated before disposal in an approved manner.

Appendix Q–II–D–1–b–(4). No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the maximum containment laboratory unless they have been autoclaved or decontaminated. Equipment or material that might be damaged by high temperatures or steam shall be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

Appendix Q–II–D–1–b–(5). When ventilated suits are required, the animal personnel shower entrance/exit area shall be equipped with a chemical disinfectant shower to decontaminate the surface of the suit before exiting the area. A neutralization or water dilution device shall be integral with the chemical disinfectant discharge piping before entering the heat sterilization system. Entry to this area shall be through an airlock fitted with airtight doors.

Appendix Q–II–D–1–b–(6). Needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q–II–D–1–b–(7). Supplies and materials needed in the animal facility shall be brought in by way of the double-door autoclave, fumigation chamber, or airlock that shall be appropriately decontaminated between each use.

Appendix Q–II–D–1–b–(8). An autoclave, incinerator, or other effective means to decontaminate animals and wastes shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.

Appendix Q–II–D–1–b–(9). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism. Liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Appendix Q–II–D–1–c. Signs (BL4–N)

Appendix Q–II–D–1–c–(1). When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) the agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director, or other responsible individual, and (iv) any special requirements for entering the laboratory.

Appendix Q–II–D–1–d. Protective Clothing (BL4–N)

Appendix Q–II–D–1–d–(1). Individuals shall enter and exit the animal facility only through the clothing change and shower rooms. Street clothing shall be removed and kept in the outer clothing change room. Complete laboratory clothing (may be disposable), including undergarments, pants, shirts, jump suits, and shoes shall be provided for all personnel entering the animal facility. When exiting the BL4–N area and before proceeding into the shower area, personnel shall remove their laboratory clothing in the inner change room. All laboratory clothing shall be autoclaved before laundering. Personnel shall shower each time they exit the animal facility.

Appendix Q–II–D–1–d–(2). A ventilated head-hood or a one-piece positive pressure suit, which is ventilated by a life-support system, shall be worn by all personnel entering rooms that contain experimental animals when appropriate. When ventilated suits are required, the animal personnel shower entrance/exit area shall be equipped with a chemical disinfectant shower to decontaminate the surface of the suit before exiting the area. A neutralization or water dilution device shall be integral with the chemical disinfectant discharge piping before entering the heat sterilization system. Entry to this area shall be through an airlock fitted with airtight doors.

Appendix Q–II–D–1–d–(3). Appropriate respiratory protection shall be worn in rooms containing experimental animals.

Appendix Q–II–D–1–e. Records (BL4–N)

Appendix Q–II–D–1–e–(1). Documents regarding experimental animal use and disposal shall be maintained in a permanent record book.

Appendix Q–II–D–1–e–(2). A system shall be established for: (i) Reporting laboratory accidents and exposures that are a result of overt exposures to organisms containing recombinant DNA, (ii) employee absenteeism, and (iii) medical surveillance of potential laboratory-associated illnesses. Permanent records shall be prepared and maintained. Any incident involving spills and accidents that results in environmental release or exposures of animals or laboratory workers to organisms containing recombinant DNA molecules shall be reported immediately to the Biological Safety Officer, Animal Facility Director, Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892, (301) 496–9838. Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q–II–D–1–e–(3). When appropriate and giving consideration to the agents handled, baseline serum samples shall be collected and stored for animal care and other at-risk personnel. Additional serum specimens may be collected periodically depending on the

agents handled or the function of the facility.

Appendix Q–II–D–1–e–(4). A permanent record book indicating the date and time of each entry and exit shall be signed by all personnel.

Appendix Q–II–D–1–f. Transfer of Materials (BL4–N)

Appendix Q–II–D–1–f–(1). No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the maximum containment laboratory unless they have been autoclaved or decontaminated. Equipment or material that might be damaged by high temperatures or steam shall be decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.

