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

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

DEPARTMENT OF AGRICULTURE

Rural Electrification Administration

7 CFR Part 1703

RIN 0572-AA60

Deferments of REA Loan Payments for Rural Development Projects

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

SUMMARY: The Rural Electrification Administration (REA) hereby adds regulations for a program that will allow REA-financed electric and telephone borrowers to defer insured or direct loan payments in an amount equal to an investment in a rural development project. Deferments of REA loan payments are provided for the purpose of promoting rural development opportunities.

EFFECTIVE DATE: May 24, 1993.

FOR FURTHER INFORMATION CONTACT: Blaine D. Stockton, Jr., Assistant Administrator, Economic Development and Technical Services, Rural Electrification Administration, telephone number (202) 720–9552.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1512–1. This action has been classified as "nonmajor" because it does not meet the criteria for a major regulation as established by the Order.

Executive Order 12778

This rule: (1) Will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule; (2) Will not have any retroactive effect; and (3) Will not require administrative proceedings before parties may file suit challenging the provisions of this rule.

Regulatory Flexibility Act

It was stated at the time the proposed rule was published in the **Federal Register** (57 FR 26782) on June 16, 1992, that this rule does not fall within the scope of the Regulatory Flexibility Act. Upon further examination, it has been determined that with respect to REA telephone borrowers this rule may fall within the scope of the Regulatory Flexibility Act. However, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

REA borrowers are eligible to receive deferments on loan payments under this rule in order to support rural development projects. REA estimates that approximately 12 of the 1,906 total REA borrowers will submit applications for deferments of REA payments to support rural development projects. Every effort has been made to minimize the application and recordkeeping burden on the applicant and yet maintain the security and integrity of the REA program. We have calculated that the additional cost burden for a REA borrower to utilize this program to be $133 and that the average man-hour burden to review the instructions, search existing data sources, collect and assemble data, and perform recordkeeping and clerical duties will be approximately a total of 3 hours per REA borrower.

As utilities, most REA borrowers serve designated or certified areas on a noncompetitive basis. This program is expected to have no significant impact on a recipient's economic condition, market share, or its competitive position with larger businesses. Comments regarding the Regulatory Flexibility Act and the Administrator's certification that this rule will not have a significant economic impact on a substantial number of small entities should be addressed to the agency as provided in this rule by May 7, 1993.

Information Collection and Recordkeeping Requirements

In compliance with the Office of Management and Budget (OMB) regulations (5 CFR part 1320) which implement the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and section 3504 of that Act, the information collection and recordkeeping requirements contained in this rule have been submitted to OMB for review. Comments concerning these requirements should be directed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USDA, room 3201, NEOB, Washington, DC 20503.

National Environmental Policy Act Certification

The Administrator has determined that this rule will not significantly impact 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 rule is listed in the Catalog of Federal Domestic Assistance Programs under numbers 10.850, Rural Electrification Loans and Loan Guarantees and 10.851, Rural Telephone Loans and Loan Guarantees. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402.

Background

On June 16, 1992, REA published a proposed rule in the **Federal Register** (57 FR 26782) that would implement a new rural development program established through amendment to section 12 of the Rural Electrification Act of 1936 (RE Act) by section 2344 of the Rural Economic Development Act of 1990 (7 U.S.C. 912). This program authorizes, subject to limitations established in appropriations Acts, the Administrator of REA to permit electric and telephone borrowers to defer the payment of principal and interest on any electric or telephone direct loan or insured loan made under the RE Act and invest the deferred amounts in rural development projects. The total amount of deferments approved under this program shall not exceed 3 percent of the total payments due during fiscal year 1993 from all borrowers on direct loans and insured loans made pursuant to the RE Act. For each subsequent fiscal year after 1993, the total amount of deferments in any year shall not

exceed 5 percent of the total payments due for the year from all borrowers on direct loans and insured loans.

Comments

REA received four comments regarding the proposed rule, which were taken into consideration in preparing the final rule. Comments were received from the following:

(1) Edison Electric Institute.

(2) Southwestern Electric Cooperative, Inc.

(3) National Rural Electric Cooperative Association.

(4) United States Department of the Treasury.

One commenter suggested that REA require the projects to be reviewed by the state Rural Economic Development Review Panels to help ensure that the most meritorious projects with the greatest community backing are selected. The 1990 amendment to section 12 of the RE Act provides for the deferral of principal and interest on direct loan and insured loan payments to promote rural development efforts through REA borrowers. REA believes Congress intended that REA borrowers would make the determination of whether or not to provide business financing or other rural development assistance under this program. This is consistent with REA's policy of promoting local involvement and initiative in its rural development programs. At the same time, the rule provides requirements that will protect REA's loan security and ensure that deferments are actually used to invest in rural development projects. REA believes the application requirements are consistent with the intent of the law and no additional review by a state board is warranted.

The same commenter also suggested that projects should be selected without regard to which entity is providing electricity to the project. REA considered this comment and a related comment suggesting that language be added to prohibit REA borrowers from conditioning assistance on the purchase of electricity. REA believes these comments have merit, but cannot at this time incorporate such a provision since this issue has not been subject to notice and comment. REA does not interpret these rules as promoting ties between the receipt of rural development assistance from REA borrowers and the acceptance of electric or telephone service. As stated in the preamble to the Rural Economic Development Loan and Grant Program published September 25, 1992 (57 FR 44313), REA supports economic development in rural areas without regard to service territory.

Another commenter suggested that REA require REA borrowers applying for deferments to set up a local public notice and comment procedure for local input on the project. As stated above, REA believes Congress intended REA borrowers to make the determination of whether to promote a particular rural development project. The REA borrowers will use public input to make these determinations because REA borrowers are by nature local institutions that respond to community concerns and opinions. The electric and telephone cooperatives consist of boards of directors elected from the local community. In addition, the projects receiving assistance through this program generally recieve public exposure through the press, newsletters, and other media. Therefore, REA does not believe a formal notice and comment procedure is necessary.

Another commenter suggested that REA add language providing that activities pursuant to the program do not supplant existing businesses and reject any request for deferment if the proposed project would result only in the transfer of employment or manufacturing. REA believes that this is already covered in § 1703.306(c) which prohibits funds from the deferment to be used to transfer existing employment or business activities from one area to another.

One commenter expressed concern that the rule would not allow an REA borrower to use the Deferment Program if REA provided a lien accommodation for private capital used by the REA borrower to make an investment in the rural development project. This concern was based on the language in § 1703.304 of the proposed rule which stated that the REA borrower's investment in the rural development project must be made from the REA borrower's own funds. "Borrower's own funds" were defined in § 1703.302 to exclude proceeds of loans made, guaranteed, or lien accommodated by the Administrator or grants made by the Administrator. REA also intended this definition to exclude proceeds from loans made by the Administrator in his capacity as Governor of the Rural Telephone Bank and proceeds from grants made pursuant to section 2331 through section 2335A of the Rural Economic Development Act of 1990.

REA intends to allow REA borrowers to use the proceeds from loans that have received a lien accommodation from REA for the required investment in the rural development project, as long as the lien accommodation is in accordance with the agency's lien accommodation regulations. REA is currently developing regulations for lien accommodations and has published an advance notice of proposed rulemaking on December 2, 1991, at 56 FR 61201.

In order to correct the technical problems involved in the proposed definition of "borrower's own funds", the definition has been deleted from § 1703.302. The limitations formerly contained in the definition have been modified as discussed and moved to separate § 1703.304(c) for clarification.

REA incorporated these restrictions on the funds that a REA borrower may use to make the required investment because REA believes Congress intended for the REA borrower to have its own financial commitment to the rural development project. Congress stated that an REA borrower may defer its debt service payments only in an amount equal to an investment made by such REA borrower. Section 1703.304(c) prohibits the REA borrower from using funds which are not actually in the REA borrower's sole discretion to use, and therefore cannot be considered the REA borrower's financial commitment to the rural development project. These restricted funds include proceeds of loans made or guaranteed pursuant to the RE Act or grants made pursuant to the RE Act or the Rural Economic Development Act of 1990, funds necessary to make payment on loans made, guaranteed, or lien accommodated pursuant to the RE Act, and funds subject to conditions or liens pursuant to REA loan documents. For example, § 1703.304 (c)(6) prohibits an REA borrower from using funds which are required to be held in trust for the Government, such as loan proceeds advanced by the Government which must be deposited in a special construction account pursuant to REA or RTB loan documents.

Several additional changes were made in order to clarify the rule or rectify the rule with the RE Act. Section 1703.304, Requirement criteria for deferment of loan payments, was clarified and divided into two sections in order to separate the restrictions for deferment of loan payments from the requirements for deferment of loan payments. Section 1703.304 now reads as Restrictions on the deferment of loan payments, and § 1703.305 now reads as Requirements for deferment of loan payments. Accordingly, former §§ 1703.305—1703.312 have been renumbered. Also, part of § 1703.304(d) has been reworded and moved to a new § 1703.309(e) for clarification.

Section 1703.305 was changed in order to limit the REA borrower's grace period for making the cushion of credit payment to 30 days. The language in the

proposed rule would have allowed the REA borrower to use those cushion of credit payments made within one year prior to the date REA received the REA borrower's application. Upon further examination of subsection 12(b)(3)(D) of the RE Act as added by section 2344 of the Rural Development Act of 1990, REA does not believe that a payment made to a cushion of credit account prior to the date of REA's approval of a deferment satisfies the statutory requirement that the borrower make such payment "at the time of a deferment." REA interprets this requirement to mean that a linkage must exist between a cushion of credit payment and its corresponding deferral. The relationship can be established by making a payment contemporaneously with the deferral. In order to facilitate administration of this requirement, once an application has been approved, REA will deem a subsequent cushion of credit payment received on or within 30 days prior to its corresponding deferment date as fulfilling this requirement, dollar for dollar.

REA recognizes that in some instances it may take a borrower several payment periods to accumulate all of the deferrals it is eligible to receive for a particular rural development project. REA does not interpret section 12(b) of the RE Act as requiring the borrower and REA to segment the related local investment, cushion of credit payment, and deferral in order to at all times exactly match all three components to a borrower's debt amortization schedule. Thus, the rule permits a borrower to consolidate in one application, all of the related deferrals it wishes to receive in the year following application approval. In such a case, amounts paid into the cushion of credit account after the date of the approval will be considered by REA as satisfying the requirement of section 12(b)(3)(D). REA believes that this approach is not only consistent with Congressional intent, but also encourages this rural development by eliminating unnecessary paperwork and by promoting efficient program administration.

For similar reasons, REA will consider an investment made by a borrower in a rural development project after the date that the borrower applies for a deferment under this subpart in determining whether the requirement in section 12(b)(3)(B) that deferments not exceed the amount of the borrower's investment in the related rural development project is met. The permissible period for making matching investments in the project is greater than the period for making matching payments into the cushion of credit account. REA believes that it has greater latitude with respect to the timing of the local investment because the statute does not contain any specific time limitation for such investment. Although this requirement is less time critical than the requirement in section 12(b)(3)(D) for making payments into the cushion of credit account, section 12(b) makes it clear that deferments must be made to "enable" the borrower to make rural development investments. REA interprets this to mean that a connection must be shown to exist between the deferral and the local investment. It would be difficult at best to establish the existence of such a connection in a case where a borrower had made its local investment before it had even applied for a deferment. Thus the application date establishes a clear line for satisfying this requirement. This objective standard will provide certainty for the borrowers and facilitate program administration by REA.

Finally, some minor changes were made in the regulatory text for the purposes of simple clarification and the elimination of ambiguity. In § 1703.302, Definitions and rules of construction, the definition of "RTB (Rural Telephone Bank)" was added, as was the definition of "Direct loan"; the definitions of "Financially distressed borrower" and of "Insured loan" were reworded slightly. In § 1703.303, Eligibility criteria for deferment of loan payments, paragraph (c) was deleted because the wording regarding not granting deferments for, "Other actions on the part of the borrower that thwart the achievement of the objectives of the REA program" was ambiguous and unnecessary. In § 1703.309, Terms of repayment of deferred loan payments, paragraph (b) was modified by clarifying the deferment payment schedule to be made on "...either a monthly or quarterly basis..."In § 1703.311, Application procedures for deferment of loan payments, paragraphs (a) (2)–(9) were reworded for clarification. Finally, in § 1703.312, REA review requirements, two sentences about borrower's applications were reworded as "...completed..." applications.

List of Subjects in 7 CFR Part 1703

Community development, Grant programs-housing and community development, Loan programs-housing and community development, Reporting and recordkeeping requirements, Rural areas.

For reasons set out in the preamble, REA hereby amends 7 CFR chapter XVII, part 1703, as follows:

PART 1703—RURAL DEVELOPMENT

1. The authority citation for 7 CFR part 1703 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.* and 950aaa *et seq.*

2. A heading is added to subpart C which is reserved and subpart E is added to part 1703 to read as follows:

Subpart C—Rural Business Incubator Program [Reserved]

* * * * *

Subpart E—Deferments of REA Loan Payments for Rural Development Projects

Sec.
1703.300 Purpose.
1703.301 Policy.
1703.302 Definitions and rules of construction.
1703.303 Eligibility criteria for deferment of loan payments.
1703.304 Restrictions on the deferment of loan payments.
1703.305 Requirements for deferment of loan payments.
1703.306 Limitation on funds derived from the deferment of loan payments.
1703.307 Uses of the deferments of loan payments.
1703.308 Amount of deferment funds available.
1703.309 Terms of repayment of deferred loan payments.
1703.310 Environmental considerations.
1703.311 Application procedures for deferment of loan payments.
1703.312 REA review requirements.
1703.313 Compliance with other regulations.

Subpart C—Rural Business Incubator Program [Reserved]

* * * * *

Subpart E—Deferments of REA Loan Payments for Rural Development Projects

§ 1703.300 Purpose.

This subpart E sets forth REA's policies and procedures for making loan deferments of principal and interest payments on direct loans or insured loans made for electric or telephone purposes, but not for loans made for rural economic development purposes, in accordance with subsection (b) of section 12 of the RE Act. Loan deferments are provided for the purpose of promoting rural development opportunities.

§ 1703.301 Policy.

It is REA's policy to encourage borrowers to invest in and promote rural development and rural job creation projects that are based on sound economic and financial analyses. Borrowers are encouraged to use this program to promote economic, business

and community development projects that will benefit rural areas.

§ 1703.302 Definitions and rules of construction.

(a) *Definitions.* For the purpose of this subpart, the following terms will have the following meanings:

Administrator means the Administrator of REA.

Borrower means any organization which has an outstanding direct loan or insured loan made by REA for the provision of electric or telephone service.

Cushion of credit payment means a voluntary unscheduled payment on an REA note made after October 1, 1987, credited to the cushion of credit account of a borrower.

Deferment means a re-amortization of a payment of principal and/or interest on an REA direct loan or insured loan for over either a 5- or 10 year period, with the first payment beginning on the date of the deferment.

Direct loan means a loan that is made by the Administrator pursuant to section 4 or section 201 of the RE Act (7 U.S.C. 901 *et seq.*) for the provision of electric or telephone service in rural areas and does not include a loan made to promote economic development in rural areas.

Financially distressed borrower means an REA-financed borrower determined by the Administrator to be either:

(i) In default or near default on interest or principal payments due on loans made or guaranteed under the RE Act;

(ii) A borrower that was in default or near default, but is currently participating in a workout or debt restructuring plan with REA; or

(iii) Experiencing a financial hardship.

Insured loan means a loan that is made, held, and serviced by the Administrator, and sold and insured by the Administrator, pursuant to Section 305 of the RE Act (7 U.S.C. 901 *et seq.*) for the provision of electric or telephone service in rural areas and does not include a loan made to promote economic development in rural areas.

Job creation means the creation of jobs in rural areas, or in close enough proximity to rural areas so that it is likely that the majority of the jobs created will be held by residents of rural areas.

Project means a rural development project that a borrower proposes and the Administrator approves as qualifying under this subpart.

RE Act means the Rural Electrification Act of 1936, as amended (7 U.S.C. 901 *et seq.*).

REA means the Rural Electrification Administration, an agency of the United States Department of Agriculture.

RTB means the Rural Telephone Bank (telephone bank), a body corporate and an instrumentality of the United States, that obtains supplemental funds from non-Federal sources and utilizes them in making loans, operating on a self-sustaining basis to the extent practicable (section 401, RE Act).

Technical assistance means market research, product or service improvement, feasibility studies, environmental studies, and similar activities that benefit rural development or rural job creation projects.

(b) *Rules of construction.* Unless the context otherwise indicates; "includes" and "including" are not limiting, and "or" is not exclusive. The terms defined in § 1703.302(a) include both the plural and the singular.

§ 1703.303 Eligibility criteria for deferment of loan payments.

The deferment of loan payments may be granted to any borrower that is not financially distressed, delinquent on any Federal debt, or in bankruptcy proceedings. However, the deferment of loan payments will not be granted to a borrower during any period in which the Administrator has determined that no additional financial assistance of any nature should be provided to the borrower pursuant to any provision of the RE Act. The determination to suspend eligibility for the deferment of loan payments under this subpart will be based on:

(a) The borrower's demonstrated unwillingness to exercise diligence in repaying loans made by REA or RTB or guaranteed by REA that results in the Administrator being unable to find that such loans, would be repaid within the time agreed; or

(b) The borrower's demonstrated unwillingness to meet the requirements in REA's or RTB's legal documents or regulations.

§ 1703.304 Restrictions on the deferment of loan payments.

(a) The deferment must not impair the security of any loans made REA or RTB, or guaranteed by REA, pursuant to the RE Act.

(b) At no point in time may the amount of the debt service payments deferred exceed 50 percent of the total cost of a community, business, or economic development project for which a deferment is provided.

(c) A borrower may defer debt service payments only in an amount equal to the investment made by such borrower in a rural development project. The investment must not be made from:

(1) Proceeds of loans made or guaranteed pursuant to the RE Act, or grants made pursuant to the RE Act or section 2331 through section 2335A of the Rural Economic Development Act of 1990 (7 U.S.C. 950aaa *et seq.*);

(2) Funds necessary to make timely payments of principal and interest on loans made, guaranteed or lien accommodated pursuant to the RE Act;

(3) Insurance proceeds from mortgaged property;

(4) Damage awards and sale proceeds resulting from eminent domain and similar proceedings involving mortgaged property;

(5) Sale proceeds from mortgaged property sales requiring specific Administrator approval; and

(6) Funds which are restricted by REA or RTB loan instruments to be held in trust for the Government or to be held for any other specific purpose.

(d) Any investment made in a rural development project prior to the date of the application for a deferment based on such project cannot be used to satisfy the requirements of this section.

§ 1703.305 Requirements for deferment of loan payments.

(a) Except as otherwise provided in paragraph (b) of this section, the borrower must make a cushion of credit payment equal to the amount of the payment deferred and subject to the following rules:

(1) Cushion of credit payments made prior to the date that an application for deferral has been approved by REA cannot be used to satisfy the requirements of this section;

(2) Once a cushion of credit payment has been made to satisfy the requirements of paragraph (a) of this section, it must remain on deposit in the cushion of credit account on the date of the deferral or the deferral will not take place; and

(3) The cushion of credit payment must be received by REA on the date the payment being deferred is due, or within 30 days prior to this date.

(b) A borrower may elect to consolidate in one application filed pursuant to § 1703.311, all of the related deferrals it wishes to receive in a twelve month period following application approval. In such a case, the requirement contained in paragraph (a)(1) of this section may alternatively be satisfied by depositing an amount equal to the aggregate deferrals covered by such application into the cushion of credit account at the time the first cushion of credit payment is due under paragraph (a)(1) of this section.

§ 1703.306 Limitation on funds derived from the deferment of loan payments.

Funds derived from the deferment of loan payments will not be used:

(a) To fund or assist projects which would, in the judgement of the Administrator, create a conflict of interest or the appearance of a conflict of interest. The borrower must disclose to the Administrator information regarding any potential conflict of interest or appearance of a conflict of interest;

(b) For any purpose not reasonably related to the project as determined by the Administrator;

(c) To transfer existing employment or business activities from one area to another; or

(d) For the borrower's electric or telephone operations, nor for any operations affiliated with the borrower unless the Administrator has specifically informed the borrower in writing that the affiliated operations are part of the approved purposes.

§ 1703.307 Uses of the deferments of loan payments.

The deferment of loan payments will be made to enable the borrower to provide funding and assistance for rural development and job creation projects. This includes, but is not limited to, the borrower providing financing to local businesses, community development assistance, technical assistance to businesses, and other community, business, or economic development projects that will benefit rural areas.

§ 1703.308 Amount of deferment funds available.

(a) The total amount of deferments made available for each fiscal year under this program will not exceed 3 percent of the total payments due during fiscal year 1993 from all borrowers on direct loans and insured loans made under the RE Act. For each subsequent fiscal year after 1993, the total amount of deferments will not exceed 5 percent of the total payments due for the year from all borrowers on direct loans and insured loans.

(b) The total amount of annual deferments are subject to limitations established by appropriations Acts.

§ 1703.309 Terms of repayment of deferred loan payments.

(a) Deferments made to enable the borrower to provide financing to local businesses will be repaid over a period of 60 months, in equal installments, with payments beginning on the date of the deferment, and continuing in such a manner until the total amount of the deferment is repaid. The deferment payments will be made on either a monthly or quarterly basis depending on the existing repayment terms of the direct loan or insured loan being deferred. The deferment will not accrue interest.

(b) In the case of deferments made to enable the borrower to provide community development assistance, technical assistance to businesses, and for other community, business, or economic development projects not included in paragraph (a) of this section, the deferment will be repaid over a period of 120 months, in equal installments, with payments beginning on the date of the deferment and continuing in such a manner until the total amount of the deferment is repaid. The deferment payments will be made on either a monthly or quarterly basis depending on the existing repayment terms of the direct loan or insured loan being deferred. The deferment will not accrue interest.

(c) The maturity date of a loan may not be extended as a result of a deferment.

(d) If the required payment is not made by the borrower or received by the Administrator when due, the Administrator will reduce the borrower's cushion of credit account established under this subpart in an amount equal to the deferment payment required.

(e) The balance in a borrower's cushion of credit account shall not be reduced by the borrower below the level of the unpaid balance of the payment deferred.

§ 1703.310 Environmental considerations.

Prospective recipients of funds received from the deferment of loan payments are encouraged to consider the potential environmental impact of their proposed projects at the earliest planning stage and plan development in a manner that reduces, to the extent practicable, the potential to affect the quality of the human environment adversely.

§ 1703.311 Application procedures for deferment of loan payments.

(a) A borrower applying for a deferment must:

(1) Submit a certified board resolution to the Administrator requesting a deferment of principal and interest. The resolution must:

(i) Be signed by the president or vice president of the borrower;

(ii) Contain information on the total amount of deferment requested for each specific project;

(iii) Contain information on the type of project and the length of deferment requested as defined in § 1703.309; and

(iv) Specify which officer of the borrower has been given the authority to certify to those matters required in this section;

(2) Submit certification by the appropriate officer to the Administrator that the proposed project will not violate the limitations set forth in § 1703.306 and disclose all information regarding any potential conflict of interest or appearance of a conflict of interest that would allow the Administrator to make an informed decision;

(3) Submit certification by the appropriate officer to the Administrator that an investment in the rural development project will be made by the borrower in an amount equal to the deferred debt service payment;

(4) Submit certification by the appropriate officer to the Administrator that the amount of the deferment will not exceed 50 percent of the total cost of the project for which the deferment is provided;

(5) Submit certification by the appropriate officer to the Administrator that it will make a cushion of credit payment necessary to satisfy the requirement of § 1703.305(a);

(6) Submit certification by the appropriate officer to the Administrator that it will comply with § 1703.313 and provide documentation showing that its total investments, including the proposed investment, will not exceed the investment limitations specified in 7 CFR part 1717, Subpart N, Investments, Loans and Guarantees by Electric Borrowers, or 7 CFR Part 1744, Post Loan Policies and Procedures Common to Guaranteed and Insured Loans. The documentation must provide a list of each rural development project the borrower has invested in to date, including the investment amounts;

(7) Submit to the Administrator written identification of the direct loan(s) and/or insured loan(s) for which payments are to be deferred;

(8) Submit to the Administrator a written narrative which contains information regarding the proposed rural development or job creation project such as the manner in which the project will promote community, business, or economic development in rural areas, the nature of the project, its location, the primary beneficiaries, and, if applicable, the number and type of jobs to be created; and

(9) Submit to the Administrator a letter of approval from the state regulatory authority, if applicable, granting its approval for the borrower to defer direct loan payment(s) and/or insured loan payment(s) and invest the amount in a rural development project.

(b) The Administrator reserves the right to determine that special circumstances require additional data from borrowers before acting on a deferment. The Administrator also reserves the right to require, as a condition of approving a loan payment deferment pursuant to this subpart, that the borrower execute and deliver any amendments or supplements to its loan documents that may be necessary or appropriate to achieve the purposes outlined in § 1703.300.

(c) The Administrator will decide whether the borrower is eligible for the deferment and will notify the borrower of the decision.

§ 1703.312 REA review requirements.

Borrowers shall ensure that funds are invested in the rural development project as approved by REA. The Administrator reserves the right to review the books and copy records of borrowers receiving loan payment deferments as necessary to ensure that the investments in the rural development project are in accordance with this subpart and the representations and purposes stated in the borrower's completed application. If an audit discloses that the amount deferred was not used for the purposes stated in the completed application, the borrower shall be required to promptly repay the amount deferred and the benefits of the deferment to the borrower will be recaptured by REA. The borrower is responsible for ensuring that disbursements and expenditures of funds covering the investment in the rural development project are properly supported with certifications, invoices, contracts, bills of sale, cancelled checks, or any other forms of evidence determined appropriate by the Administrator and that such supporting material is available at the borrower's premises for review by the REA field accountant, borrower's certified public accountant, the Office of Inspector General, the General Accounting Office and any other accountant conducting an audit of the borrower's financial statements for this rural development program.

§ 1703.313 Compliance with other regulations.

(a) Investments in a rural economic development project made by an electric borrower under this subpart are subject to the provisions of 7 CFR part 1717, Subpart N, Investments, Loans and Guarantees by Electric Borrowers.

(b) Investments in a rural economic development project made by a telephone borrower under this subpart are subject to the provisions of 7 CFR Part 1744, Post Loan Policies and Procedures Common to Guaranteed and Insured Loans.

Dated: April 14, 1993.

Robert Peters,

Acting Under Secretary, Small Community and Rural Development.

[FR Doc 93-9541 Filed 4-22-93; 8:45 am]

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NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701 and 705

Community Development Revolving Loan Program for Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA regulations govern loans made from a revolving loan fund and technical assistance offered to certain credit unions that serve predominately low-income members. The NCUA Board is amending these regulations to make the Community Development Revolving Loan Program ("Program") more accessible to credit unions. The NCUA Board is also issuing technical amendments to another regulatory provision to conform it to the revised Program regulations.

EFFECTIVE DATE: May 24, 1993.

ADDRESSES: National Credit Union Administration, 1776 G Street NW., Washington, DC 20456.

FOR FURTHER INFORMATION CONTACT: Michael J. McKenna, Staff Attorney, Office of General Counsel, at the above address, or telephone: (202) 682-9630.

SUPPLEMENTARY INFORMATION

A. Background

The NCUA Board, as part of its ongoing program of regulatory review, is revising the regulation under which the Community Development Revolving Loan Program operates. The purpose of the Program is to make reduced rate loans and provide technical assistance to both federal and state-chartered credit unions serving low-income communities so that those credit unions may provide needed financial services and help to stimulate the economy in the communities served. Although there have not been any major problems with the Program, the NCUA Board believes there are several areas that can be improved.

The NCUA Board is amending the Program for the following reasons: First, to increase the number of participating credit unions; second, to make the Program more accessible to participating credit unions; third, to provide technical assistance to participating credit unions that may not necessarily receive loans; and finally, to reduce regulatory burden.

B. Comments

The NCUA Board issued proposed amendments to the Program on November 12, 1992 (57 FR 56868, December 1, 1992). The Board also issued proposed amendments to Section 701.32 of NCUA's Regulations to conform it to the recommended changes in part 705. Fifteen comment letters were received. Eight comments were received from federal credit unions, two from state-chartered credit unions, three from state credit union leagues, and two from national trade associations. The commenters expressed general approval of the proposed amendments. The final regulation contains the same structure as the proposed regulation. The comments and the substantive changes made to the regulation from the proposed rule are discussed below. Unless otherwise noted, the final regulation is the same as the proposed.

Section 705.3—Definitions

The issue that drew the most comment was the definition of "low-income member." Comment was requested on whether the definition of "low-income member" was satisfactory. In order for a credit union to participate in the Program, it must serve predominantly low-income members. Predominantly means a simple majority. Under the proposed rule, low income members were defined by either individual wage of members or household income of the geographic service area. A credit union could demonstrate that it predominantly serves low-income members either by documentation for the individual wage definition or geographic area for the household income definition.

Nine commenters approve of the proposed definition. One commenter suggests that instead of using the "median" standard in determining annual household income that NCUA adopt the "average" standard. An "average" standard would raise the annual household income included within the definition of low-income. The NCUA board believes the proposed median income level is more appropriate. Therefore, the NCUA Board will retain the "median" standard for household income.

One commenter posed the following questions concerning the new definition:

(1) What is the origin of the list of cities with a cost differential? Does this list correspond to usage by other governmental agencies? How wide is the geographic area taken in by "New York" for example? The list of cities with a cost differential was obtained from a list maintained by the Bureau of Labor Statistics, as updated by the Employment and Training Administration (the same agency the "lower level standard of living" was obtained from under the current regulation). The Bureau of Labor Statistics data showed lower level standard of living numbers for the 25 largest metropolitan areas. The proposed and final rule includes those that are above the national average. This is a government standard which is used by other government agencies and programs. Each metropolitan area is the "metropolitan statistical area" as defined by the Census Bureau.

(2) Will the presumption that credit unions which serve "a geographic area where a majority of residents fall at or below the annual income standard" are low-income apply to a church credit union, with an associational common bond which is situated in a geographic area? The geographically based method of establishing income may be applicable to more credit unions than just those that have a geographically defined field of membership. Zip codes may be an easy way to accomplish it. If a credit union can show that most of its members live in a cluster of zip codes which together meet the income standard, then the credit union would be assumed to meet the standard. A church-based associational credit union could meet this standard. A church-based associational credit union can also qualify as serving predominately low-income members under the current regulation.

(3) Is it NCUA's intention to eliminate from the definition the previous language which qualifies as low-income people those who reside in public housing or qualify for Community Action Agency services? The public housing standard was eliminated because public housing is a very restrictive standard, with incomes almost as low as the poverty line. By definition, the standard set forth in the new rule will include public housing residents as well as members who qualify as recipients in a community action program.

Furthermore, this commenter recommends additional language to this section to permit NCUA to determine that credit unions which may not meet the exact 80 percent test, but which serve and benefit low-income residents of a community and whose mission and goals are identical to those set out in the purpose section of the regulation, may also be granted the low-income designation by NCUA. The NCUA Board agrees that in certain cases it may be appropriate for credit unions that do not meet the exact 80 percent test to still be able to receive the low-income designation. Accordingly, this section has been amended to allow the NCUA Board to define other members as low-income members by order of the Board.

Credit unions that already have a low-income designation from NCUA need not reapply. Such credit unions will be grandfathered under this regulation. However, NCUA may review a credit union's low-income designation during the examination process to ensure that the credit union continues to serve predominantly low-income members.

One commenter specifically approves of the proposed definition of "participating credit union" which expands the current rule by allowing credit unions that do not have a loan, but have the low-income designation, to receive technical assistance under the Program. Two commenters request that the definition of "participating credit union" require credit unions to have a specific mission of serving low-income residents. These two commenters believe this expansion would include credit unions that primarily benefit or serve low-income persons within the definition of low-income members. It is the opinion of the NCUA Board that the suggested language, by adding an additional factor to be met, would limit the number of credit unions participating in the Program. The Board has not adopted the suggested language in the final rule.

NCUA requested comment on whether the term "low-income credit union" found in § 705.3 should be changed to either "economic development credit union" or "community development credit union." Three commenters preferred "low-income credit union." Two of these commenters believe this wording is more accurate than the alternatives. One commenter believes confusion will result if the name is changed to "community development credit union." Three commenters suggest the use of "economic development credit union" to avoid negative connotations and possible confusion. Six commenters recommend using the term "community development credit union." These commenters believe this term avoids the negative connotation some associate with the term "low-income credit union."

NCUA believes that the term "low-income credit union" may have negative connotations in the credit union community. Furthermore, NCUA believes the term "community development credit union" may cause confusion due to the fact that many credit unions that have not participated in the Program are members of a trade association called the National Federation of Community Development Credit Unions. The term "economic development credit union" may be misleading since the purpose of the Program is to assist credit unions serving low-income members. Therefore the final rule deletes the reference to "low-income credit unions" in Section 705.3, without replacing it with any of the suggested terms. Instead credit unions taking part in the Program will simply be referred to in the final regulation as "participating credit unions" as defined in § 705.3(b).

Section 705.4 Program Activities

The proposed rule eliminated the list of services participating credit unions can provide. The only commenter addressing this issue supports this modification because he believes it will provide greater flexibility in providing credit union services. NCUA continues to believe that a participating credit union's focus should be basic member share account and loan services. Accordingly, the Board has adopted this proposed section in final form without modification.

Section 705.5 Application for Participation

This section sets forth the application procedures for those credit unions wishing to receive a Program loan or technical assistance. The only commenter addressing this issue supports the changes but recommends that the regulation address what is required in making an application for technical assistance. An application for technical assistance is in development and will be available from the Chairman of the Revolving Loan Fund Program. Except for an editorial change, this section remains unchanged in the final rule.

Section 705.6 Community Needs Plan

The proposed rule eliminated the requirement for a community development committee and transferred the responsibility for the development of a community needs plan to the credit union's board of directors. Furthermore, the community needs plan would be required at the time of the application instead of 60 days after qualifying for the loan. Two commenters approve of

the elimination of the community development committee. Four commenters approve of requiring the community needs plan at the time of the application. These commenters believe it is prudent to have the plan proposed and submitted with the loan application. They also believe it will help expedite the loan process. One commenter objects to the timing of the submission of the community needs plan. NCUA believes it is necessary for a credit union to determine the needs of the community prior to seeking a loan to meet those needs. Furthermore, the community needs plan will provide assistance to the agency in determining where loan proceeds should go based on a community's demonstrated need.

One commenter notes that the requirement to "establish and set forth liaison activities with government agencies and others having developmental projects in the community" found in § 705.6(a) may not be practical in small communities where there are few such activities or in very large cities where the activities and programs are too numerous to even mention. This commenter recommends that NCUA drop this requirement from the regulation. NCUA agrees and believes the elimination of this requirement will reduce regulatory burden. The final regulation reflects this position.

Section 705.7 Loans to Participating Credit Unions

Under the proposed rule, the loan limit was raised from $200,000 to $300,000. Six commenters approve of the increased limit. Two commenters believe the limit should be indexed to keep pace with inflation, while four commenters oppose any indexing. NCUA does not believe indexing is necessary or appropriate considering the limited amount of funds available under the Program. The final rule incorporates the increase to $300,000.

NCUA also requested comment on whether the matching requirement should be reduced by fifty percent if the share increase is entirely member deposits (e.g., if a credit union receives a $100,000 loan, it would only have to increase shares by $50,000 if the increase is due entirely to member deposits rather than nonmember deposits). Currently the 100% match can be met by member and/or nonmember deposits. Two commenters favor this member deposit reduction approach. Seven commenters oppose making such a change. Most of them believe the current requirement should remain unchanged as it provides incentive to promptly match the loan and encourages community participation. One commenter states that requiring the recipient credit union to increase shares by the amount of the loan encourages continuing commitment on the part of the directors and officers of the credit union regardless of whether the deposit increase comes primarily from natural persons or other institutions.

One commenter believes that the matching requirement should be eliminated. This commenter believes the credit union may be motivated to attract shares of an undesirable nature or source, in order to comply with the matching requirement.

One commenter supports the concept that the matching requirement should be reduced whenever the share increase is made up of member deposits but does not support the proposal that only if the share increase is "entirely" member deposits should the matching requirement be reduced by half. This commenter believes that any member deposits should be counted as a two-for-one match and any nonmember deposits should be counted as a one-for-one match. NCUA agrees and believes that it is important to encourage member share growth in regard to the matching requirement. Member share growth provides increased stability for the credit union. Therefore, a two-for-one match for member deposits is incorporated into the final rule.

NCUA requested comment on whether it is desirable to have uniform treatment of booking the loan. Currently the loan can be booked as a note payable or a nonmember deposit, at NCUA's discretion. Four commenters favor uniform treatment. Three would book it as a note payable and one would book it as a nonmember deposit. Five commenters believe this section should remain unchanged and NCUA should retain discretion on how to book the loan. These commenters believe that, given the level of regulatory participation in this Program, NCUA should have the flexibility to determine the appropriate method for loan booking, particularly when varying state requirements are considered. In light of the commenters' concern and since some state-chartered participating credit unions may not be permitted to record loans as nonmember deposits, NCUA will retain discretion on how the loans should be recorded. However, it is anticipated that most loans will be recorded as nonmember deposits.

One commenter supports continuing the exemption from the 20% rule in § 701.32 for any matching nonmember deposits obtained by participating credit unions, up to the proposed new ceiling of $300,000. One commenter suggests that the exemption from the 20% ceiling should not be terminated when the loan is repaid. NCUA disagrees with this suggestion, since most credit unions that can accept nonmember deposits are well below the 20% ceiling. Therefore, once the loan is repaid, nonmember share deposits accepted to meet the matching requirement are subject to the nonmember deposit limitations in § 701.32.