Appendix Q–II–D–1–f–(2). Biological materials removed from the animal maximum containment laboratory in a viable or intact state shall be transferred to a non-breakable sealed primary container and then enclosed in a non-breakable sealed secondary container that shall be removed from the animal facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose. Advance approval for transfer of material shall be obtained from the Animal Facility Director. Such packages containing viable agents can only be opened in another BL4–N animal facility if the agent is biologically inactivated or incapable of reproduction. Special safety testing, decontamination procedures, and Institutional Biosafety Committee approval shall be required to transfer agents or tissue/organ specimens from a BL4–N animal facility to one with a lower containment classification.

Appendix Q–II–D–1–f–(3). Supplies and materials needed in the animal facility shall be brought in by way of the double-door autoclave, fumigation chamber, or airlock that shall be appropriately decontaminated between each use. After securing the outer doors, personnel within the animal facility retrieve the materials by opening the interior doors of the autoclave, fumigation chamber, or airlock. These doors shall be secured after materials are brought into the animal facility.

Appendix Q–II–D–1–g. Other (BL4–N)

Appendix Q–II–D–1–g–(1). All genetically engineered neonates shall be permanently marked within 72 hours after birth, if their size permits. If their size does not permit marking, their containers should be marked. In addition, transgenic animals should contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals.

Appendix Q–II–D–1–g–(2). Eating, drinking, smoking, and applying cosmetics shall not be permitted in the work area.

Appendix Q–II–D–1–g–(3). Individuals who handle materials and animals containing recombinant DNA molecules shall be required to wash their hands before exiting the containment area.

Appendix Q–II–D–1–g–(4). Experiments involving other organisms that require containment levels lower than BL4–N may be conducted in the same area concurrently with experiments requiring BL4–N containment provided that they are conducted in accordance with BL4–N practices.

Appendix Q–II–D–1–g–(5). Animal holding areas shall be cleaned at least once a day and decontaminated immediately following any spill of viable materials.

Appendix Q–II–D–1–g–(6). All procedures shall be performed carefully to minimize the creation of aerosols.

Appendix Q–II–D–1–g–(7). A double barrier shall be provided to separate male and female animals. Animal isolation barriers shall be sturdy and accessible for cleaning. Reproductive incapacitation may be used.

Appendix Q–II–D–1–g–(8). The containment area shall be in accordance with state and Federal laws and animal care requirements.

Appendix Q–II–D–1–g–(9). The life support system for the ventilated suit or head hood is equipped with alarms and emergency back-up air tanks. The exhaust air from the suit area shall be filtered by two sets of high efficiency particulate air/HEPA filters installed in series or incinerated. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source shall be provided. The air pressure within the suit shall be greater than that of any adjacent area. Emergency lighting and communication systems shall be provided. A double-door autoclave shall be provided for decontamination of waste materials to be removed from the suit area.

Appendix Q–II–D–1–g–(10). Needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Following use, needles shall not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe. The needles and syringes shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

Appendix Q–II–D–1–g–(11). An essential adjunct to the reporting-surveillance system is the availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory-associated illnesses.

Appendix Q–II–D–1–g–(12). A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and required to read and follow instructions on practices and procedures.

Appendix Q–II–D–1–g–(13). Vacuum lines shall be protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.

Appendix Q–II–D–2. Animal Facilities (BL4–N)

Appendix Q–II–D–2–a. Animals shall be contained within an enclosed structure (animal room or equivalent) to minimize the possibility of theft or unintentional release and avoid arthropod access.

Appendix Q–II–D–2–b. The interior walls, floors, and ceilings shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat, to facilitate cleaning. Penetrations in these structures and surfaces (e.g., plumbing and utilities) shall be sealed.

Appendix Q–II–D–2–c. Windows in the animal facility shall be closed, sealed, and breakage resistant (e.g., double-pane tempered glass or equivalent).

Appendix Q–II–D–2–d. An autoclave, incinerator, or other effective means to decontaminate animals and wastes shall be available, preferably within the containment area. If feasible, a double-door autoclave is preferred and should be positioned to allow removal of material from the containment area.