Section 705.8 State-Chartered Credit Unions

No substantive changes were proposed to this section but comment was requested on whether it was still necessary. One commenter believes that state-chartered credit unions should continue to coordinate their participation in the Program with state authorities. One commenter was unclear why state-chartered credit union loan applicants should have to obtain written permission from their state regulators to participate. NCUA believes it is important for the state regulator to approve of a state-chartered credit union's decision to participate in the Program since the state regulator is the primary regulator. It is important that the state regulator be informed to avoid any potential safety and soundness problems. Therefore, except for the rewording of the first sentence to provide clarity, this section remains unchanged in the final rule.

Section 705.10 Technical Assistance

Three commenters support the modification to provide technical assistance to credit unions qualifying as low-income credit unions but not receiving loans from the revolving loan fund. One commenter urges NCUA to consider ways that it can increase the $120,000 annual limit for technical assistance. Currently, technical assistance is not fully funded. Therefore, this section is being amended to provide for technical assistance from all earnings (generally interest payments provided to the Program). The current regulation limited technical assistance funds to one-half the interest paid on Program loans. The $120,000 limit on technical assistance is being retained due to the limit on funds availability.

One commenter requests that credit unions that do not have a low-income designation be able to receive technical assistance. This Program is only for credit unions serving predominantly low-income members and therefore technical assistance cannot be provided to additional credit unions.

Section 701.32 Low-income Designation

The term "low-income member" found in § 701.32(d)(2) has been changed to conform to the new definition of "low-income member" found in part 705. The only difference from the definition found in part 705 is that the § 701.32(d)(2) definition continues to include those members who are enrolled as full-time students or part-time students in a college, university, high school, or vocational school. Although student federal credit unions are "low-income credit unions" for purposes of receiving nonmember deposits, they do not qualify for participation in the Program because they are not specifically involved in the stimulation of economic development activities and community revitalization efforts.

Financial Statements

NCUA requested comment on whether a credit union should be required to submit its latest financial statement when applying for a loan, technical assistance, or an exemption from the nonmember deposit limitation. Eight commenters believe a financial statement should be submitted with each application or exemption request. These commenters believe the submission of financial statements is a prudent business practice and not a burden to credit unions. One commenter opposes any such requirement, believing that it generates unnecessary paperwork. NCUA believes that the submission of a financial statement provides the agency useful information in making an informed decision. Therefore, the final rule contains a new § 701.32(b)(1)(D) that requires a copy of the latest financial statement for a nonmember deposit exemption. Section 705.5(b)(1) is also amended to require a credit union to provide a financial statement with the loan application. Furthermore, the technical assistance application will also require a financial statement.

Miscellaneous

Although not specifically solicited, comment was received on the following additional issues. Five commenters believe that nonfederally insured credit unions should not be allowed to participate in the Program. One commenter believes that nonfederally insured credit unions should be allowed to participate in the Program. The legislation establishing the Program did not differentiate between nonfederally insured and federally insured credit unions. Therefore, the final rule continues to permit nonfederally insured credit unions to participate in the Program. One commenter urges NCUA to implement twelve regulatory and legislative proposals concerning low-income credit unions. The proposals do not address the substance of the proposed amendments and do not merit further discussion in relation to this regulation.

Paperwork Reduction Act

The Office of Management and Budget has approved the collection requirements contained in part 705 of NCUA's Regulations (OMB No. 3133–0109). The amendments reduce the paperwork requirements.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires the NCUA to prepare an analysis to describe any significant economic impact a proposed regulation may have on a substantial number of small credit unions (primarily those under $1 million in assets). The revised rule is less restrictive than the current regulation. Overall, the NCUA Board expects the change to benefit credit unions by permitting them easier access to loans and technical assistance. Accordingly, the Board determines and certifies that this final rule does not have a significant economic impact on a substantial number of small credit unions and that a Regulatory Flexibility Analysis is not required.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. The Program is implemented in its entirety by the NCUA. The final rule will make it easier for all credit unions participating in the Program, including state-chartered credit unions, to receive loans and technical assistance and will not have a substantial direct effect 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. State chartered credit unions are required to obtain approval from state regulators prior to participation.

List of Subjects

12 CFR Part 701

Credit unions, Low-income designation.

12 CFR Part 705

Community development, Credit unions, Loan programs-housing and community development, Reporting and recordkeeping requirements, Technical assistance.

By the National Credit Union Administration Board on April 19, 1993.

Becky Baker,

Secretary of the Board.

Accordingly, NCUA amends 12 CFR part 701 and 12 CFR part 705 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, 1789, 1798, and Pub. L. 101–73. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 et seq., 42 U.S.C. 1981 and 42 U.S.C. 3601–3610.

2. Section 701.32 is amended by revising paragraphs (b)(1) and (d) to read as follows:

§ 701.32 Payments on shares by public units and nonmembers, and low-income designation.

(a) * * *

(b) *Limitations.* (1) Unless a greater amount has been approved by the Regional Director, the maximum amount of all public unit and nonmember accounts shall not, at any given time, exceed 20% of the total shares of the federal credit union. A federal credit union seeking an exemption from the 20% limit must submit to the Regional Director a written request including:

(i) The new maximum level of public unit and nonmember shares requested, either as a dollar amount or a percentage of total shares;

(ii) A plan concerning use of public unit and nonmember shares that includes:

(A) A statement of the credit union's need and intended use of additional public unit and nonmember shares;

(B) Provision for matching maturities of public unit and nonmember shares with corresponding assets, or justification for any mismatch;

(C) Provision for adequate income spread between public unit and nonmember shares and corresponding assets; and

(D) A copy of the credit union's latest financial statement;

(iii) A copy of the credit union's loan and investment policies;

* * * * *

(c) * * *

(d) *Designation of low-income status.* (1) Section 107(6) of the Federal Credit Union Act (12 U.S.C. 1757(6)) authorizes federal credit unions serving

predominantly low-income members to receive shares, share drafts and share certificates from nonmembers. In order to utilize this authority, a federal credit union must receive a low-income designation from its Regional Director. The designation may be removed by the Regional Director upon notice to the federal credit union if the definitions set forth in paragraphs (d)(2) and (3) of this section are no longer met. Removals may be appealed to the NCUA Board in a timely manner. Appeals should be submitted through the Regional Director.

(2) The term "low-income members" shall mean those members who make less than 80 percent of the average for all wage earners as established by the Bureau of Labor Statistics or those members whose annual household income falls at or below 80 percent of the median household income for the nation as established by the Census Bureau or those members otherwise defined as low-income members as determined by order of the NCUA Board.

(i) In documenting its low-income membership, a credit union that serves a geographic area where a majority of residents fall at or below the annual income standard is presumed to be serving predominantly low-income members. In applying the standards, Regional Directors shall make allowances for geographical areas with higher costs of living. The following is the exclusive list of geographic areas with the differentials to be used:

	Percent
Hawaii	40
Alaska	36
Washington, DC	19
Boston	17
San Diego	15
Los Angeles	14
New York	13
San Francisco	13
Seattle	10
Chicago	7
Philadelphia	7

(ii) The term "low-income member" also includes those members who are enrolled as full-time or part-time students in a college, university, high school, or vocational school.

(3) The term "predominantly" is defined as a simple majority.

3. Part 705 is revised to read as follows:

PART 705—COMMUNITY DEVELOPMENT REVOLVING LOAN PROGRAM FOR CREDIT UNIONS

Sec.
705.0 Applicability.
705.1 Scope.
705.2 Purpose of the program.
705.3 Definitions.
705.4 Program activities.
705.5 Application for participation.
705.6 Community needs plan.
705.7 Loans to participating credit unions.
705.8 State-chartered credit unions.
705.9 Application period.
705.10 Technical assistance.

Authority: Pub. L. 97–35, 42 U.S.C. 9822; Pub. L. 99–609, note to 42 U.S.C. 9822; Pub. L. 101–144, 12 U.S.C. 1766(k).

§ 705.0 Applicability.

Monies from the Community Development Revolving Loan Fund for Credit Unions are governed by this part.

§ 705.1 Scope.

(a) This part implements the Community Developments Revolving Loan Program for Credit Unions (Program) under the sole administration of the National Credit Union Administration.

(b) This part establishes the following:

(1) Definitions;

(2) The application process and requirements for qualifying for a loan under the program;

(3) How loan funds are to be made available and their repayment; and

(4) Technical assistance to be provided to participating credit unions.

§ 705.2 Purpose of the program.

(a) The Community Development Revolving Loan Program for Credit Unions is intended to support the efforts of participating credit unions through loans and technical assistance to those credit unions in:

(1) Providing basic financial and related services to residents in their communities; and

(2) Stimulating economic activities in the communities they service which will result in increased income, ownership and employment opportunities for low-income residents, and other community growth efforts.

(b) The policy of NCUA is to revolve loan funds to qualifying credit unions as often as practical in order to gain maximum economic impact on as many participating credit unions as possible.

§ 705.3 Definitions.

(a)(1)The term "low-income members" shall mean those members who make less than 80 percent of the average for all wage earners as established by the Bureau of Labor Statistics or those members whose annual household income falls at or below 80% of the median household income for the nation as established by the Census Bureau or those members otherwise defined as low-income members as determined by order of the NCUA Board.

(2) In documenting its low-income membership, a credit union that serves a geographic area where a majority of residents fall at or below the annual income standard is presumed to be serving predominantly low-income members. In applying the standards, Regional Directors shall make allowances for geographical areas with higher costs of living. The following is the exclusive list of geographic areas and the differentials to be used:

	Percent
Hawaii	40
Alaska	36
Washington, DC	19
Boston	17
San Diego	15
Los Angeles	14
New York	13
San Francisco	13
Seattle	10
Chicago	7
Philadelphia	7

(b) For purposes of this part, a "participating credit union" means a state- or federally chartered credit union that is specifically involved in stimulation of economic development activities and community revitalization efforts aimed at benefiting the community it serves; whose membership consists of predominantly low-income members as defined in paragraph (a) of this section or applicable state standards as reflected by a current low income designation pursuant to § 701.32(d)(1) or § 741.6(b) of the NCUA Regulations or, in the case of a state-chartered nonfederally insured credit union, under applicable state standards; and has submitted an application for a loan and/or technical assistance and has been selected for participation in the Program in accordance with this part.

§ 705.4 Program activities.

In order to meet the objectives of the Program, a credit union applicant should provide a variety of financial and related services designed to meet the particular needs of the low-income community served. These activities shall include basic member share account and member loan services.

§ 705.5 Application for participation.

(a) Applications to participate and qualify for a loan or technical assistance under the Program may be obtained from the National Credit Union Administration, Community Development Revolving Loan Program For Credit Unions.

(b) The application for a loan shall contain the following information:

(1) Information demonstrating a sound financial position and the credit union's ability to manage its day-to-day business affairs, including the credit union's latest financial statement. Nonfederally insured credit unions must include the following for the most recent month-end and each of the twelve months preceding that month-end:

(i) Balance sheet;

(ii) Income and expense statement;

(iii) Delinquent loan list.

(2) Evidence that the credit union has a need for increased funds in order to improve financial services to its members.

(3) The following information concerning a state-chartered credit union's field of membership:

(i) Current field of membership as set forth in the credit union's charter;

(ii) Changes, if any, to be made to the field of membership for participation in the Program, including;

(A) Evidence of approval of change by credit union board of directors;

(B) Evidence of submission and approval of change by the state supervisor;

(iii) Current designation as a low-income credit union if the credit union is not federally insured.

(4) Along with a community needs plan, specifics of how the credit union proposes to serve the needs of its members and the community with Program funds. The applicant credit union will also construct and submit a plan for its growth and development. The plan will set forth objectives for financial growth, credit union development and capitalization, and the means for achieving these objectives.

(5) Indication of any other involvement in existing community development programs of state and federal agencies.

(c) NCUA will notify applicant credit unions as to whether or not they have qualified for a loan or technical assistance under this part. Reasons for nonqualification will be stated. Any applicant whose qualification is denied may appeal that decision to the NCUA Board.

§ 705.6 Community needs plan.

(a) The credit union's board of directors will prepare a Community Needs Plan and submit it with its loan application. The Plan will contain a list of needed community services that the credit union will provide.

(b) The credit union's board of directors will report on the progress of providing needed community services to the credit union members once a year, either at the annual meeting or in a written report sent to all members. The credit union will also submit the written report or a summary of the report given at the annual meeting to NCUA.

§ 705.7 Loans to participating credit unions.

(a) *Amount and recording of loans.* A participating credit union will be eligible to receive up to $300,000, as determined by the NCUA Board, in the form of a loan from the Community Development Revolving Loan Fund for Credit Unions. The amount of the loan will be based on funds availability, the creditworthiness of the participating credit union, financial need, and a demonstrated capability of a participating credit union to provide financial and related services to its members. At the discretion of NCUA, a loan will be recorded by a participating credit union as either a note payable or a nonmember deposit.

(b) *Matching requirements.* Participating credit unions will be encouraged to develop, as rapidly as possible, a permanent source of member shares.

(1) Generally loan monies made available must be matched by the participating credit union by increasing its share deposits in an amount equal to the loan amount. However, any loan monies matched by member share deposits will be credited as a two-for-one match. Nonmember share deposits accepted to meet the matching requirement are not subject to the 20% limitation on nonmember deposits under § 701.32. Participating credit unions must meet this matching requirement within one year of the approval of the loan application and must maintain the increase in the total amount of share deposits for the duration of the loan. Once the loan is repaid, nonmember share deposits accepted to meet the matching requirement are subject to § 701.32.

(2) Upon approval of its loan application, and before it meets its matching requirement, a participating credit union may receive the entire loan commitment in a single payment. If any funds are withheld, the remainder of the funds committed will be available to the participating credit union only after it has documented that it has met the match requirement for the total amount of the loan committed.

(3) Failure of a participating credit union to generate the required match within one year of the approval of the loan will result in the reduction of the loan proportionate to the amount of match actually generated. Payment of any additional funds initially approved will be limited as appropriate to reflect the revised amount of the loan approved. Any funds already advanced to the participating credit union in excess of the revised amount of loan approval must be repaid immediately to NCUA. Failure to repay such funds to NCUA upon demand shall result in the default of the entire loan.

(c) *Terms and repayment.* (1) Assistance made available through Program loans, whether recorded by the credit union as a note payable or nonmember deposit at NCUA's direction, is in the form of a loan and must be repaid to NCUA. All loans will be scheduled for repayment within the shortest time compatible with sound business practices and with objectives of the Program, but in no case will the term exceed five years.

(2) Semiannual interest payments (beginning six months after the initial distribution of a loan) and semiannual principal payments (beginning one year after the initial distribution of a loan) will be required.

(d) *Interest rates.* Loans made under this part shall bear interest at a fixed annual percentage rate of not more than 3 percent and not less than 1 percent as determined by the NCUA Board.

(e) *Default, collections and adjustments.* The terms of each loan agreement shall provide for the immediate acceleration of the unpaid balance for breach or default in the performance by the participating credit union of the terms or conditions of the loan. This will include misrepresentation, default in making interest/principal payments, failure to report, insolvency, failure to maintain adequate match for the duration of the loan period, etc. The unpaid balance will also be accelerated and immediately due if any part of the loan funds are improperly used, or if uninvested loan proceeds remain unused for an unreasonable or unjustified period of time.

§ 705.8 State-chartered credit unions.

State-chartered credit union loan applicants approved for participation by NCUA must obtain written concurrence from their respective state regulatory authority. Such applicants shall make copies of their state examination reports available to NCUA and shall agree to examination by NCUA for the limited purpose of compliance with this part.

§ 705.9 Application period.

NCUA will announce annually and publish in the **Federal Register** when applications for participation in the

program may be submitted. Such notice will be dependent upon the availability of funds.

§ 705.10 Technical assistance.

Based on available earnings, NCUA may contract with outside providers to render technical assistance to participating credit unions but such amount will not exceed $120,000 per year. Participating credit unions can be provided with technical assistance without obtaining a Program loan. Technical assistance provided will aid participating credit unions in providing services to their members and in the efficient operation of such credit unions.

[FR Doc. 93-9533 Filed 4-22-93; 8:45 am]

BILLING CODE 7535-01-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 166

[Docket No. 82P-0186]

Margarine; Amendment of the Standard of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standard of identity for margarine to remove the list of permitted emulsifiers and the maximum use level restrictions for each and to retain the provision for the use of safe and suitable emulsifiers without specified limitations. Appropriate use levels for the emulsifiers are those no greater than necessary to accomplish the intended functional effect in the margarine. This action responds to a petition filed by the National Association of Margarine Manufacturers and will promote honesty and fair dealing in the interest of consumers.

DATES: Effective June 22, 1993. All affected products initially introduced or initially delivered for introduction into interstate commerce shall comply on or after this date.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5112.

SUPPLEMENTARY INFORMATION:

I. The Proposal

In the **Federal Register** of October 30, 1984 (49 FR 43560), FDA published a proposal, based on a petition from the National Association of Margarine Manufacturers (NAMM), 1101 15th St. NW., Suite 202, Washington, DC 20005, to amend the standard of identity for margarine (§ 166.110 (21 CFR 166.110)) to remove the specified limits on the amounts of emulsifiers that may be used. FDA also proposed to delete two types of emulsifiers, mono- and diglycerides of fatty acids esterified with citric acid and with tartaric acid, which were inadvertently listed in the standard when it was revised in consideration of the Codex standard (38 FR 25671, September 14, 1973). Section 166.110(b)(4) currently lists certain specific emulsifiers and the maximum use levels for each, but it also allows manufacturers the option of using other safe and suitable emulsifiers not listed in the standard. Appropriate use levels for the emulsifiers are those no greater than necessary to accomplish the intended functional effect in the margarine. Interested persons were given until December 31, 1984, to submit comments. In the **Federal Register** of January 31, 1985 (50 FR 4525), FDA extended the comment period to January 30, 1985.

The agency received two comments in response to the proposal. One was in favor of the proposal and the other, from NAMM, opposed deletion of the reference to mono- and diglycerides of fatty acids esterified with either citric acid or tartaric acid. NAMM subsequently withdrew its objection to deletion of the specific reference to mono- and diglycerides of fatty acids esterified with either citric acid or tartaric acid.

II. The Tentative Final Rule

The NAMM petition was filed under section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)), which required formal rulemaking in any action for the amendment of a food standard. However, in November of 1990, the Nutrition Labeling and Education Act of 1990 was signed into law, and it removed food standard rulemaking proceedings, except for action for the amendment or repeal of food standards of identity for dairy products or maple sirup, from the formal rulemaking proceedings of section 701(e) of the act. Therefore, further action on the NAMM petition is subject to the rulemaking proceedings of section 701(a) of the act. FDA published a tentative final rule in the **Federal Register** of July 31, 1992 (57 FR 33916), to give notice of this change in the applicable rulemaking procedures. Interested persons were given until August 31, 1992, to comment.