Appendix Q–II–D–2–e. Access doors to the containment area shall be self-closing.

Appendix Q–II–D–2–f. All perimeter joints and openings shall be sealed to form an arthropod-proof structure.

Appendix Q–II–D–2–g. The BL4–N laboratory provides a double barrier to prevent the release of recombinant DNA containing microorganisms into the environment. Design of the animal

facility shall be such that if the barrier of the inner facility is breached, the outer barrier will prevent release into the environment. The animal area shall be separated from all other areas. Passage through two sets of doors shall be the basic requirement for entry into the animal area from access corridors or other contiguous areas. Physical separation of the animal containment area from access corridors or other laboratories or activities shall be provided by a double-door clothes change room equipped with integral showers and airlock.

Appendix Q–II–D–2–h. A necropsy room shall be provided within the BL4–N containment area.

Appendix Q–II–D–2–i. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism. Liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Appendix Q–II–D–2–j. A ducted exhaust air ventilation system shall be provided that creates directional airflow that draws air into the laboratory through the entry area. The exhaust air, which is not recirculated to any other area of the building, shall be discharged to the outside and dispersed away from the occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the animal room) is proper.

Appendix Q–II–D–2–k. Exhaust air from BL4–N containment area shall be double high efficiency particulate air/HEPA filtered or treated by passing through a certified HEPA filter and an air incinerator before release to the atmosphere. Double HEPA filters shall be required for the supply air system in a BL4–N containment area.

Appendix Q–II–D–2–l. All high efficiency particulate air/HEPA filters' frames and housings shall be certified to have no detectable smoke [dioctylphthalate] leaks when the exit face (direction of flow) of the filter is scanned above 0.01 percent when measured by a linear or logarithmic photometer. The instrument must demonstrate a threshold sensitivity of at least 1×10^{-3} micrograms per liter for 0.3 micrometer diameter dioctylphthalate particles and a challenge concentration of 80–120 micrograms per liter. The air sampling rate should be at least 1 cfm (28.3 liters per minute).

Appendix Q–II–D–2–m. If an air incinerator is used in lieu of the second high efficiency particulate air/HEPA filter, it shall be biologically challenged to prove all viable test agents are sterilized. The biological challenge must be minimally 1×10^{8} organisms per cubic foot of airflow through the incinerator. It is universally accepted if bacterial spores are used to challenge and verify that the equipment is capable of killing spores, then assurance is provided that all other known agents are inactivated by the parameters established to operate the equipment. Test spores meeting this criterion are *Bacillus subtilis* var. *niger* or *Bacillus stearothermophilis*. The operating temperature of the incinerator shall be continuously monitored and recorded during use.

Appendix Q–II–D–2–n. All equipment and floor drains shall be equipped with deep traps (minimally 5 inches). Floor drains shall be fitted with isolation plugs or fitted with automatic water fill devices.

Appendix Q–II–D–2–o. Each animal area shall contain a foot, elbow, or automatically operated sink for hand washing. The sink shall be located near the exit-door.

Appendix Q–II–D–2–p. Restraining devices for animals may be required to avoid damage to the integrity of the containment animal facility.

Appendix Q–II–D–2–q. The supply water distribution system shall be fitted with a back-flow preventer or break tank.

Appendix Q–II–D–2–r. All utilities, liquid and gas services, shall be protected with devices that avoid back-flow.

Appendix Q–II–D–2–s. Sewer and other atmospheric ventilation lines shall be equipped minimally with a single high efficiency particulate/HEPA filter. Condensate drains from these type housings shall be appropriately connected to a contaminated or sanitary drain system. The drain position in the housing dictates the appropriate system to be used.

Appendix Q–III. Footnotes and References for Appendix Q

Appendix Q–III–A. If recombinant DNA is derived from a Class 2 organism requiring BL2 containment, personnel shall be required to have specific training in handling pathogenic agents and directed by knowledgeable scientists.