III. Comments to the Tentative Final Rule

The agency received one comment supporting the tentative final rule to amend the standard of identity for margarine to remove the list of permitted emulsifiers and the maximum use level restrictions for each and to retain the provision for the use of safe and suitable emulsifiers without specific limitations. The comment agreed that appropriate use levels for emulsifiers should be no greater than necessary to accomplish the intended functional effect in margarine.

After considering this comment and other available information, FDA concludes that it is reasonable to provide for the optional use of "safe and suitable" emulsifiers in margarine and that doing so will promote honesty and fair dealing in the interest of consumers.

IV. Economic Impact

FDA has examined the economic implications of this final rule to amend 21 CFR part 166 as required by Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12291 compels Federal agencies to use cost-benefit analysis as a component of decisionmaking. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. FDA noted in the tentative final rule that labels would not need to be changed, and that any reformulation would be unlikely. Thus, the agency tentatively concluded that the regulation would have zero costs associated with it. FDA has received no new information or comments that would alter the tentative finding that it set out in the tentative final rule that there is no substantive economic issue in this rulemaking, and that this is not a major rule as defined by either Executive Order 12291 or the Regulatory Flexibility Act.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 166

Food grades and standards, Food labeling, Margarine.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs, 21 CFR part 166 is amended as follows:

PART 166—MARGARINE

1. The authority citation for 21 CFR part 166 continues to read as follows:

Authority: Secs. 201, 401, 403, 407, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 347, 348, 371, 376).

2. Section 166.110 is amended by revising the third sentence in the introductory text of paragraph (a) and paragraph (b)(4) to read as follows:

§ 166.110 Margarine.

(a) * * * Margarine contains only safe and suitable ingredients, as defined in § 130.3(d) of this chapter. * * *

* * * * *

(b) * * *

(4) Emulsifiers.

* * * * *

Dated: February 19, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-9520 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Parts 1309 and 1313

[Docket No. 89-02; Notice 5]

RIN 2127-AD01

Incentive Grant Criteria for Drunk Driving Prevention Programs

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

ACTION: Final rule.

SUMMARY: On June 30, 1992, NHTSA published an interim final rule amending portions of the agency's regulation on incentive grant criteria for drunk driving programs to reflect statutory changes enacted by the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), and requesting public comment. This final rule finalizes the changes made in the interim final rule, responds to comments received by the agency in response to that document and makes minor revisions and clarifications based on NHTSA's experience reviewing and approving section 410 grant applications in FY 1992. This final rule also includes amendments to reflect technical corrections enacted by Congress as part of the Department of Transportation and Related Agencies Appropriations Act for 1993 and makes minor conforming changes to the agency's section 408 implementing regulation.

EFFECTIVE DATE: This final rule becomes effective April 23, 1993.

FOR FURTHER INFORMATION CONTACT: Ms. Marlene Markison, Chief, Program Support Staff, NRO-10, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590; telephone (202) 366-0166 or Mr. James Hedlund, Director, Office of Alcohol and State Programs, NTS-20; telephone (202) 366-2753.

SUPPLEMENTARY INFORMATION: The Anti-Drug Abuse Act of 1988, Public Law 100-690, was signed into law on November 18, 1988. Subtitle A of Title IX of the Act, entitled the Drunk Driving Prevention Act of 1988, amended chapter 4 of title 23, United States Code, by adding section 410, which established an incentive grant program under which States could qualify for basic and supplemental grant funds for adopting and implementing comprehensive drunk driving prevention programs which met certain specified statutory criteria.

On January 12, 1990, NHTSA published a final rule in the **Federal Register** (55 FR 1185) to implement this new incentive grant program. When the rule had been in place for nearly a year, and no State had submitted an application to NHTSA under the regulation's certification requirements, Congress made technical corrections to the statutory requirements contained in section 410. These technical corrections, contained in section 336 of Public Law 101-516, were signed into law on November 5, 1990. Corresponding changes were made to the agency's regulation by final rule published in the **Federal Register** on May 1, 1991 (56 FR 19930). The agency approved two State applications for section 410 funding under this final rule.

Section 2004 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), signed into law on December 18, 1991, further revised section 410. These revisions, among other things, provided for additional basic and supplemental grant criteria and changed the formula used to determine the amount of section 410 incentive grants. An interim final rule (57 FR 29002) was published in the **Federal Register** on June 30, 1992, to change the agency's implementing regulation to conform to these amendments, and to request public comments.

Comments were received from New York, Wisconsin, the National Association of Governors' Highway Safety Representatives (NAGHSR) and the National Beer Wholesalers Association, Inc.

During FY 1992, the agency received section 410 grant applications from 18 States, and processed these applications in accordance with the interim final rule. Seventeen State applications were approved.

On October 6, 1992, the Department of Transportation and Related Agencies Appropriations Act for 1993 (Pub. L. 102-388) was signed into law. It contained additional technical corrections to section 410.

Except where noted below, this final rule adopts the provisions that were included in the interim final rule. Each change to the interim final rule is discussed further below. For a more detailed discussion of other provisions in the implementing regulation, interested persons are encouraged to review the **Federal Register** notices referenced above.

Award Procedures

When ISTEA was enacted, it modified the manner in which section 410 grants were to be awarded. Under section 410, as amended by ISTEA, the total amount of funds authorized for the section 410 program was required to be apportioned to all States under the same formula that governs the distribution of section 402 highway safety grant funds (75 percent on the basis of population and 25 percent on the basis of road mileage). Out of these apportioned funds, basic and supplemental grants were to be awarded to qualified States, in accordance with certain grant limitations. At the end of each fiscal year, the funds that were apportioned to States that did not qualify for section 410 funding in that fiscal year were to be withdrawn from apportionment and reapportioned on the first day of the succeeding fiscal year to the States that did qualify.

The DOT FY 1993 Appropriations Act, which contained technical corrections to section 410, essentially repealed the changes to this grant award process made by ISTEA. Beginning in FY 1993, section 410 funds no longer need to be apportioned, withdrawn from apportionment and reapportioned, as required under the amendments included in ISTEA. Rather, grants will be awarded, subject to the limitations described below, upon the agency's receipt and approval of a State's application and plan. Today's final rule conforms the regulation accordingly.

In the past, section 410 grants have been awarded on a first come-first served basis. The first States to submit a complete application, if the application and plan were approved, were the first in line to receive grant funds. When there were sufficient funds to cover all State grants, this system proved to be satisfactory. However, based on current estimates, NHTSA anticipates that there could be a shortfall in FY 1993 as well as in future years.

To avoid inequities among the States, NHTSA has decided to modify the system. Today's final rule provides that, if the agency expects there may be insufficient funds to award full grant amounts to all eligible States in any fiscal year, it may release less than the full grant amounts to each State upon initial approval of the State's application and plan. The agency would select a percentage, based on its best estimate of the number of grants likely to be awarded in a fiscal year, and apply that same percentage to each State qualified to receive grants. Before the end of that fiscal year, NHTSA would determine the number of grants actually awarded and release to each eligible State its proportionate share of any remaining available section 410 funds, up to the full amount for which it is eligible.

For example, each State may receive 65 percent of each basic and supplemental grant for which it qualifies upon initial approval of its application and plan. If, at the end of the fiscal year, there are sufficient funds to award full grant amounts to all eligible States, each of these States would receive the remaining 35 percent. If sufficient funds are not available, each State would receive less than 35 percent, but the same percentage would apply to all States. The statute does not permit States that receive less than 100 percent of any grant in one fiscal year to recover the difference in a later fiscal year.

NHTSA intends to prepare and distribute more precise procedures to the States, as necessary, detailing this system's application in each fiscal year.

Limitations on Grant Amounts

Section 410, as amended by ISTEA, provided that a State was to receive 65 percent of its section 410 apportionment if it was eligible for a basic grant and an additional 5 percent for each supplemental grant for which it qualified.

Under section 410, as revised by the DOT FY 1993 Appropriations Act, an eligible State will receive instead a basic grant equal to 30 percent of its FY 1992 highway safety grant (section 402) apportionment and a supplemental grant equal to 5 percent of its FY 1992 section 402 apportionment for each supplemental grant criterion which it meets. There are seven supplemental grant criteria in all.

The DOT FY 1993 Appropriations Act also amended section 410 to provide that States can receive section 410 grants for up to five fiscal years, beginning after September 30, 1992. In addition, it changed the matching requirements, to provide that States are required to match section 410 grant funds they receive as follows: The Federal share cannot exceed 75 percent of the cost of implementing and enforcing the drunk driving prevention program adopted to qualify for these funds in the first fiscal year the State receives funds, 50 percent in the second fiscal year and 25 percent in the third and in subsequent fiscal years.

The agency's implementing regulation has been amended to reflect these new limitations. In addition, it clarifies that the five year limit applies independently to each individual basic and supplemental grant.

Qualification Procedures

The qualification procedures for section 410 incentive grants have been modified to account for the latest changes in the authorizing legislation. The interim final rule, which was based on the provisions of ISTEA, provided for States to submit documentation to receive a grant out of the initial apportionment and additional, though abbreviated, documentation to receive a grant out of reapportioned funds.

Since the DOT FY 1993 Appropriations Act changed section 410 to provide that there will no longer be an apportionment and reapportionment of funds, this second submission is not necessary and, therefore, has been dropped from the implementing regulation. The final rule also clarifies the difference between an application, certifications and a plan, and makes other minor conforming changes.

The regulation continues to require that States submit a drunk driving prevention plan, describing the programs the State is or will be implementing, within 120 days after being informed by NHTSA of its eligibility for a grant. Wisconsin asserted that 120 days provides insufficient time to submit a plan, particularly in light of the funding mechanism enacted by ISTEA, that was then in effect, under which a considerable but undetermined amount of funds could be reapportioned on the first day of the following fiscal year to qualifying States. NHTSA believes that 120 days are sufficient, even under the provisions of ISTEA. In fact, the 120 day time limit did not prevent any State from qualifying for section 410 funds in FY 1992 (including Wisconsin). In addition, since the DOT FY 1993 Appropriations Act changed the funding mechanism enacted by ISTEA, the agency believes it is no longer necessary to consider a change to this time limit.

Basic Grant Criteria

As amended by ISTEA, section 410 provided that, to be eligible for a basic grant, a State had to qualify for four out of five basic criteria. The DOT FY 1993 Appropriations Act amended section 410 to add a sixth criterion, described below in greater detail, and provided that, to be eligible for a basic grant, a State now must qualify for five out of six basic criteria.

Today's final rule adds a regulatory provision to implement this sixth criterion and makes other conforming changes. The rule also modifies the regulatory provisions implementing the other five criteria, as described below.

The State of Wisconsin indicated that it is not convinced that each basic (and supplemental) grant criterion (most notably, the statewide system for stopping motor vehicles) has been demonstrated to be effective and merits being included as a qualification requirement. Wisconsin suggested the inclusion instead of criteria that would focus on the development of innovative programs. The State also objected to the manner in which the drugged driving criterion reads and questioned whether a 5 percent grant provides sufficient incentive for the States to adopt such a far-reaching program. The agency will not respond to these comments in detail since they pertain to statutory requirements that cannot be addressed within the scope of this rulemaking action.

1. Expedited Driver's License Suspension or Revocation System

This criterion continues to require that States adopt an expedited driver's license suspension or revocation system for persons who operate motor vehicles while under the influence of alcohol. To qualify, the system must contain each of the elements defined in the Federal statute. One of these elements, however, was changed in the DOT FY 1993 Appropriations Act, and today's final rule conforms the regulation accordingly.

When section 410 was enacted originally, on November 18, 1988, it required that States must suspend or revoke an offender's driver's license and

hold an administrative review (if the offender requested one) within 15 days, or 30 days if the State could show that meeting the 15-day requirement would impose a hardship on the State.

On November 5, 1990, Congress enacted three technical corrections to section 410, one of which removed the requirement that the administrative review must be held within the statutory time frame. Under that correction, States were still required to provide offenders with the right to an administrative review of a license suspension or revocation action and the officer was required to provide the offender with notice of this right, but the review was no longer required to be conducted within 15 or 30 days. The statute continued to require that the suspension or revocation occur within that period of time.

ISTEA amended section 410 to extend this time frame to 30 days, without requiring that the State demonstrate hardship, but it tracked the original language in section 410, rather than the amended language that was enacted in November 1990. Accordingly, to meet this aspect of this criterion, States were given a full 30 days to suspend the offender's license, but they were once again required to hold administrative reviews (if requested) within that period of time.

The DOT FY 1993 Appropriations Act corrected this language. As amended, section 410 now provides that States are required to provide offenders with the right to an administrative review of a license suspension or revocation action and the officer is required to provide the offender with notice of this right, but the review is no longer required to be conducted within a defined period of time. The statute continues to require that the State suspend or revoke the offender's driver's license within 30 days of the date on which the offender received notice. Today's final rule amends the regulation to reflect this change.

The implementing regulation continues to provide that States may qualify under this criterion as either "Law States" or "Data States." A Law State (a State that has in effect a law which provides for each element of the expedited suspension system criterion) may qualify in the first year it receives a basic grant based on this criterion by submitting just its law. It need not submit data. A Data State (a State that has in effect a law which provides for the elements contained in paragraphs (i)-(iv) of the criterion, but contains inconsistencies with elements contained in paragraphs (v) and (vi)) may overcome these inconsistencies in the first year by submitting both its law and data. Both Law and Data States must submit data in subsequent years.

In the past, if a State's law contained an inconsistency with one element in paragraph (v) or (vi), that State was required (as a Data State) to submit data addressing all elements in both paragraphs to qualify in the first year. The State of Wisconsin objected to this aspect of the regulation. Based on Wisconsin's comment and NHTSA's experience administering the section 410 program, the agency has decided to relax this requirement. Instead, a Data State will be required in the first year to submit data demonstrating compliance only with the elements not specifically provided for in the State's law. Both Law and Data States will continue to be required to submit data in subsequent years. Today's final rule makes conforming changes to implement this change in the regulations for both the section 410 and section 408 programs.

The final rule also makes other minor changes, including the removal of the word "administrative" several times it appears to avoid confusion in situations in which a nonconforming element can be cured with the use of data. This change does not affect the requirement that States must provide for administrative procedures, including an administrative review of a driver's license suspension or revocation, and provide to the driver notice of the impending action and information on the administrative procedures under which the action may be taken.

NHTSA wishes to remind States that, to qualify under this criterion in subsequent years, they must submit data. The data must demonstrate that, on average, the State meets the requirements for promptness and lengths of suspension. (Data States also must submit data to qualify in the first year, but only on those requirements not specifically provided for in their law.) The agency has permitted States to exclude from these averages, outliers which represent extremely unusual and extenuating circumstances. To be excluded, outliers must be explained to NHTSA by the State and the agency must approve their exclusion. States continue to be permitted to provide data based on a representative sample.

2. Per se level of 0.10 and 0.08

This criterion continues to require that States must have a law which establishes a per se level of 0.10 or lower in the first three fiscal years in which a basic grant is received and 0.08 or lower in the last two.

As previously discussed, section 410 now provides that States may receive grants in no more than 5 fiscal years beginning after September 30, 1992. A conforming change has been included in this portion of the regulation to clarify that the three year period contained in this criterion does not begin to run until after September 30, 1992.

3. Statewide Program for Stopping Motor Vehicles

This criterion continues to require that States establish a statewide program for stopping motor vehicles on a nondiscriminatory lawful basis for the purpose of determining whether or not the operators of such motor vehicles are driving while under the influence of alcohol. Minor editorial changes have been made to this portion of the interim final rule, including a clarification of the materials States must submit in subsequent years to demonstrate that their programs are being publicized. No other changes have been made.

NAGHSR commented that the requirement that States must provide dates and approximate locations in their applications is unreasonable and may be detrimental to the deterrence value of these enforcement efforts if the information were to be publicized. NAGHSR proposed instead that a State should be permitted to submit a more generalized plan that indicates the anticipated locations by major area, region or county, but not specific location, and the planned month, but not precise date, of the operation. NHTSA agrees with NAGHSR's comment and, in fact, accepted under this criterion in FY 1992 plans from States that did not specify exact dates and locations. States were required to demonstrate only that stops were conducted on a monthly basis and that each major area of the State was covered during the course of the year.

NAGHSR also objected to the requirement that States must develop detailed statewide implementation plans. NAGHSR asserted that it is unnecessary for a State to develop a Statewide plan if local law enforcement agencies are conducting stops throughout the State or to involve State law enforcement personnel in every roadside checkpoint conducted. By requiring that stops must be "made by both State and local * * * police agencies," NHTSA did not mean to suggest that personnel from both State and local agencies must be involved in each and every stop. Rather, NHTSA intended only that, during the course of the year, both State and local agencies conduct stops (either separately or together). To ensure that the times and locations of stops are coordinated, NHTSA continues to believe that the

development of a Statewide plan is essential.

The National Beer Wholesalers Association (NBWA) asserted that the agency's interpretation of this criterion in the rule provides insufficient flexibility to States in which courts have found roadblocks or checkpoints to be unconstitutional. NBWA argues that, as a result of the agency's interpretation, these States must either take action that may be declared unconstitutional or qualify under the other basic grant criteria, even if they do not support the other criteria.

NHTSA believes it has provided as much flexibility as possible, within the meaning and intent of the statute. We agree that some States may have to qualify under the other criteria. We wish to remind the commenter, however, that at least the States have a choice. Prior to ISTEA, States were required to meet all basic criteria to receive a grant under section 410. (States continue to be required to meet all basic criteria under section 408.) If a State did not meet all basic criteria, it was unable to qualify for basic or supplemental grants altogether.

4. Self-Sustaining Drunk Driving Prevention Program

NHTSA received comments regarding this criterion from NAGHSR and the State of Wisconsin. NAGHSR's comments cautioned NHTSA to remember that States conduct and finance their programs by very different means, and that States may have difficulty generating precise data on revenues collected and expenditures made. Both comments requested additional clarification of this criterion.

NHTSA does recognize that States conduct and finance their programs differently, and did not require that State programs fit one single mold to be approved under this criterion. Recognizing also the difficulty in generating certain data, the agency accepted reasonable estimates from States. As a result, in FY 1992, States that made the effort and submitted the necessary material, were able to qualify under this criterion. Of the nineteen States that received section 410 grant funds in FY 1992 (including Indiana and New Mexico), fourteen met this criterion. Wisconsin asked NHTSA to identify the States that met this criterion, so other States may use them as models. NHTSA's Regional Offices can provide to any interested State a list of States that have qualified under this or any other criterion and a copy of the relevant portions of their applications.

This criterion continues to provide that: (1) The State, through its communities, must institute a "comprehensive" drunk driving prevention program; (2) while the program may not be completely "self-sustaining," a substantial portion of its costs must be supported with non-Federal funds; and (3) a significant portion of the fines or surcharges generated by drunk driving prevention programs, or an equivalent amount, must be used for the program's continued operation.

Today's final rule, however, has made a number of changes to the portion of the regulation that describes the information that States must submit to demonstrate compliance. These changes attempt to clarify this portion of the regulation, which States found confusing, and to streamline the application process by eliminating the need for States to gather or generate and submit unnecessary documentation. NHTSA believes these changes clarify the regulation and address the concerns that were raised in the comments from Wisconsin and NAGHSR.

In the past, different information was required from "centralized states" (States that collect revenues at the State level and then distribute those revenues to communities) and "other States" (States that do not have a purely centralized system). Based on its experience administering the section 410 program, NHTSA has decided to eliminate this distinction. Under today's revision, all States will be required to submit the same information.

States will continue to be required to submit laws providing for a self-sustaining program and for fines or surcharges to be imposed on drunk drivers. They must also show at least two detailed examples of representative comprehensive programs. These programs must be representative of different types of communities, such as communities in urban, suburban or rural areas. The examples should provide sufficient detail to show that activities were conducted in each of the four program areas described in the regulation's definition for a "comprehensive drunk driving prevention program," that public and private entities were involved, and that activities are sustained over time. This information can be provided by submitting the community program's annual plan, its annual report, or specific program materials from activities covering each of the four program areas.

States must also continue to submit data (from a census or representative sample) showing the aggregate amount of fines and surcharges actually collected and the aggregate amount of revenues actually returned (or the equivalent amount provided) to community programs. If a State is demonstrating compliance based on an equivalent amount of non-Federal funds, the State must continue to identify the source of these funds. Under today's final rule, State data must also identify the aggregate cost of comprehensive drunk driving prevention programs and the portion of these costs that are non-Federal. This change simply clarifies the regulation and conforms it to current practice.

Today's final rule also clarifies the definition of "fines or surcharges collected" to include fines, penalties, fees or additional assessments collected. Fees that are paid to the provider of the services (such as rehabilitation or treatment costs) need not be identified if they are not collected by the licensing agency or the court or other State or local government agency.

The regulation continues to provide that States must certify that revenues returned (or the equivalent amount provided) to communities are being used to continue the operation of comprehensive drunk driving prevention programs. Rather than require that States certify that a significant number of communities have such programs, today's final rule provides that a State must certify that a significant portion of the State's population resides in communities with comprehensive programs and the State must submit a list of such communities. NHTSA has made this change based on its conclusion that the latter is a more meaningful measure of the coverage of a State's program.

5. Minimum Drinking Age Prevention Program

This criterion continues to require that States provide for an effective system for preventing operators of motor vehicles under age 21 from obtaining alcoholic beverages. The portion of the interim final rule that implements this criterion has been adopted in today's final rule without change.

Wisconsin commented that its legislature enacted a law requiring the issuance of easily distinguishable licenses, but the State was not certain at the time that it could implement the law before the end of fiscal year 1992. The State asserted that this delayed implementation should not disqualify the State for funding under this criterion. NHTSA disagrees with this assertion. To qualify under this criterion, a State's system for issuing distinguishable drivers licenses to persons under age 21 must be in place. Wisconsin did put its system in place

administratively before the end of FY 1992 and was able to qualify under this criterion.

6. Mandatory Sentencing

This criterion was added in the DOT FY 1993 Appropriations Act, and is identical to the mandatory sentencing criterion contained in the section 408 program, 23 U.S.C. 408. It requires that States provide for a mandatory sentence, which shall not be subject to suspension or probation, of imprisonment for not less than 48 consecutive hours, or not less than 10 days of community service for any person convicted of driving while intoxicated more than once in any five year period.

The section 408 regulation, 23 CFR 1309.5(b), implements this criterion, and provides that States can demonstrate compliance either as Law States (States that have laws that meet each element of this criterion) or as Data States (States that have laws that meet each element, except that they do not specifically provide that the 48 hour term of imprisonment must be served consecutively). To demonstrate compliance in the first and in subsequent fiscal years, Law States must simply submit their law; Data States must submit their law and also data showing that they substantially comply with the consecutiveness requirement.

Today's final rule adopts in its entirety the language that appears in 23 CFR 1309.5(b).

Supplemental Grant Criteria

Section 410 continues to provide for seven separate supplemental grant programs. States that are eligible for basic grants and also meet one or more of the supplemental criteria, may receive supplemental grants. These supplemental grant programs include: (1) Per se level of 0.02 for persons under age 21; (2) open container and anti-consumption law; (3) suspension of registration and return of license plates of certain offenders; (4) mandatory alcohol concentration testing programs for certain drivers; (5) drugged driving prevention program; (6) per se level of 0.08 (for the first three years in which a basic grant is received) and (7) program for acquiring and using video equipment for the detection of drunk and drugged drivers.

As amended by ISTEA, section 410 provided that a State that was eligible for any of these supplemental grant programs could receive 5 percent of the amount apportioned to the State in the fiscal year under this section for each grant. The DOT FY 1993 Appropriations Act amended section 410 to provide that the amount of each supplemental grant shall equal instead 5 percent of the State's section 402 apportionment for FY 1992. Conforming changes have been made in the implementing regulation. NHTSA has also made modifications to some of the supplemental grant criteria, as described below.

Open Container and Anti-Consumption Law

Today's final rule adds a requirement that, to be eligible for a supplemental grant under the open container and anti-consumption law criterion in subsequent years, a State must submit information demonstrating that the State is actively enforcing its open container and anti-consumption law. This change makes this criterion consistent with other supplemental criteria, such as the suspension of registration and return of license plate and the mandatory alcohol concentration testing programs, under which States are currently required to submit this type of information in subsequent years. The agency is not requiring the submission of any particular data, but it believes submission of some information demonstrating enforcement is important under this criterion because an open container and anti-consumption law has little effect without an active enforcement program.

New York suggested, since NHTSA has permitted States to qualify as Data States under other criteria, that the agency permit States to qualify under this criterion if local laws are in effect that cover 80 percent of the State's population. NHTSA has not adopted this suggestion. The agency has permitted States to qualify as Data States under other criteria to overcome inconsistencies or exceptions contained in their Statewide laws. The agency has not permitted the Data State concept to be used under any criterion as a substitute for a Statewide law. NHTSA believes that a Statewide law is essential to provide consistency and complete coverage throughout each State.

Suspension of Registration and Return of License Plates

With regard to the suspension of registration and return of license plate criterion, the agency explained in the preamble to the interim final rule that States which do not provide for the suspension of the registration and the return of the license plate may demonstrate compliance by showing that they instead provide for the immobilization, impoundment or confiscation of the vehicle. Today's final rule includes language to this effect in the regulation.

Mandatory Alcohol Concentration Testing

NAGHSR urged the agency to make two changes to the mandatory alcohol concentration testing criterion. Firstly, NAGHSR suggested that the definition of the term "serious bodily injury" be changed to mean that the person required transportation to a medical facility (away from the scene of the crash). Such a definition, asserted NAGHSR, is consistent with the definition of the term "injury" included in CADRE and can more easily be applied by law enforcement officials. NHTSA agrees that such a definition could be applied more easily by enforcement officers, but presently not all States collect, maintain or have available data on whether a person was transported to a medical facility. Accordingly, the definition of the term serious bodily injury has not been changed in the regulation. However, if a State defines an injury in the manner suggested by NAGHSR, NHTSA will accept such a definition as a serious bodily injury.

NAGHSR also expressed concern "about the statutory requirement that a state have probable cause in order to conduct mandatory BAC testing * * * a lower evidentiary standard (e.g. reasonable suspicion) would have been more implementable [and easier for states to meet]." NHTSA believes NAGHSR misunderstood the requirements of this criterion. The criterion requires (by statute) that the State provide for mandatory testing whenever the law enforcement officer has probable cause to believe that a driver involved in a serious bodily injury or fatal crash has committed an alcohol-related traffic offense. If the State requires testing whenever the law enforcement officer has reasonable suspicion, then probable cause cases would be captured and the State would satisfy this requirement.

The State of Wisconsin asserted that the regulation is confusing because it requires that States must test all drivers "just in case" alcohol is later suspected to have been a factor or an injured party later dies. The agency disagrees that the regulation mandates such a result. Probable cause must be determined at the time of the crash, not at a later date. For a State applying as a Data State under this criterion, it is true that the data may reveal instances in which an individual involved in a crash later died and the driver had not been tested. However, this criterion requires testing only when there is probable cause to believe that the driver had committed an alcohol-related traffic offense. It is

NHTSA's belief, and hope, that testing will be conducted whenever there is such probable cause, even if the crash does not involve a fatality or serious bodily injury. In addition, NHTSA does not require that Data States show that testing is performed in all cases. The number of times that an individual who does not appear to be seriously injured later dies is small and should easily be accommodated within the margins allowed by the agency.

Today's final rule clarifies that a Law State, under the mandatory alcohol concentration testing criterion, is a State that has a law that requires that enforcement officers must order and offenders must submit to testing. If the State's law authorizes, rather than requires, the officer to order, or if the law permits offenders to refuse to submit to, the test, the State must qualify instead as a Data State under this criterion.

Per Se Level of 0.08

As previously mentioned, States may receive a supplemental grant in the first three years in which a basic grant is received if the State has in effect a law which establishes a per se level of 0.08 or lower. Consistent with the portion of the section 410 regulation that implements the per se basic grant criterion, described above, a conforming change has been included in this portion of the regulation to clarify that the three year period contained in this criterion does not begin to run until after September 30, 1992.

Other minor editorial and conforming changes have also been made in today's final rule.

States Previously Eligible

Section 2004(b) of the ISTEA provided that States which were eligible to receive a grant under section 410, as in effect before December 18, 1991, may elect in any fiscal year to receive a grant under that statute, in lieu of a grant under section 410, as amended on that date.

The DOT FY 1993 Appropriations Act left this option intact. Accordingly, the States of Indiana and New Mexico may continue, in any fiscal year, to choose to apply for a grant under section 410, as in effect prior to December 18, 1991. The regulations that were in effect at that time governing the eligibility requirements, funding amounts and grant limitations will apply. For example, these States may receive grants under the old law in no more than three fiscal years. To continue to receive funding beyond these three fiscal years, Indiana and New Mexico must qualify under the section 410 requirements, as in effect at the time of application.

The Appropriations Act reserved funds for New Mexico to continue its drunk driving prevention program under the "old" section 410. It did not reserve funds for Indiana. NHTSA interprets the statute to mean that, while New Mexico and Indiana both have the option of qualifying under the old criteria, Indiana's grants (regardless of which version of the criteria the State satisfies) must be funded out of current appropriations. Accordingly, current regulations governing award procedures would apply. In the event the agency expects a shortfall of funding, Indiana would be in the same position as other States, and may receive less than the full grant amount for which it had qualified.

The Appropriations Act also provided that States which received basic grants in FY 1992 under section 410, as in effect on September 30, 1992, and continue to meet the basic grant criteria, as in effect on that date, shall be eligible for a basic grant under section 410, as amended. This provision, in effect, serves as a grandfather clause for the seventeen States (not including Indiana and New Mexico) that qualified for a section 410 basic grant under the Act, as amended by ISTEA. To be eligible for a basic grant, these States must meet four out of the original five, rather than five out of six, basic grant criteria.

As explained earlier, as amended by the Appropriations Act, section 410 provides that States can receive section 410 grants for up to five fiscal years, beginning after September 30, 1992. Grants received by New Mexico, Indiana and the other seventeen States in fiscal years 1991 and 1992, therefore, do not count toward this five year period, and the five year period will begin to run in FY 1993, regardless of which version of section 410 the State uses to qualify.

Accordingly, in FY 1993, these States will be considered "first-year" States for the purpose of counting this five year period. They will also be considered "first-year" States in FY 1993 for the purpose of counting the three year period under the per se law basic and supplemental criteria and for the purpose of determining their matching share.

However, where the regulation provides for States to submit different information to demonstrate compliance with a criterion in the first and in subsequent years, these States will be considered subsequent year States if they qualified for a grant based on that criterion in previous years.

Federalism Assessment

This rulemaking action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it will have no federalism implication that warrants the preparation of a federalism assessment. The section 410 grant program is entirely optional for the States, and the eligibility requirements are mandated by the section 410 statute.

Regulatory Analyses and Notice

A. Executive Order 12291 and DOT Regulatory Policies and Procedures

NHTSA has analyzed the effect of this action and has determined that it is not "major" within the meaning of Executive Order 12291 or "significantly" within the meaning of Department of Transportation regulatory policies and procedures. State participation in the section 410 program is voluntary. Accordingly, a full regulatory evaluation is not necessary. Moreover, most of the changes in this rule merely modify the existing section 410 implementing regulation to reflect technical corrections enacted recently by Congress.

When the agency originally promulgated a regulation to implement the section 410 program on January 12, 1990 (55 FR 1185), it determined that the rulemaking should be classified as significant under the Department's regulatory policies and procedures. A regulatory evaluation was prepared at that time and placed in the public docket (Docket No. 89–02; Notice 2). Persons interested in reviewing this document should request it by writing to NHTSA's Docket Section, room 5109, 400 Seventh Street SW., Washington, DC 20590, or by calling the Docket Section at (202) 366–4949.

B. Regulatory Flexibility Act

Since this matter relates to grants, the notice and comment requirements established in the Administrative Procedure Act, 5 U.S.C. 553, are not applicable. Because the agency is not required to publish a notice of proposed rulemaking regarding this rule, the agency is not required to analyze the effect of this rule on small entities, in accordance with the Regulatory Flexibility Act. The agency has nonetheless evaluated the effects of this final rule on small entities. Based on the evaluation, I certify that this rule will not have a significant economic impact on a substantial number of small entities. States will be recipients of any funds awarded under the regulation and, accordingly, the preparation of a

Regulatory Flexibility Analysis is unnecessary.

C. Paperwork Reduction Act

The requirements in this rule that States retain and report to the Federal government information which demonstrates compliance with drunk driving prevention incentive grant criteria, are considered to be information collection requirements as that term is defined by the Office of Management and Budget (OMB) in 5 CFR part 1320. Accordingly, these requirements have been submitted to and approved by OMB, pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). These requirements have been approved through 11/30/95; OMB No. 2127–0501.

D. National Environmental Policy Act

The agency has also analyzed this action for the purpose of the National Environmental Policy Act. The agency has determined that this action will not have any effect on the human environment.

List of Subjects

23 CFR Part 1309

Alcohol and alcoholic beverages, Drugs, Grant programs, Transportation, Highway safety.

23 CFR Part 1313

Alcohol and alcoholic beverages, Drugs, Grant programs, Transportation, Highway safety.

In accordance with the foregoing, 23 CFR chapter III is amended as follows:

A. Part 1309 is amended as follows:

PART 1309—INCENTIVE GRANT CRITERIA FOR ALCOHOL TRAFFIC SAFETY PROGRAMS

1. The authority citation for part 1309 continues to read as follows:

Authority: 23 U.S.C. 408; delegation of authority at 49 CFR 1.50.

2. In § 1309.4, paragraph (a)(2) is removed, paragraph (a)(3) is redesignated as paragraph (a)(2), and paragraphs (a) introductory text and (a)(1) are revised to read as follows:

§ 1309.4 General requirements.

(a) Qualification requirements. To qualify for a grant under 23 U.S.C. 408, a State must, for each year it seeks to qualify:

(1) Submit an application to Regional Operations, NRO–01, 400 Seventh Street SW., Washington, DC 20590 that demonstrates that it meets the requirements of § 1309.5 and, if applicable, § 1309.6, and includes certifications that:

(i) It has an alcohol traffic safety program that meets those requirements;

(ii) It will use the funds awarded under 23 U.S.C. 408 only for the implementation and enforcement of alcohol traffic safety programs;

(iii) It will administer the funds in accordance with 49 CFR part 18 and OMB Circulars A–102 and A–87 and

(iv) It will maintain its aggregate expenditures from all other sources for its alcohol traffic safety programs at or above the average level of such expenditures in fiscal years 1981 and 1982 (either State or Federal fiscal year 1981 and 1982 can be used); and

* * * * *

3. In Section 1309.5, paragraph (a)(3)(ii) is redesignated as paragraph (a)(3)(iv), (a)(3)(i) is revised and paragraphs (a)(3)(ii) and (a)(3)(iii) are added to read as follows:

§ 1309.5 Requirements for a basic grant.

* * * * *

(a) * * *

(3) (i) To demonstrate compliance in the first fiscal year the State receives a basic grant, a Data State shall submit a copy of the law, regulation or binding policy directive implementing or interpreting the law or regulation, which provides for the prompt license suspension requirement and data showing that it substantially complies with each element not specifically provided for in the State's law, regulation or binding policy directive.

(ii) To demonstrate compliance in subsequent fiscal years the State receives a basic grant, a Data State shall submit, in addition to the information identified in paragraph (a)(3)(i) of this section, data showing the number of licenses suspended, that the average length of the suspension terms for first offenders, first refusers, repeat offenders and repeat refusers meets the terms defined in § 1309.3(f) and that the average number of days it took to suspend the licenses meets definition for promptness in § 1309.3(d).

(iii) The State can provide the necessary data based on a representative sample. Data on the average length of the suspension term must not include license suspension periods which exceed the terms actually prescribed by the State, and must reflect terms only to the extent that they are actually completed.

* * * * *

B. Part 1313 as amended in the interim rule published at 57 FR 29002 on June 30, 1992, is adopted as final with the following changes:

PART 1313—INCENTIVE GRANT CRITERIA FOR DRUNK DRIVING PREVENTION PROGRAMS

1. The authority citation for part 1313 continues to read as follows:

Authority: 23 U.S.C. 410; delegation of authority at 49 CFR 1.50.

§ 1313.1 [Amended]

2. In § 1313.1, the word "estal·lished" is removed and, in its place, the word "establishes" is added.

3. Section 1313.3(d) is revised to read as follows:

§ 1313.3 Definitions.

* * * * *

(d) *Fines or surcharges collected* means fines, penalties, fees or additional assessments collected.

* * * * *

§ 1313.3 [Redesignated]

4. Section 1313.3(i) is redesignated as § 1313.6(e)(3) and, in § 1313.3, paragraphs (j) through (m) are redesignated as paragraphs (i) and (l).

5. In § 1313.4, paragraph (a)(2) is removed, paragraph (a)(3) is redesignated as paragraph (a)(2), and paragraphs (a) introductory text and (a)(1) are revised to read as follows:

§ 1313.4 General requirements.