Appendix Q–III–B. Personnel who handle pathogenic and potentially lethal agents shall be required to have specific training and be supervised by knowledgeable scientists who are experienced in working with these agents. BL3–N containment also minimizes escape of recombinant DNA-containing organisms from exhaust air or waste material from the containment area.

Appendix Q–III–C. Classes 4 and 5 microorganisms pose a high level of individual risk for acquiring life-threatening diseases to personnel and/or animals. To import Class 5 agents, special approval must be obtained from U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Import-Export Products, Room 756, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782.

Laboratory staff shall be required to have specific and thorough training in handling extremely hazardous infectious agents, primary and secondary containment, standard and special practices, and laboratory design characteristics. The laboratory staff shall be supervised by knowledgeable scientists who are trained and experienced in working with these agents and in the special containment facilities.

Within work areas of the animal facility, all activities shall be confined to the specially equipped animal rooms or support areas. The maximum animal containment area and support areas shall have special engineering and design features to prevent the dissemination of microorganisms into the environment via exhaust air or waste disposal.

Appendix Q–III–D. Other research with non-laboratory animals, which may not appropriately be conducted under conditions described in Appendix Q, may be conducted safely by applying practices routinely used for controlled culture of these biota. In aquatic systems, for example, BL1 equivalent conditions could be met by utilizing growth tanks that provide adequate physical means to avoid the escape of the aquatic species, its gametes, and introduced exogenous genetic material. A mechanism shall be provided to ensure that neither the

organisms nor their gametes can escape into the supply or discharge system of the rearing container (e.g., tank, aquarium, etc.) Acceptable barriers include appropriate filtration, irradiation, heat treatment, chemical treatment, etc. Moreover, the top of the rearing container shall be covered to avoid escape of the organism and its gametes. In the event of tank rupture, leakage, or overflow, the construction of the room containing these tanks should prevent the organisms and gametes from entering the building's drains before the organism and its gametes have been inactivated.

Other types of non-laboratory animals (e.g., nematodes, arthropods, and certain forms of smaller animals) may be accommodated by using the appropriate BL1 through BL4 or BL1–P through BL4–P containment practices and procedures as specified in Appendices G and P.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined to be not cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Effective Date: June 24, 1994.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 94–16200 Filed 7–1–94; 8:45 am]

BILLING CODE 4140–01–P

federal register

Tuesday
July 5, 1994

Part V

The President

Executive Order 12923—Continuation of Export Control Regulations

Federal Register
Vol. 59, No. 127
Tuesday, July 5, 1994

Presidential Documents

Title 3—

The President

Executive Order 12923 of June 30, 1994

Continuation of Export Control Regulations

By the authority vested in me as President by the Constitution and the laws of the United States of America, including but not limited to section 203 of the International Emergency Economic Powers Act ("Act") (50 U.S.C. 1702), I, WILLIAM J. CLINTON, President of the United States of America, find that the unrestricted access of foreign parties to U.S. goods, technology, and technical data and the existence of certain boycott practices of foreign nations, in light of the expiration of the Export Administration Act of 1979, as amended (50 U.S.C. App. 2401 *et seq.*), constitute an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States and hereby declare a national emergency with respect to that threat.

Accordingly, in order (a) to exercise the necessary vigilance with respect to exports and activities affecting the national security of the United States; (b) to further significantly the foreign policy of the United States, including its policy with respect to cooperation by U.S. persons with certain foreign boycott activities, and to fulfill its international responsibilities; and (c) to protect the domestic economy from the excessive drain of scarce materials and reduce the serious economic impact of foreign demand, it is hereby ordered as follows:

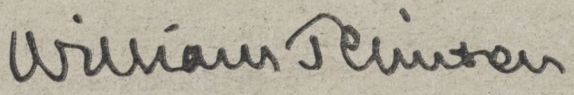
Section 1. To the extent permitted by law, the provisions of the Export Administration Act of 1979, as amended, and the provisions for administration of the Export Administration Act of 1979, as amended, shall be carried out under this order so as to continue in full force and effect and amend, as necessary, the export control system heretofore maintained by the Export Administration Regulations issued under the Export Administration Act of 1979, as amended. The delegations of authority set forth in Executive Order No. 12002 of July 7, 1977, as amended by Executive Order No. 12755 of March 12, 1991; Executive Order No. 12214 of May 2, 1980; Executive Order No. 12735 of November 16, 1990; and Executive Order No. 12851 of June 11, 1993, shall be incorporated in this order and shall apply to the exercise of authorities under this order.