(a) Qualification requirements. To qualify for a grant under 23 U.S.C. 410, a State must, for each year it seeks to qualify:

(1) Submit an application to Regional Operations, NRO–01, 400 Seventh Street SW., Washington, DC 20590 that demonstrates that it meets the requirements of § 1313.5 and, if applicable, § 1313.6, and includes certifications that:

(i) It has a drunk driving prevention program that meets those requirements;

(ii) It will use the funds awarded under 23 U.S.C. 410 only for the implementation and enforcement of drunk driving prevention programs;

(iii) It will administer the funds in accordance with 49 CFR part 18 and OMB Circulars A–102 and A–87 and

(iv) It will maintain its aggregate expenditures from all other sources for its drunk driving prevention programs at or above the average level of such expenditures in fiscal years 1990 and 1991 (either State or Federal fiscal year 1990 and 1991 can be used); and

* * * * *

6. In § 1313.4, paragraph (b) is removed and paragraph (c) is redesignated as paragraph (b) and revised to read as follows:

§ 1313.4 General requirements.

* * * * *

(b) Limitation on grants. A State may receive each grant for up to five fiscal years beginning after September 30, 1992, subject to the following limitations:

(1) The amount of a basic grant, under § 1313.5, shall equal 30 percent of the State's 23 U.S.C. 402 apportionment for FY 1992, subject to the availability of funds.

(2) The amount of each supplemental grant, under § 1313.6, shall equal 5 percent of the State's 23 U.S.C. 402 apportionment for FY 1992, subject to the availability of funds.

(3) In the first fiscal year a State receives a basic or supplemental grant, it shall be reimbursed for up to 75 percent of the cost of its drunk driving prevention program adopted pursuant to 23 U.S.C. 410.

(4) In the second fiscal year a State receives a basic or supplemental grant, it shall be reimbursed for up to 50 percent of the cost of its drunk driving prevention program adopted pursuant to 23 U.S.C. 410.

(5) In the third, fourth and fifth fiscal year a State receives a basic or supplemental grant, it shall be reimbursed for up to 25 percent of the cost of its drunk driving prevention program adopted pursuant to 23 U.S.C. 410.

§ 1313.5 [Redesignated and Revised]

7. In Section 1313.5, paragraph (a)(3)(ii) is redesignated as paragraph (a)(3)(iv), the introductory text for the section and paragraphs (a)(1)(vi) and (a)(3)(i) are revised and paragraphs (a)(3)(ii) and (a)(3)(iii) are added to read as follows:

§ 1313.5 Requirements for a basic grant.

To qualify for a basic incentive grant of 30 percent of the State's 23 U.S.C. 402 apportionment for FY 1992, a State must have in place and implement or adopt and implement five of the following six requirements:

(a) * * *

(1) * * *

(vi) The suspension and revocation referred to under paragraph (a)(1)(v) of this section shall take effect not later than 30 days after the individual first received notice of the suspension or revocation.

* * * * *

(3) (i) To demonstrate compliance in the first fiscal year the State receives a basic grant based on this criterion, a Data State shall submit a copy of the law, regulation or binding policy directive implementing or interpreting the law or regulation, which provides for an expedited suspension system and data showing that it substantially complies with each element not specifically provided for in the State's law, regulation or binding policy directive.

(ii) To demonstrate compliance in subsequent fiscal years the State receives a basic grant based on this criterion, a Data State shall submit, in addition to the information identified in paragraph (a)(3)(i) of this section, data showing the number of licenses suspended, that the average length of the suspension terms for first offenders, first refusers, repeat offenders and repeat refusers meets the terms defined in § 1313.3(k) and that the average number of days it took to suspend the licenses meet the 30-day requirement in paragraph (a)(1)(vi) of this section.

(iii) The State can provide the necessary data based on a representative sample. Data on the average length of the suspension term must not include license suspension periods which exceed the terms actually prescribed by the State, and must reflect terms only to the extent that they are actually completed.

* * * * *

§ 1313.5 [Amended]

8. In Section 1313.5, the word "administrative" is removed each time it appears after the word "expedited", in the heading for paragraph (a) and in paragraphs (a)(1) introductory text, (a)(2)(i), (a)(2)(iii), and newly redesignated (a)(3)(iv).

9. In Section 1313.5(a)(2)(ii), the words "provide the administrative reviews and" are removed and the reference "§ 1313.3(l)" is revised to read "§ 1313.3(k)".

10. Section 1313.5(b)(1) is amended by adding the words "beginning after September 30, 1992" after the words "based on this criterion".

11. Section 1313.5 is amended by redesignating paragraphs (c)(2) (i) through (iv) as paragraphs (c)(2)(i) (A) through (D), designating the last sentence of newly redesignated paragraph (2)(i)(D) as paragraph (c)(2)(ii), and redesignated paragraph (c)(2) introductory text as paragraph (c)(2)(i) introductory text.

12. In the last sentence of § 1313.5(c)(3), the words "report public information events used" are removed and, in their place, the words "submit materials used or document activities conducted" are added.

13. In § 1313.5, paragraphs (d) (2) and (4) are removed, paragraphs (d) (3) and (5) are redesignated as paragraphs (d) (2) and (3) and newly redesignated paragraph (d)(2) is revised to read as follows:

§ 1313.5 Requirements for a basic grant.

* * * * *

(d) * * *

(2) To demonstrate compliance in the first and in subsequent years the State receives a basic grant based on this criterion, a State shall:

(i) Submit a copy of the law, regulation or binding policy directive implementing or interpreting the law or regulation, which provides for a self-sustaining drunk driving prevention program, and for fines or surcharges to be imposed on individuals apprehended and fined for operating a motor vehicle while under the influence of alcohol;

(ii) Show at least two detailed examples of distinct and representative community programs that are comprehensive, as defined in § 1313.3(b);

(iii) Certify that a significant portion of the State's population resides in communities with comprehensive drunk driving prevention programs and list such communities;

(iv) Submit data (or a representative sample) showing the aggregate amount of fines or surcharges, as identified in paragraph (d)(2)(i) of this section, which are actually collected, the aggregate amount of revenues actually returned or the equivalent amount provided to community drunk driving prevention programs under the State's self-sustaining system, the aggregate cost of the State's comprehensive drunk driving prevention programs and the portions of these costs that are non-Federal;

(v) Certify that these revenues, as identified in paragraph (d)(2)(iv) of this section, or the equivalent amount are being used to continue the operation of comprehensive drunk driving prevention programs; and

(vi) If the State is demonstrating compliance based on the equivalent amount of non-Federal funds it provides to communities, identify the source of these funds.

* * * * *

14. Section 1313.5(f) is added to read as follows:

§ 1313.5 Requirements for a basic grant.

* * * * *

(f) (1) A mandatory sentence, which shall not be subject to suspension or probation, of imprisonment for not less than 48 consecutive hours, or not less than 10 days of community service for any person convicted of driving while intoxicated more than once in any five year period.

(2) (i) To demonstrate compliance in the first and in subsequent fiscal years the State receives a basic grant, a Law State shall submit a copy of the law, regulation or binding policy directive

implementing or interpreting the law or regulation, which provides for each element of the mandatory sentence criterion.

(ii) For the purpose of this subsection, "Law State" means that the State has a law, regulation or binding policy directive implementing or interpreting an existing law or regulation which provides for each element of the mandatory sentence criterion, including the requirement that the 48 hour term of imprisonment must be served consecutively.

(3) (i) To demonstrate compliance in the first and in subsequent fiscal years the State receives a basic grant, a Data State shall submit, in addition to the information identified in paragraph (f)(2)(i) of this section, data showing that it substantially complies with the consecutiveness requirement. The State can provide the necessary data based on a representative sample.

(ii) For the purpose of this subsection, "Data State" means a State that has a law, regulation or binding policy directive implementing or interpreting an existing law or regulation which provides for each element of the mandatory sentence criterion, except that it need not specifically provide that the 48 hour term of imprisonment must be served consecutively.

§ 1313.6 [Amended]

15. In § 1313.6, the words "amount of funds apportioned to the State, in accordance with 23 U.S.C. 410(g), in that fiscal year" are removed each time they appear after the words "supplemental grant of 5 percent of the" and, in their place, the words "State's 23 U.S.C. 402 apportionment for FY 1992" are added, in paragraphs (a)(1), (b)(1), (c)(1), (d)(1), (e)(1) and (g)(1).

16. Section 1313.6 is amended by redesignating paragraph (b)(2) as paragraph (b)(2)(i), by removing the words "and in subsequent fiscal years" and "consumption" and, in their place, respectively, adding the words "fiscal year" and "anti-consumption" in newly redesignated paragraph (b)(2)(i) and by adding a new paragraph (b)(2)(ii) to read as follows:

§ 1313.6 Requirements for supplemental grants.

* * * * *

(b) * * *

(2) * * *

(ii) To demonstrate compliance in subsequent years the State receives a supplemental grant under this paragraph, the State shall submit, in addition to the information identified in paragraph (b)(2)(i) of this section, information showing that it is actively enforcing its open container and anti-consumption statute.

17. In § 1313.6(c)(2)(ii), the reference "§ 1313.3(m)" is revised to read "§ 1313.3(1)" and the words "are being" are removed and, in their place, the word "were" is added.

18. In § 1313.6, a new paragraph (c)(2)(iii) is added to read as follows:

§ 1313.6 Requirements for supplemental grants.

* * * * *

(c) * * *

(2) * * *

(iii) If the State does not provide for the suspension of the registration and the return of the license plate, the State can demonstrate compliance with this element by showing that it instead provides for the immobilization, impoundment or confiscation of the vehicle.

* * * * *

19. In § 1313.6, the word "invloved" is revised to read "involved" in paragraph (d)(2)(ii), the words "and offenders must submit to" are added after the words "enforcement officers must order" in paragraph (d)(2)(iii), the word "are" that appears before the words "probable cause" is removed and, it its place, the word "is" is added in paragraph (d)(3)(i), and the words "and offenders may be permitted to refuse to submit to" are added after the words "required by law to order" in paragraph (d)(3)(ii).

20. In § 1313.6(f)(1), the words "amount of funds apportioned to the State, in accordance with 23 U.S.C. 410(g)" are removed and, in their place, the words "State's 23 U.S.C. 402 apportionment for FY 1992" are added, and the words "beginning after September 30, 1992" are added after the words "basic grant is received".

21. Sections 1313.7 and 1313.8 are revised to read as follows:

§ 1313.7 Award procedures.

In each Federal fiscal year, grants will be made to eligible States upon submission and approval of the application and drunk driving prevention plan required by § 1313.4(a) and subject to the limitations in § 1313.4(b). The release of the full grant amounts shall be subject to the availability of funding for that fiscal year. If there are expected to be insufficient funds to ward full grant amounts to all eligible States in any fiscal year, NHTSA may release less than the full grant amounts upon initial approval of the State's application and plan and the remainder of the full grant amounts, up to the State's proportionate share of available funds, before the end of that fiscal year. Project approval, and the contractual obligation of the Federal government to provide grant funds, shall be limited to the amount of funds released.

§ 1313.8 States eligible under 410 prior to September 30, 1992.

(a) A State which, before December 18, 1991, was eligible to receive a grant under 23 U.S.C. 410, and its implementing regulation, as in effect on December 17, 1991, may elect to receive in a fiscal year grants under such section 410, and implementing regulation, as so in effect, in lieu of receiving in such fiscal year grants under section 410, as amended, and this regulation, except that such States shall be subject to § 1313.7 of this regulation.

(b) A state that received a basic grant, under section 410, after December 18, 1991 and on or before September 30, 1992, and that continues to meet the criteria for a basic grant, as in effect on September 30, 1992, shall be eligible for a basic grant under section 410, as amended on October 6, 1992.

Issued on: April 13, 1993.

Howard M. Smolkin,

Executive Director, National Highway Traffic Safety Administration.

[FR Doc. 93-9453 Filed 4-22-93; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Parts 215, 236, 813, 905, and 913

[Docket No. R-93-1654; FR-3494-C-03]

Definition of Annual Income: Holocaust Reparations, Final Rule; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule; correction.

SUMMARY: On March 24, 1993 (58 FR 15773), the Department published in the **Federal Register**, a final rule that indicated that although HUD takes family income into account in determining eligibility and the level of benefits in certain housing assistance programs, reparation payments made by foreign governments in connection with the Holocaust would be excluded and not considered as part of family income.

The purpose of this document is to clarify the effective date of that final rule.

EFFECTIVE DATE: April 23, 1993.

FOR FURTHER INFORMATION CONTACT:

Issues related to 24 CFR parts 215, 236, and 813: James J. Tahash, Director, Planning and Procedures Division, Office of Multifamily Housing Management, room 6182, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–3944. A telecommunications device for deaf persons (TDD) is available at (202) 708–4594. (These are not toll-free telephone numbers.)

Issues related to 24 CFR parts 905 and 913: Casimir Bonkowski, Director, Office of Management and Policy, Office of Public and Indian Housing, room 4224, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–0444. A telecommunications device for deaf persons (TDD) is available at (202) 708–0850. (These are not toll-free telephone numbers.)

SUPPLEMENTARY INFORMATION: On March 24, 1993 (58 FR 15773), the Department published in the **Federal Register**, a final rule regarding the Definition of Annual Income: Holocaust Reparations. It has come to the Department's attention that there may be confusion associated with the effective date of that rule.

The effective date indicated for the published rule in the "EFFECTIVE DATE" section was April 23, 1993. However, the last paragraph under the section heading, "SUPPLEMENTARY INFORMATION", and preceding the heading, "Findings and Certifications", in the preamble, made reference to "section 7(o)(3) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(o)(3))", and indicated that "* * * this rule will not become effective until HUD publishes a separate notice announcing a specific effective date." That paragraph was incorrect and is being removed with this corrected document.

Accordingly, in FR Doc. 93–6625, published in the **Federal Register** on March 24, 1993 (58 FR 15773), the final rule for 24 CFR parts 215, 236, 813, 905, and 913, is corrected to read as follows:

On page 15774, under the "SUPPLEMENTARY INFORMATION" section, in the preamble, in the first column, the second full paragraph that begins with, "Under section 7(o)(3) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(o)(3)), * * * and ends with "* * *, this rule will not become effective until HUD publishes a separate notice announcing a specific effective date." is removed.

(Note that the only effect of removing the quoted paragraph is to leave clear that the cited rule is intended to be, and is, effective on April 23, 1993.)

Dated: April 19, 1993.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 93–9487 Filed 4–22–93; 8:45 am]

BILLING CODE 4210–32–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Ohio Regulatory Program; Revision of Administrative Rule

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of proposed Revised Program Amendment Number 58 to the Ohio permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was initiated by Ohio and is intended to revise one rule in the Ohio Administrative Code. The proposed rule revisions would phase in, over a two-year period, the requirement for two years of ground cover and productivity evaluation for final bond release on pasture land or grazing land.

EFFECTIVE DATE: April 23, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Seibel, Director, Columbus Field Office, Office of Surface Mining Reclamation and enforcement, 2242 South Hamilton Road, room 202, Columbus, Ohio 43232; (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program, can be found in the August 10, 1982, **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Submission of Amendment

In response to an OSM requirement, Ohio submitted proposed Program Amendment Number 43 by letter dated January 16, 1990 (Administrative Record No. OH–1265). In part, this amendment proposed to revise Ohio Administrative Code (OAC) section 1501:13–9–15(I)(3)(c) to add the requirement that, for phase III bond release, certain revegetated areas must meet ground cover and production standards for any two years of the five-year period of extended responsibility, except the first year. The Director of OSM approved this proposed rule revision on July 27, 1992 (57 FR 33122).

By letter dated may 12, 1992 (Administrative Record No. OH–1699), Ohio submitted proposed Program Amendment Number 58. This amendment proposed to add new paragraphs (D) (1) and (2) at OAC section 1501:13–1–01 concerning the termination and possible reassertion of regulatory jurisdiction over all or part of a reclaimed coal mine following the release of performance bond. The Director of OSM approved these proposed additions on September 11, 1992 (57 FR 41690).

On October 14, 1992, Ohio held a public hearing on the final filing of the rule revision to OAC section 1501:13–9–15(I)(3)(c) as approved by OSM in Program Amendment Number 43. At that hearing, Ohio received comments recommending a two-year period to phase in the new requirements for final bond release. Ohio decided to adopt this suggestion by revising OAC section 1501:13–1–01 which establishes the effective date and applicability of the Ohio rules over mining and reclamation operations.

As discussed above, OSM recently approved Program Amendment Number 58 which revises OAC section 1501:13–1–01. Because Ohio had not yet promulgated Program Amendment Number 58, Ohio decided to resubmit proposed Revised Program Amendment 58 to further revise OAC section 1501:13–1–01 to incorporate the two-year phase-in period suggested at its public hearing. Ohio resubmitted Revised Program Amendment Number 58 on December 9, 1992 (Administrative Record No. OH–1798). Program Amendment Number 58 (termination of jurisdiction) which was approved by OSM on September 11, 1992 (57 FR 41690) is unaffected by this amendment and remains approved.

OSM announced receipt of proposed Revised Program Amendment Number 58 in the January 14, 1993, **Federal Register** (58 FR 4388), and, in the same

notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on February 16, 1993. The public hearing scheduled for February 8, 1993, was not held as no one requested an opportunity to testify.

On February 26, 1993, OSM informally sent its comments on the proposed amendment to Ohio. By letter dated March 26, 1993 (Administrative Record Number OH–1853), Ohio submitted clarifying information in support of its proposed amendment.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

As discussed earlier, Ohio submitted the proposed amendment in response to comments made by the Ohio Mining and Reclamation Association (OMRA) at a public hearing on October 14, 1992. The OMRA was concerned that, if the rule revision to OAC section 1501:13–9–15(I)(3)(c) were effective immediately, an operator ready for phase III bond release with only one year of recorded ground cover data might be barred from obtaining final bond release. The OMRA believed this would hurt that limited group of operators who were not previously required to collect the data for two years and who had waited the full responsibility period.

Ohio is proposing to revise a portion of paragraph (B) of OAC section 1501:13–1–01 to phase in the new provision at paragraph (I)(3)(c) of OAC section 1501:13–9–15. Ohio is proposing that each area for which there has been no phase III bond release and which is planted with a permanent cover of herbaceous species shall not be required to meet the requirements of paragraph (I)(3)(c) of rule 1501:13–9–15 of the Administrative Code for two years of the extended responsibility period until after January 1, 1994.

The revision to paragraph (I)(3)(c) of OAC section 1501:13–9–15 approved by OSM on July 27, 1992, added the requirement for two years of ground cover and productivity measurements for bond release. Prior to this revision, Ohio required that the bond release area meet ground cover and productivity standards only once at the time of the operator's bond release request. The proposed revision of OAC section 1501:13–1–01(B) is intended to create a 12-month grace period during which operators need not meet the new two-year requirement at OAC section 1501:13–9–15(I)(3)(c) until after January 1, 1994. However, Ohio's proposed amendment language was unclear as to which bond release requirements would be in effect in lieu of the new two-year requirement during the grace period.

The Federal regulations at 30 CFR 816/817.116(c)(2) require that revegetation success standards for cropland and grazing or pasture land be met during at least two years of the responsibility period. The Federal regulations allow these measurements to be taken during any two years of the responsibility period except the first year. On February 26, 1993, OSM informally commented to Ohio that Ohio must clarify that operators applying for phase III bond release during the 12-month period from January 1, 1993, through December 31, 1993, will be required to make the same ground cover and productivity demonstrations that were required prior to the revision of OAC section 1501:13–9–15(I)(3)(c). By letter dated March 26, 1993 (Administrative Record No. OH–1853), Ohio submitted a clarification of the implementation of the new language at OAC section 1501:13–1–01(B). Ohio stated that the intent of the new language is to phase in the new requirement of OAC section 1501:13–9–15(I)(3)(c) for a demonstration of compliance with the ground cover and productivity standards for two years, rather than one year, of the revegetation liability period. Permittees who request phase III bond release on areas reclaimed to pasture or grazing land prior to January 1, 1994, must demonstrate compliance with the ground cover and production standards for one year (presumably, the final year) of the revegetation liability period, except the first year. Ohio further stated that the proposed language at OAC section 1501:13–1–01(B) is by no means meant to excuse permittees from this requirement or any other bond release requirement.

The Director believes that those operators who were not previously required to collect data for two years and who waited the full responsibility period should not be denied bond release. The Director believes that to require these operators to immediately satisfy this requirement would penalize the operators because they would have to delay obtaining final bond release. As such, the Director finds that the proposed rule is not inconsistent with SMCRA and the Federal regulations provided that, except for those permittees who request phase III bond release from January 1, 1993, through December 31, 1993, all remaining operators will be required to comply with the rule revisions contained in Program Amendment 43 approved on July 27, 1992.

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing in the January 14, 1993, **Federal Register** closed on February 16, 1993. Comments were received from the Ohio Historic Preservation Office (OHPO). The OHPO did not object to the proposed amendment. The scheduled public hearing was not held as no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Ohio program. The U.S. Department of Agriculture, Soil Conservation Service, and the U.S. Army Corps of Engineers responded that they had no comments. The U.S. Environmental Protection Agency concluded that the proposed amendment to Ohio's program demonstrates the legal authority, administrative capability, and the technical conformity with controlling National Pollutant Discharge Elimination System regulations necessary to maintain water quality standards promulgated under the authority of the CWA, as amended (33 U.S.C. 1251 *et seq.*) No other comments were received.

V. Director's Decision

Based on the above findings, the Director is approving Ohio Revised Program Amendment Number 58, as submitted by Ohio on December 9, 1992, and as clarified by the March 26, 1993, letter.

The Federal regulations at 30 CFR part 935 codifying decisions concerning the Ohio program are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to conform their programs with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated

under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no such provisions and that EPA concurrence is therefore, unnecessary. However, by letter dated February 8, 1993 (Administrative Record No. OH–1833), the EPA submitted its concurrence.

VI. Procedural Determinations

Executive Order No. 12291

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

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR Parts 730, 731 and 732 have been met.

National Environmental Policy Act

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

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the office of Management and Budget under 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

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

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: April 15, 1993.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

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

PART 935—OHIO

1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In Section 935.15, a new paragraph (lll) is added to read as follows:

§ 935.15 Approval of regulatory program amendments.

* * * * *

(lll) The following amendment to the Ohio regulatory program, as submitted to OSM on December 9, 1992, and as clarified by letter dated March 26, 1993, is approved, effective on April 23, 1993: Revised Amendment Number 58 which consists of a revision to the Ohio Administrative Code (OAC) at 1501:13–1–01(B) to phase in the new requirement at OAC 1501:13–9–15(I)(3)(c) concerning two years of ground cover and productivity measurements for bond release.

[FR Doc. 93–9497 Filed 4–22–93; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF EDUCATION

34 CFR Part 668

RIN 1840–AB47

Student Assistance General Provisions

AGENCY: Department of Education.

ACTION: Final regulations; Correction.

SUMMARY: This document corrects an error in the final regulations published in the **Federal Register** on December 17, 1992 for the Student Assistance General Provisions, 57 FR 60032, by making the decision of the hearing official in a proceeding under Subpart G of part 668 take effect only after the expiration of the 30-day period provided for the filing of an appeal of that decision to the Secretary under 34 CFR 668.90(c)(2).

FOR FURTHER INFORMATION CONTACT: Fred J. Marinucci, Office of the General Counsel, U.S. Department of Education, 400 Maryland Avenue, SW., room 4083, Washington, DC 20202–2244. Telephone (202) 401–2732. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

Dated: April 19, 1993.

Richard W. Riley,

Secretary of Education.

(Catalog of Federal Domestic Assistance Numbers: Supplemental Educational Opportunity Grant Program, 84.008; Guaranteed Student Loan Program, 84.032; PLUS Program, 84.032; Supplemental Loans for Students Program, 84.032; College Work-Study Program, 84.033; Perkins Loan Program, 84.038; Income Contingent Loan Program, 84.038; Pell Grant Program, 84.063; State Student Incentive Grant Program, 84.069; Robert C. Byrd Honors Scholarship Program, 84.185)

The following correction is made in FR Doc. 92–0388, published on December 17, 1992 (57 FR 60032).

§ 668.90 [Amended]

1. On page 60034, column 1, in Amendment 4, § 668.90 is further amended by amending paragraph (c)(1) by removing "20 day" and "20 days" and adding in, their place "30 days" and "30-day", respectively.

[FR Doc. 93–9485 Filed 4–22–93; 8:45 am]

BILLING CODE 4000–01–U

Proposed Rules

Federal Register
Vol. 58, No. 77
Friday, April 23, 1993

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

DEPARTMENT OF AGRICULTURE

Rural Electrification Administration

7 CFR Parts 1710 and 1735

Title Evidence Policies and Procedures

AGENCY: Rural Electrification Administration, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Rural Electrification Administration (REA) is considering a revision to its title policy to change REA policies and procedures regarding the submittal of title evidences in connection with real property and right-of-way acquisitions by its borrowers. To assist REA in this endeavor, REA is soliciting written comments and suggestions from interested parties. The receipt of written comments from other lenders which have made loans to REA borrowers is particularly desired.

DATES: Written comments and recommendations must be received by REA by May 24, 1993.

ADDRESSES: Written comments should be addressed to F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, Rural Electrification Administration, room 2234, 14th and Independence Avenue, SW., Washington, DC 20250–1500. REA requires a signed original and three copies of all comments (7 CFR 1700.30(e)). All comments received will be made available for public inspection at room 2234-S (address as above) during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, room 2234-S, at the above address. Telephone: (202) 720–0736.

SUPPLEMENTARY INFORMATION: Advance notice is given that REA is considering the development of proposed regulations which will revise its policies and procedures regarding the submittal of title evidences in connection with real property and right-of-way acquisitions by REA borrowers. Interested parties are invited to submit written comments and recommendations concerning this advance notice. The submittal of written comments from other lenders which have made loans to REA borrowers is particularly desired.

Background

Standard loan contracts entered into between REA and its borrowers contain provisions which provide as follows:

(1) that funds will not be advanced to finance the acquisition of real property or construction thereon, until evidence is submitted, in form and substance satisfactory to the Administrator, that the borrower has acquired such right, title or interest in such property as the Administrator may require;

(2) that the borrower shall obtain such easements as may be required in connection with the borrower's system and cause such easements to be recorded; and

(3) that the borrower shall not enter into contracts for the purchase, lease or other acquisition of real property in connection with the construction or operation of the borrower's system, without making the effectiveness of such contract subject to the Administrator's approval.

It should be noted that REA exercises these contractual rights solely for the protection of the government's interests. Other lenders to the extent they may wish to have similar protection, cannot rely on REA's procedures but must contract with the borrower for such rights.

REA is considering the development of proposed regulations which will revise its policies implementing the requirements of the Rural Electrification Act and borrowers' contractual obligations currently set forth in REA electric Bulletin 20–3 entitled "Obtaining Adequate Right-of-Way and Submission of Title Evidence by REA Electric Borrowers" and REA telephone Bulletin 380–1 entitled "Right-of-Way and Title Procedures, Telephone". Although the full scope of the revised policy has not yet been determined, written comments concerning the appropriateness of the items below are requested:

I. General Matters

(a) the types of evidence which REA should require (for example, attorney opinion letters, officer certificates, title insurance policies, deeds, lease or easement agreements, use permits, condemnation orders and plats);

(b) whether some or all of the title requirements should be modified based on the property's value and/or the proposed use of the property; and

(c) under what circumstances borrowers should be able to acquire a lease, right-of-way, easement or use permit for sites to be put to certain uses, such as substation sites, rather than acquiring the site in fee.

II. Title Insurance

(a) the instances in which REA should require title insurance based upon the cost and/or proposed use to be made of the property;

(b) whether to require the submittal of insurance commitments for comment prior to the issuance of final policies;

(c) whether to require mortgagee policies versus owners policies;

(d) whether insurance policies should follow a particular form such as that prescribed by the American Land Title Association;

(e) whether to maintain a list of approved title insurance companies; and

(f) what amount of insurance to require.

III. Attorney Opinion Letters and/or Officer Certificates—whether to require the submission of attorney opinion letters and/or officer certificates which cover the following matters:

(a) the accuracy of the description of the acquired property in the deed;

(b) the existence of judgments or pending suits which might affect a borrower's title or proposed use of the property;

(c) the adequacy of a borrower's access to and within the property;

(d) the acquisition of permits, licenses or other authorizations required for construction, operation and maintenance;

(e) the reasonableness of the price paid for the property;

(f) the impact of any reservation of oil, gas, water or mineral rights on the proposed use of the property;

(g) the impact of any restrictive covenants on the proposed use of such property;

(h) whether the property is located in a flood hazard area and, if so, whether

flood hazard insurance has been obtained;

(i) whether the requirements of the Uniform Relocation Assistance and Real Property Acquisition Act of 1970, as amended, apply and, if so, whether such requirements have been complied with;

(j) the adequacy of the water supply, sewage facilities, electrical or other energy sources and telephone service;

(k) whether any safety or other hazards involve the property; and

(l) the environmental condition of the property and whether environmental laws have been complied with.

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

Dated: April 15, 1993.

Robert Peters,

Acting Under Secretary, Small Community and Rural Development.

[FR Doc 93-9542 Filed 4-22-93; 8:45 am]

BILLING CODE 3410-15-F

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

RIN 3150-AE49

FY 1991 and 1992 Proposed Rule Implementing the U.S. Court of Appeals Decision and Revision of Fee Schedules; 100% Fee Recovery, FY 1993

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend the licensing, inspection, and annual fees charged to its applicants and licensees. The proposed amendments are necessary to implement Public Law 101-508, enacted November 5, 1990, which mandates that the NRC recover approximately 100 percent of its budget authority in Fiscal Year (FY) 1993 less amounts appropriated from the Nuclear Waste Fund (NWF). The amount to be recovered for FY 1993 is approximately $518.9 million.

In addition, the NRC is soliciting comments on a proposed rule implementing the March 16, 1993, U.S. Court of Appeals for the District of Columbia Circuit decision remanding to the NRC portions of the FY 1991 annual fee rule. The remanded portions pertain to: The NRC's decision to exempt nonprofit educational institutions, but not other enterprises, on the ground in part that educational institutions are unable to pass through the costs of annual fees to their customers; and the Commission's decision to allocate generic costs associated with low-level waste (LLW) disposal by groups of licensees, rather than by individual licensee. The NRC in this proposed rule is soliciting comments on the alternative approaches that may be taken on these issues in light of the court's decision. Because the court's reasoning calls into question portions of the NRC's FY 1992 annual fee rule, this proposed rule addresses that rule as well.

DATES: The comment period expires May 24, 1993. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure only that comments received on or before this date will be considered. Because Public Law 101-508 requires that NRC collect the FY 1993 fees by September 30, 1993, and it is the NRC's current intent to resolve the court's remand issues no later than the issuance of the FY 1993 final rule, requests for extensions of the comment period will not be granted.

ADDRESSES: Submit written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attn: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone 301-504-1678).

Copies of comments received may be examined at the NRC Public Document Room at 2120 L Street, NW., Washington, DC 20555, in the lower level of the Gelman Building.

The agency workpapers that support these proposed changes to 10 CFR Parts 170 and 171 are available in the Public Document Room at 2120 L Street, NW., Washington, DC, in the lower level of the Gelman Building.

FOR FURTHER INFORMATION CONTACT: C. James Holloway, Jr., Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301-492-4301.

SUPPLEMENTARY INFORMATION:

I. Background.
II. U.S. Court of Appeals remand decision.
III. Proposed action.
IV. Section-by-section analysis.
V. Environmental impact: categorical exclusion.
VI. Paperwork reduction act statement.
VII. Regulatory analysis.
VIII. Regulatory flexibility analysis.
IX. Backfit analysis.

I. Background

Public Law 101-508, the Omnibus Budget Reconciliation Act of 1990 (OBRA-90), enacted November 5, 1990, requires that the NRC recover approximately 100 percent of its budget authority less the amount appropriated from the Department of Energy (DOE) administered NWF for FYs 1991 through 1995 by assessing fees. Public Law 101-576, the Chief Financial Officers Act of 1990 (CFO Act), enacted November 15, 1990, requires that the NRC perform a biennial review of its fees and other charges imposed by the agency and revise those charges to reflect costs incurred in providing those services.

The NRC assesses two types of fees to recover its budget authority. First, license and inspection fees, established in 10 CFR part 170 under the authority of the Independent Offices Appropriation Act (IOAA) (31 U.S.C. 9701), recover the NRC's costs of providing individually identifiable services to specific applicants and licensees. The services provided by the NRC for which these fees are assessed are generally for the review of applications for the issuance of new licenses or approvals, amendments to or renewal of licenses or approvals, and inspections of licensed activities. Second, annual fees, established in 10 CFR Part 171 under the authority of OBRA-90, recover generic and other regulatory costs not recovered through 10 CFR part 170 fees.

Subsequent to enactment of OBRA-90, the NRC published three final fee rules after evaluation of public comments. On July 10, 1991 (56 FR 31472), the NRC published a final rule in the **Federal Register** that established the part 170 professional hourly rate and the materials licensing and inspection fees, as well as the part 171 annual fees to be assessed to recover approximately 100 percent of the FY 1991 budget. In addition to establishing the FY 1991 fees, the final rule established the underlying basis and method for determining the 10 CFR part 170 hourly rate and fees, and the 10 CFR part 171 annual fees. The FY 1991 rule was challenged in Federal court by several parties and the U.S. Court of Appeals for the District of Columbia Circuit decided the lawsuits on March 16, 1993. The Court case and the NRC's request for comment on the issues remanded by the court are discussed in section II of this rulemaking.

On April 17, 1992 (57 FR 13625), the NRC published in the **Federal Register** two limited changes to 10 CFR parts 170 and 171. The limited changes became effective May 18, 1992. The limited change to 10 CFR part 170 allowed the NRC to bill quarterly for those license fees that were previously billed every six months. The limited change to 10 CFR part 171 adjusted the maximum

annual fee of $1,800 assessed a materials licensee who qualifies as a small entity under the NRC's size standards. A lower tier small entity fee of $400 per licensed category was established for small business and non-profit organizations with gross annual receipts of less than $250,000 and small governmental jurisdictions with a population of less than 20,000.

On July 23, 1992 (57 FR 32691), the NRC published a final rule in the Federal Register that established the licensing, inspection, and annual fees necessary for the NRC to recover approximately 100 percent of its budget authority for FY 1992. The basic methodology used in the FY 1992 final rule was unchanged from that used to calculate the 10 CFR part 170 professional hourly rate, the specific materials licensing and inspection fees in 10 CFR part 170, and the 10 CFR part 171 annual fees in the final rule published July 10, 1991 (56 FR 31472).

Section 2903(c) of the Energy Policy Act requires the NRC to review its policy for assessment of annual fees under section 6101(cx) of OBRA–90, solicit public comment on the need for changes to this policy, and recommend changes in existing law to the Congress that the NRC finds are needed to prevent the placement of an unfair burden on certain NRC licensees. To comply with the Energy Policy Act requirements, the NRC intends to solicit public comment on the need for changes to NRC fee policy in a separate notice that is expected to be published in the Federal Register in April 1993. The Federal Register notice for this action would allow for a 90-day public comment period.

II. U.S. Court of Appeals for the District of Columbia Circuit Remand Decision—FY 1991–1993 Fee Schedules

On March 16, 1993, the U.S. Court of Appeals for the District of Columbia Circuit decided *Allied-Signal, Inc.* v. *U.S. Nuclear Regulatory Commission and the United States of America*, No. 91–1407 and Consolidated Cases. The court remanded for reconsideration two aspects of the NRC's FY 1991 annual fee rule, codified at 10 CFR Part 171. First, the court questioned the Commission's decision to exempt nonprofit educational institutions from Commission fees on the ground (in part) that they are unable to pass through the costs of those fees to their customers, without attempting a similar "passthrough" analysis for other licensees. Second, the court questioned the Commission's decision to allocate generic costs associated with low-level waste (LLW) disposal by classes of licensees, rather than by individual licensees.

The court did not vacate the FY 1991 rule, but returned it to the Commission for a better explanation or for appropriate changes in the rule. The Commission in this rulemaking seeks comments on its proposed response to the Court decision. The comments should address not only the "passthrough" and "LLW" aspects of the FY 1991 rule, but also the same aspects of the FY 1992 rule and the proposed FY 1993 rule.[1] The Commission will consider all "passthrough" and "LLW" comments together in connection with all three rules.[2] These issues are explored in more detail below.

Cost Passthrough

a. Court Decision

The court initially addressed the claim, advanced by Allied-Signal, Inc., that the Commission failed to consider the inability of uranium hexafluoride (UF6) converters to pass through the costs of their annual fees to their customers. Allied claimed that its competitive position was weak, that sales turned on as little as one cent per pound, and that NRC annual fees placed an intolerable burden on competitiveness, especially as foreign converters are not charged annual fees. Allied pointed to legislative history of the NRC fee statutes suggesting the Commission "take [passthrough] into account" when charging fees to, among others, uranium producers. The court rejected Allied's statutory argument. The court ruled that the legislative history did not mean that the Commission was barred from charging annual fees to licensees with an inability to pass through fees to customers through higher prices. Indeed, the court commented that "[b]ecause [price] elasticities are typically hard to discover with much confidence, the Commission's refusal to read the statute as a rigid mandate to do so is not only understandable but reasonable." Slip op. at 6–7.

The court found, however, that the Commission had not consistently declined to consider passthrough concerns. The court noted that the Commission chose to exempt nonprofit educational institutions on the ground (in part) of an inability to pass through costs to customers. Because the rule did not address why it was possible to calculate the effects of passthrough on educational institutions but not on UF6 converters like Allied, the court remanded that portion of the rule to the Commission to "develop a reasoned treatment" of passthrough-based claims. The court suggested that education alone, unhinged from a general "passthrough" rationale, might "yield exceptionally large externalized benefits that cannot be captured in tuition or other market prices." Slip op. at 8. The court also ordered the Commission to consider on remand a related claim of Combustion Engineering, Inc. ("CE"), that long-term fixed price contracts in its business (production of low enriched uranium) required a phase-in of passed-through costs.