Sec. 2. All rules and regulations issued or contained in effect by the Secretary of Commerce under the authority of the Export Administration Act of 1979, as amended, including those published in Title 15, Subtitle B, Chapter VII, Subchapter C, of the Code of Federal Regulations, Parts 768 through 799, and all orders, regulations, licenses, and other forms of administrative action issued, taken, or continued in effect pursuant thereto, shall, until amended or revoked by the Secretary of Commerce, remain in full force and effect as if issued or taken pursuant to this order, except that the provisions of sections 203(b)(2) and 206 of the Act (50 U.S.C. 1702(b)(2) and 1705) shall control over any inconsistent provisions in the regulations. Nothing in this section shall affect the continued applicability of administrative sanctions provided for by the regulations described above.

Sec. 3. Provisions for administration of section 38(e) of the Arms Export Control Act (22 U.S.C. 2778(e)) may be made and shall continue in full force and effect until amended or revoked under the authority of section 203 of the Act (50 U.S.C. 1702). To the extent permitted by law, this order also shall constitute authority for the issuance and continuation in full force and effect of all rules and regulations by the President or his

delegate, and all orders, licenses, and other forms of administrative actions issued, taken, or continued in effect pursuant thereto, relating to the administration of section 38(e).

Sec. 4. This order shall be effective as of midnight between June 30, 1994, and July 1, 1994, and shall remain in effect until terminated. It is my intention to terminate this order upon the enactment into law of a bill reauthorizing the authorities contained in the Export Administration Act.



THE WHITE HOUSE,
June 30, 1994.

[FR Doc. 94–16403
Filed 7–1–94; 10:38 am]
Billing code 3195–01–P

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CFR CHECKLIST

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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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200-End	(869-022-00028-4)	23.00	Jan. 1, 1994
10 Parts:			
0-50	(869-022-00029-2)	29.00	Jan. 1, 1994
51-199	(869-022-00030-6)	22.00	Jan. 1, 1994
200-399	(869-022-00031-4)	15.00	[6] Jan. 1, 1993
400-499	(869-022-00032-2)	21.00	Jan. 1, 1994
500-End	(869-022-00033-1)	37.00	Jan. 1, 1994
11	(869-022-00034-9)	14.00	Jan. 1, 1994
12 Parts:			
1-199	(869-022-00035-7)	12.00	Jan. 1, 1994
200-219	(869-022-00036-5)	16.00	Jan. 1, 1994
220-299	(869-019-00037-2)	26.00	Jan. 1, 1993
300-499	(869-022-00038-1)	22.00	Jan. 1, 1994
500-599	(869-022-00039-0)	20.00	Jan. 1, 1994
600-End	(869-022-00040-3)	32.00	Jan. 1, 1994
13	(869-022-00041-1)	30.00	Jan. 1, 1994
14 Parts:			
1-59	(869-022-00042-0)	32.00	Jan. 1, 1994
60-139	(869-022-00043-8)	26.00	Jan. 1, 1994
140-199	(869-022-00044-6)	13.00	Jan. 1, 1994
200-1199	(869-022-00045-4)	23.00	Jan. 1, 1994
1200-End	(869-022-00046-2)	16.00	Jan. 1, 1994
15 Parts:			
0-299	(869-022-00047-1)	15.00	Jan. 1, 1994
300-799	(869-022-00048-4)	26.00	Jan. 1, 1994
800-End	(869-022-00049-7)	23.00	Jan. 1, 1994
16 Parts:			
0-149	(869-022-00050-1)	6.50	Jan. 1, 1994
150-999	(869-022-00051-9)	18.00	Jan. 1, 1994
1000-End	(869-022-00052-7)	25.00	Jan. 1, 1994
17 Parts:			
1-199	(869-019-00054-2)	18.00	Apr. 1, 1993
200-239	(869-019-00055-1)	23.00	June 1, 1993
240-End	(869-019-00056-9)	30.00	June 1, 1993
18 Parts:			
1-149	(869-019-00057-7)	16.00	Apr. 1, 1993
150-279	(869-022-00058-6)	19.00	Apr. 1, 1994
280-399	(869-019-00059-3)	15.00	Apr. 1, 1993
400-End	(869-022-00060-8)	11.00	Apr. 1, 1994
19 Parts:			
1-199	(869-019-00061-5)	35.00	Apr. 1, 1993
200-End	(869-022-00062-4)	12.00	Apr. 1, 1994
20 Parts:			
1-399	(869-022-00063-2)	20.00	Apr. 1, 1994
400-499	(869-019-00064-0)	31.00	Apr. 1, 1993
*500-End	(869-022-00065-9)	31.00	Apr. 1, 1994
21 Parts:			
1-99	(869-019-00066-6)	15.00	Apr. 1, 1993
100-169	(869-019-00067-4)	21.00	Apr. 1, 1993
170-199	(869-019-00068-2)	20.00	Apr. 1, 1993
200-299	(869-022-00069-1)	7.00	Apr. 1, 1994
300-499	(869-019-00070-4)	34.00	Apr. 1, 1993
500-599	(869-019-00071-2)	21.00	Apr. 1, 1993
600-799	(869-019-00072-1)	8.00	Apr. 1, 1993
800-1299	(869-019-00073-9)	22.00	Apr. 1, 1993
1300-End	(869-022-00074-8)	13.00	Apr. 1, 1994
22 Parts:			
1-299	(869-019-00075-5)	30.00	Apr. 1, 1993
300-End	(869-022-00076-4)	23.00	Apr. 1, 1994
23	(869-019-00077-1)	21.00	Apr. 1, 1993
24 Parts:			
0-199	(869-019-00078-0)	38.00	Apr. 1, 1993
200-499	(869-019-00079-8)	36.00	Apr. 1, 1993
*500-699	(869-022-00080-2)	20.00	Apr. 1, 1994
700-1699	(869-019-00081-0)	39.00	Apr. 1, 1993
1700-End	(869-019-00082-8)	15.00	Apr. 1, 1993
25	(869-019-00083-6)	31.00	Apr. 1, 1993
26 Parts:			
§§ 1.0-1-1.60	(869-019-00084-4)	21.00	Apr. 1, 1993
§§ 1.61-1.169	(869-019-00085-2)	37.00	Apr. 1, 1993
§§ 1.170-1.300	(869-019-00086-1)	23.00	Apr. 1, 1993
§§ 1.301-1.400	(869-019-00087-9)	21.00	Apr. 1, 1993
§§ 1.401-1.440	(869-019-00088-7)	31.00	Apr. 1, 1993
§§ 1.441-1.500	(869-019-00089-5)	23.00	Apr. 1, 1993
§§ 1.501-1.640	(869-019-00090-9)	20.00	Apr. 1, 1993
§§ 1.641-1.850	(869-019-00091-7)	24.00	Apr. 1, 1993
§§ 1.851-1.907	(869-019-00092-5)	27.00	Apr. 1, 1993
§§ 1.908-1.1000	(869-019-00093-3)	26.00	Apr. 1, 1993
§§ 1.1001-1.1400	(869-019-00094-1)	22.00	Apr. 1, 1993
§§ 1.1401-End	(869-019-00095-0)	31.00	Apr. 1, 1993
2-29	(869-019-00096-8)	23.00	Apr. 1, 1993
30-39	(869-019-00097-6)	18.00	Apr. 1, 1993
40-49	(869-019-00098-4)	13.00	Apr. 1, 1993
50-299	(869-019-00099-2)	13.00	Apr. 1, 1993
300-499	(869-017-00100-0)	23.00	Apr. 1, 1993
500-599	(869-022-00101-9)	6.00	[4] Apr. 1, 1990

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600-End	(869-019-00102-6)	8.00	Apr. 1, 1993
27 Parts:			
1-199	(869-019-00103-4)	37.00	Apr. 1, 1993
200-End	(869-022-00104-3)	13.00	Apr. 1, 1994
28 Parts:			
1-42	(869-019-00105-1)	27.00	July 1, 1993
43-end	(869-019-00106-9)	21.00	July 1, 1993
29 Parts:			
0-99	(869-019-00107-7)	21.00	July 1, 1993
100-499	(869-019-00108-5)	9.50	July 1, 1993
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900-1899	(869-019-00110-7)	17.00	July 1, 1993
1900-1910 (§§ 1901.1 to 1910.999)	(869-019-00111-5)	31.00	July 1, 1993
1910 (§§ 1910.1000 to end)	(869-019-00112-3)	21.00	July 1, 1993
1911-1925	(869-019-00113-1)	22.00	July 1, 1993
1926	(869-019-00114-0)	33.00	July 1, 1993
1927-End	(869-019-00115-8)	36.00	July 1, 1993
30 Parts:			
1-199	(869-019-00116-6)	27.00	July 1, 1993
200-699	(869-019-00117-4)	20.00	July 1, 1993
700-End	(869-019-00118-2)	27.00	July 1, 1993
31 Parts:			
0-199	(869-019-00119-1)	18.00	July 1, 1993
200-End	(869-019-00120-4)	29.00	July 1, 1993
32 Parts:			
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1-190	(869-019-00121-2)	30.00	July 1, 1993
191-399	(869-019-00122-1)	36.00	July 1, 1993
400-629	(869-019-00123-9)	26.00	July 1, 1993
630-699	(869-019-00124-7)	14.00	[5] July 1, 1991
700-799	(869-019-00125-5)	21.00	July 1, 1993
800-End	(869-019-00126-3)	22.00	July 1, 1993
33 Parts:			
1-124	(869-019-00127-1)	20.00	July 1, 1993
125-199	(869-019-00128-0)	25.00	July 1, 1993
200-End	(869-019-00129-8)	24.00	July 1, 1993
34 Parts:			
1-299	(869-019-00130-1)	27.00	July 1, 1993
300-399	(869-019-00131-0)	20.00	July 1, 1993
400-End	(869-019-00132-8)	37.00	July 1, 1993
35	(869-019-00133-6)	12.00	July 1, 1993
36 Parts:			
1-199	(869-019-00134-4)	16.00	July 1, 1993
200-End	(869-019-00135-2)	35.00	July 1, 1993
37	(869-019-00136-1)	20.00	July 1, 1993
38 Parts:			
0-17	(869-019-00137-9)	31.00	July 1, 1993
18-End	(869-019-00138-7)	30.00	July 1, 1993
39	(869-019-00139-5)	17.00	July 1, 1993
40 Parts:			
1-51	(869-019-00140-9)	39.00	July 1, 1993
52	(869-019-00141-7)	37.00	July 1, 1993
53-59	(869-019-00142-5)	11.00	July 1, 1993
60	(869-019-00143-3)	35.00	July 1, 1993
61-80	(869-019-00144-1)	29.00	July 1, 1993
81-85	(869-019-00145-0)	21.00	July 1, 1993
86-99	(869-019-00146-8)	39.00	July 1, 1993
100-149	(869-019-00147-6)	36.00	July 1, 1993
150-189	(869-019-00148-4)	24.00	July 1, 1993
190-259	(869-019-00149-2)	17.00	July 1, 1993
260-299	(869-019-00150-6)	39.00	July 1, 1993
300-399	(869-019-00151-4)	18.00	July 1, 1993
400-424	(869-019-00152-2)	27.00	July 1, 1993
425-699	(869-019-00153-1)	28.00	July 1, 1993
700-789	(869-019-00154-9)	26.00	July 1, 1993
790-End	(869-019-00155-7)	26.00	July 1, 1993
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1, 1-1 to 1-10		13.00	[3] July 1, 1984
1, 1-11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
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7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
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201-End	(869-019-00159-0)	12.00	July 1, 1993
42 Parts:			
1-399	(869-019-00160-3)	24.00	Oct. 1, 1993
400-429	(869-019-00161-1)	25.00	Oct. 1, 1993
430-End	(869-019-00162-0)	36.00	Oct. 1, 1993
43 Parts:			
1-999	(869-019-00163-8)	23.00	Oct. 1, 1993
1000-3999	(869-019-00164-6)	32.00	Oct. 1, 1993
4000-End	(869-019-00165-4)	14.00	Oct. 1, 1993
44	(869-019-00166-2)	27.00	Oct. 1, 1993
45 Parts:			
1-199	(869-019-00167-1)	22.00	Oct. 1, 1993
200-499	(869-019-00168-9)	15.00	Oct. 1, 1993
500-1199	(869-019-00169-7)	30.00	Oct. 1, 1993
1200-End	(869-019-00170-1)	22.00	Oct. 1, 1993
46 Parts:			
1-40	(869-019-00171-9)	18.00	Oct. 1, 1993
41-69	(869-019-00172-7)	16.00	Oct. 1, 1993
70-89	(869-019-00173-5)	8.50	Oct. 1, 1993
90-139	(869-019-00174-3)	15.00	Oct. 1, 1993
140-155	(869-019-00175-1)	12.00	Oct. 1, 1993
156-165	(869-019-00176-0)	17.00	Oct. 1, 1993
166-199	(869-019-00177-8)	17.00	Oct. 1, 1993
200-499	(869-019-00178-6)	20.00	Oct. 1, 1993
500-End	(869-019-00179-4)	15.00	Oct. 1, 1993
47 Parts:			
0-19	(869-019-00180-8)	24.00	Oct. 1, 1993
20-39	(869-019-00181-6)	24.00	Oct. 1, 1993
40-69	(869-019-00182-4)	14.00	Oct. 1, 1993
70-79	(869-019-00183-2)	23.00	Oct. 1, 1993
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1 (Parts 1-51)	(869-019-00185-9)	36.00	Oct. 1, 1993
1 (Parts 52-99)	(869-019-00186-7)	23.00	Oct. 1, 1993
2 (Parts 201-251)	(869-019-00187-5)	16.00	Oct. 1, 1993
2 (Parts 252-299)	(869-019-00188-3)	12.00	Oct. 1, 1993
3-6	(869-019-00189-1)	23.00	Oct. 1, 1993
7-14	(869-019-00190-5)	31.00	Oct. 1, 1993
15-28	(869-019-00191-3)	31.00	Oct. 1, 1993
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49 Parts:			
1-99	(869-019-00193-0)	23.00	Oct. 1, 1993
100-177	(869-019-00194-8)	30.00	Oct. 1, 1993
178-199	(869-019-00195-6)	20.00	Oct. 1, 1993
200-399	(869-019-00196-4)	27.00	Oct. 1, 1993
400-999	(869-019-00197-2)	33.00	Oct. 1, 1993
1000-1199	(869-019-00198-1)	18.00	Oct. 1, 1993
1200-End	(869-019-00199-9)	22.00	Oct. 1, 1993
50 Parts:			
1-199	(869-019-00200-6)	20.00	Oct. 1, 1993
200-599	(869-019-00201-4)	21.00	Oct. 1, 1993
600-End	(869-019-00202-2)	22.00	Oct. 1, 1993
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Complete 1994 CFR set		829.00	1994
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Individual copies		2.00	1994

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1994. The CFR volume issued April 1, 1990, should be retained.

[5] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1993. The CFR volume issued July 1, 1991, should be retained.

[6] No amendments to this volume were promulgated during the period January 1, 1993 to December 31, 1993. The CFR volume issued January 1, 1993, should be retained.

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