Despite the remand, the court did not vacate the rule, both because vacating the rule might lead to refunds that could not be recaptured "under a later-enacted rule," and because the court found a "serious possibility that the Commission will be able to substantiate its decision on remand." Slip op. at 8–9.

b. Proposed Resolution

In this remanded rulemaking, the Commission views two options as possible. The first is to take passthrough into account for those licensees for whom it can be done, as the court put it, "with reasonable accuracy and at reasonable cost." Slip op. at 7. The second is to abandon the passthrough concept and to determine, as the court suggested, whether an exemption for nonprofit educational institutions remains justifiable. For a number of reasons, including those stated in the court opinion, the Commission proposes to take the latter approach.

It is an impossible administrative task to assess the passthrough capability of the NRC's approximately 6,800 licensees. Each of these licensees operates in a specialized business environment, and must take many factors into account when making daily business decisions. The NRC is a regulatory agency with the responsibility of safeguarding the public health and safety with regard to peaceful uses of nuclear power. It is not a financial regulatory agency, and does not possess the knowledge or resources necessary to successfully and

[1] The Court remanded only the FY 1991 rule. But the FY 1992 rule and the proposed FY 1993 rule raise identical questions. The same petitioners who challenged the FY 1991 rule in court also brought a judicial challenge to the FY 1992 rule. The NRC expects the court to decide the FY 1992 challenge promptly, and in accord with the Court's decision in the FY 1991 rule.

[2] In a separate request for public comments, the NRC in April 1993 will also be publishing another Federal Register notice requesting public views on the overall administration of and policy underlying its annual fee rules pursuant to section 2903(c) of Public Law 102–486 (the Energy Policy Act of 1992).

continuously evaluate purely business factors. Such an effort would require the hiring of financial specialists and expanded training of existing employees to cope with these new tasks. This would in turn lead to diversion of the agency's budget from its mission responsibilities, and a possible increase in the NRC's budget (and therefore annual fees) to handle these new demands. An ironic result could be higher fees charged to licensees to pay for an expanded bureaucracy to determine if each licensee can pass on the cost of its fees. The Commission, for obvious reasons, does not see this as an optimum solution. The court itself viewed "the difficulty of assessing the ability * * * to pass through costs" as a "entirely legitimate concern." Slip op. at 6.

Passthrough also is an elusive inquiry as a matter of economics, requiring a sophisticated study of domestic and international markets. It depends, as the court pointed out, "on the price elasticities of supply and demand"—"elasticities [that] are typically hard to discover with much confidence." Slip op. at 6–7. The Commission, therefore, feels that a general passthrough approach would fail the "reasonable accuracy and cost" test proposed by the court.

The Commission, in short, proposes to reject use of the passthrough concept in annual fee-setting. This means that the Commission does not intend to apply it to reduce Allied's fees, to "phase-in" CE's fees, or to justify special treatment of any licensee or class of licensees. However, as part of its continuing efforts to reevaluate and improve fee collection process and policy, the Commission seeks public comment from interested parties on ways that the Commission feasibly could evaluate the passthrough capability of its licensees.

That leaves the question whether to continue to exempt nonprofit educational institutions, an exemption justified in the past both because of "passthrough" concerns and because of the societal value of education. The Commission proposes to continue to exempt these licensees from fees for Fys 1991, 1992 and 1993, as it has for many years in the past, but solely because of its policy interest in supporting nuclear-related education. The Commission continues to believe that "educational research provides an important benefit to the nuclear industry and the public at large and should not be discouraged." Final FY 1991 Rule, 56 FR 31477; July 10, 1991. A vibrant nuclear education sector also is important as a source of talent and ideas for the NRC itself and for the whole government.

As the Commission noted in the statement of considerations for the 1991 fee rule, many colleges and universities supported continuing this longstanding exemption, as it "facilitates academic research and educational use of licensed materials, [which] both furthers understanding of important research questions and provides training in nuclear science." See NRC Final Rule, 56 FR 31477; July 10, 1991. The commenters described how imposition of fees on their nuclear programs would lead, in many cases, to severe cutbacks in and shutdowns of these programs. This in turn would lead to shortages of scientific personnel trained in the use of radioactivity in such areas as reactor safety, with detrimental effects suffered not only by nuclear science but by society at large. The court itself suggested that NRC financial incentives to education may be justified because of the possibility of "externalized benefits that cannot be captured in tuition or other market prices." Slip op. at 8.

The Commission therefore is soliciting comments on whether to leave the exemption for nonprofit educational institutions in place on the ground of supporting education for the benefits it provides both to the nuclear field and to society as a whole. In particular, the Commission invites public comments on the court's suggested "externalized benefits" approach. The Commission also invites public comments on whether to discontinue the educational exemption.

LLW Costs

a. Court Decision

Allied argued to the court that the Commission allocated generic LLW costs for fuel facilities, which totaled $1.9 million in FY 1991, in an arbitrary and capricious manner. The court assumed that the agency possessed licensee-specific LLW generation data, and found that the NRC lacked justification for allocating LLW costs simply by the amount of LLW generated per class, instead of allocating the costs licensee-by-licensee. The court stated:

> [a]ssuming that the Commission calculated each class's quantity of LLW waste from data supplied by each licensee (as seems necessarily true), it is hard to see any administrative problem with apportioning the fees within the class on the basis of output; the data are available and the required computations would be rudimentary.

Slip op. at 11.

To avoid what it viewed as an unjust windfall (*i.e.*, complete vacation of the LLW fees, and full refunds), the court did not vacate this part of the FY 1991 rule. It instead remanded the LLW issue to the Commission for reconsideration. The court indicated that if on remand the Commission decided to charge LLW costs based on the amount of waste produced by each licensee, licensees could permissibly receive refunds for the difference between what they paid under the old and new rules, rather than total refunds.

b. Proposed Resolution

The options for addressing the remand should be developed and analyzed in view of the purpose of the NRC budgeted resources for LLW disposal. To implement the Low Level Radioactive Waste Policy Amendments Act of 1985, and the Atomic Energy Act, the NRC must perform certain generic activities. These activities include developing rules, policies and guidance, performing research, and providing advice and consultation to LLW compacts and Agreement States who will license some of the future LLW disposal sites. The budgeted costs for these types of generic activities are generally recovered in annual fees from the class of licensees to whom the activities directly relate. (For example, reactor research is recovered from reactor licensees, and guidance and rule development for regulation of uranium producers is recovered from uranium recovery licensees.) However, for LLW generic activities, there is no disposal site licensed by the NRC from whom to recover the generic budgeted costs that must be incurred.[3] Since there is no LLW disposal site licensee, these costs must be allocated to other NRC licensees in order to recover 100% of the NRC budget as required by OBRA–90. In addition, the LLW costs budgeted by NRC in FY 1991, FY 1992 and FY 1993 are not for the wastes being disposed during these years or prior years, but are devoted to creating the regulatory framework for disposal of LLW at some future date.[4] In fact, the sites where LLW was disposed of in FY 1991–1993 are licensed and regulated by Agreement States, not the NRC.

Given the 100 percent budget recovery requirement of OBRA–90, and the fact that there are no NRC LLW licensees from whom to recover FY

[3] There are organizations that hold a NRC license for the disposal of Special Nuclear Material (SNM). The LLW at issue is not SNM, but other byproduct and source materials.

[4] In the FY 1991 rule, the NRC indicated that "once the NRC issues a license to dispose of byproduct LLW, the Commission will reconsider the assessment of generic costs attributable to LLW disposal activities" (56 FR 31487; July 10, 1991).

1991–1993 budgeted costs for NRC generic activities, the basic question is how should NRC allocate these costs. Congress spoke briefly to this issue in developing OBRA–90 by recognizing that certain expenses cannot be attributed directly either to an individual licensee or to classes of NRC licensees. The conferees intended that the NRC fairly and equitably recover these expenses from its licensees through the annual charge, even though these expenses cannot be attributed to individual licensees or classes of licensees. These expenses may be recovered from those licensees whom the Commission, in its discretion, determines can fairly, equitably, and practicably contribute to their payment. 1356 Cong Rec. at H12692, 3.

Consistent with the Congressional guidance, the Commission concluded that all classes of NRC licensees which generate a substantial amount of LLW should be assessed annual fees to cover the agency's generic LLW costs. The NRC viewed current LLW generation as a reasonable proxy for benefits likely to accrue in the future from the NRC's LLW program. The court appeared to approve this basic approach, but questioned the method for determining the amount of the fee to be assessed to each of the licensees that generate LLW. The NRC believes that there are three alternatives (with variations within each alternative) for determining the LLW fee amount for the various licensees. However, as noted above, none of these alternatives is intended to recover the cost of a service provided during a particular year, but instead is intended to recover today's costs for a future benefit (the availability of LLW disposal).

Within this context, and given the court opinion, the Commission is considering the following four alternatives for determining the amount of the LLW surcharge (fee) to be assessed to the various licensees:

(1) Assess all licensees that generate LLW a uniform annual fee.

(2) Allocate the LLW budgeted cost based on the amount of LLW disposed of by groups of licensees and assess each licensee in a group the same annual fee as was done in the FY 1991 and FY 1992 rules.

(3) Assess each licensee an annual fee based on the amount of waste generated/disposed by the individual licensee, as was suggested by Allied-Signal and by the court.

(4) Base the LLW annual fees on curies generated or disposed of.

Under alternative 1, the NRC would not try to distinguish between the potential future benefits to the diverse NRC licensees, but would assess the same LLW fee to all NRC licensees that generate low level waste, regardless of amount of LLW generated. The theory is, as expressed by the court, "that the real benefit of LLW disposal is merely the availability of such services." Slip op. at 11. This alternative would result in a hospital, for example, paying the same LLW annual fee as a reactor, who would pay the same LLW annual fee as a fuel facility. If this alternative were used, the uniform LLW annual fee assessed to licensees in categories that generate low-level waste would be $7,200 for FY 1991, $7,900 for FY 1992, and $7,900 for FY 1993. The Commission currently has difficulty perceiving this as a fair and equitable means to determine licensees' future benefits from the Commission's LLW program, but will consider the approach after receiving comments.

Alternative 2 rests on the premise that it is not possible to predict the exact future benefit for each individual licensee (for reasons discussed below), but that current volume of LLW disposed by each class of licensees is a good gross indicator of the relative future benefit to the various classes. In other words, the LLW volume disposed today is a good proxy for future benefits—but in a "macro", not a "micro" sense. The Commission believes fairness and equity support keeping this broad approach in effect.

There are various ways to separate the licensees by classes. The FY 1991–1993 rules separate the licensees by the same classes that are used for all other annual fees. Obviously this approach results in efficiencies for the NRC annual fee billing process. But there are other possibilities. The Commission could divide the licensees into two categories—"large" waste generators and "small" waste generators. Under this alternative, reactor and major fuel facilities, for example, could comprise a single group of large generators paying larger fees; and other licensees could comprise a group of small generators paying smaller fees.

Alternative 3 would base the annual fee for LLW on the amount of waste generated by each licensee during a particular year. This is the approach apparently favored by the court, and would of course be a "fair and equitable" indicator of future benefits if (as the court assumed) the NRC had ready access to reliable licensee-by-licensee data on waste generation. But it does not. The Commission's gross data on LLW derive from LLW disposal data it receives through various means from existing LLW waste disposal sites. These data are roughly accurate with regard to large classes of licensees, as it is reasonable to assume that individual distortions even out over the years and over relatively large numbers of licensees. But the NRC sees problems in using the waste disposal data as a proxy for future benefits to individual licensees. The amount of waste disposed of annually by individual licensees is affected by many variables that do not relate to the amount of waste generated by each licensee.

For one thing, many licensees (particularly large ones) have access to technology that compacts large volumes of LLW into small packages for disposal. Thus, individual disposal data do not necessarily reflect a fair and accurate comparison of waste generated among individual licensees. In addition, some licensees by choice or by law store waste (temporarily) rather than dispose of it. These licensees' LLW would not be picked up in the NRC's disposal data. For example, NRC licensees in Michigan did not dispose of any waste in 1991 or 1992 because by law they were not permitted to use existing LLW disposal sites. However, these licensees obviously will benefit in the future just as much as, or maybe more than, others do from NRC regulatory costs today, since ultimately Michigan must dispose of its LLW. But under a licensee-by-licensee alternative based on disposal data, the annual fee assessed to licensees in Michigan would have to be zero, implying no future benefits to each licensee. Finally, it is far from clear that most NRC licensees would willingly permit use of individual disposal data for fee purposes, due to proprietary concerns. Plainly, if the NRC developed a fee structure based on individual licensee disposal data, the amount of LLW disposed of by specific licensees would be revealed to the public and to competitors.

Alternative 4 would base LLW annual fees on the amount of LLW curies generated or disposed of. Adoption of this alternative, would imply that the number of curies generated or disposed of is a better indicator of future benefits from NRC's LLW program than the volume of LLW generated or disposed of as discussed in alternatives 2 and 3.

On balance, while the NRC recognizes that there are many conceivable ways to allocate its low-level waste costs, it does not believe that Alternatives 1 and 3 provide a major or workable improvement on the current system. However, the Commission is requesting comments on each method (and variations) prior to issuing the final rule. The Commission notes that for FY 1993, it is making a minor improvement to its allocation by adjusting the percentage of

use in the allocation to better reflect the impact of waste generated by licensees in Agreement States.

In sum, the approach taken in the provisions of the proposed regulations that address nonprofit educational institutions and LLW disposal would apply to the FY 1993 fee schedule and also respond to the court's remand.

III. Proposed Action

In addition to soliciting comments on a proposed rule implementing the March 16, 1993, court decision, the NRC is also proposing to amend its licensing, inspection, and annual fees for FY 1993. OBRA–90 requires that the NRC recover approximately 100 percent of its FY 1993 budget authority, including the funding of its Office of the Inspector General, less the appropriations received from the NWF, by assessing licensing, inspection and annual fees. The CFO Act requires that the NRC review, on a biennial basis, the fees imposed by the agency.

For FY 1993, the NRC's budget authority is $540.0 million, of which approximately $21.1 million has been appropriated from the NWF. Therefore, OBRA–90 requires that the NRC collect approximately $518.9 million in FY 1993 through 10 CFR Part 170 licensing and inspection fees and 10 CFR Part 171 annual fees. The NRC estimates that approximately $116.6 million will be recovered in FY 1993 from the fees assessed under 10 CFR Part 170. The remaining $402.3 million would be recovered through the FY 1993 10 CFR Part 171 annual fees.

The NRC has not changed the basic approach, policies, or methodology for calculating the 10 CFR Part 170 professional hourly rate, the specific materials licensing and inspection fees in 10 CFR Part 170, and the 10 CFR Part 171 annual fees set forth in the final rules published July 10, 1991 (56 FR 31472) and July 23, 1992 (57 FR 32691). With respect to the FY 1993 fees, the NRC is requesting public comment on the issue of whether the methodology adopted in FY 1991 and FY 1992 has been properly applied to the FY 1993 budget authority.

Under this proposed rule, fees for most licenses will increase because—

(1) NRC's new budget authority has increased resulting in a corresponding increase in the professional hourly rate; and

(2) The number of licenses in some classes have decreased due to license termination or consolidation resulting in fewer licensees to pay for the costs of regulatory activities not recovered under 10 CFR Part 170.

The NRC contemplates that any fees to be collected as a result of this proposed rule would be assessed on an expedited basis to ensure collection of the required fees by September 30, 1993, as stipulated in the Public Law. Therefore, as in FY 1991 and FY 1992, the fees, if adopted, would become effective 30 days after publication of the final rule in the **Federal Register**. The NRC will send a bill for the amount of the annual fee to the licensee or certificate, registration, or approval holder upon publication of the final rule. Payment is due on the effective date of the FY 1993 rule which is estimated to be August 1, 1993.

A. Amendments to 10 CFR Part 170: Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services

The NRC proposes five amendments to Part 170. These amendments do not change the underlying basis for the regulation—that fees be assessed to applicants, persons, and licensees for specific identifiable services rendered. These revisions also comply with the guidance in the Conference Committee Report on OBRA–90 that fees assessed under the Independent Offices Appropriation Act (IOAA) recover the full cost to the NRC of all identifiable regulatory services each applicant or licensee receives.

First, the NRC proposes that the agency-wide professional hourly rate, which is used to determine the Part 170 fees, be increased about seven percent from $123 per hour to $132 per hour ($229,912 per direct FTE). The rate is based on the FY 1993 direct FTEs and that portion of the FY 1993 budget that is not recovered through the appropriation from the NWF.

Second, the NRC proposes that the current Part 170 licensing and inspection fees in §§ 170.21 and 170.31 for all applicants and licensees be revised to reflect both the increase in the professional hourly rate and the results of the review required by the CFO Act. To comply with the requirements of the CFO Act, the NRC has evaluated historical professional staff hours used to process a licensing action (new license, renewal, and amendment) and to conduct routine and nonroutine inspections for those licensees whose fees are based on the average cost method (flat fees).

The evaluation of the historical data shows that the average number of professional staff hours needed to complete materials licensing actions should be increased in some categories to reflect the costs incurred in completing the licensing actions. For other categories, the average number of professional staff hours per licensing action decreased. Thus, the revised average professional staff hours reflect the changes in the NRC licensing review program that have occurred since FY 1990. The proposed licensing fees are based on the new average professional staff hours needed to process the licensing actions multiplied by the proposed professional hourly rate for FY 1993 of $132 per hour. The data for the average number of professional staff hours needed to complete licensing actions were last updated in FY 1990 (55 FR 21173; May 23, 1990).

In the materials inspection area, the historical data for the average number of professional staff hours necessary to complete routine and nonroutine inspections show that inspection hours used to determine the amount of the inspection fee have increased and in many cases significantly, when compared to the hours currently used under 10 CFR part 170. The data for the average number of professional staff hours necessary to conduct routine and nonroutine inspections were last updated in FY 1984 (49 FR 21293; May 21, 1984). As a result, the average number of professional staff hours used in the current fee schedule for inspections is outdated. Since 1985, the amount of the inspection fees has been updated based only on the increased professional hourly rate. The increased average professional staff hours reflects the changes in the inspection program that have been made for safety reasons. In some program areas, for example, NRC management guidance in recent years has emphasized that inspections be more thorough, in-depth and of higher quality. The proposed inspection fees are based on the new average professional staff hours necessary to conduct the inspections multiplied by the proposed professional hourly rate for FY 1993 of $132 per hour.

In summary, the NRC is proposing to revise both materials licensing and inspection fees assessed under 10 CFR part 170 in order to comply with the CFO Act's requirement that fees be revised to reflect the cost of the agency of providing the service.

The review of the inspection information also indicates that over 90 percent of the inspections conducted by NRC are routine inspections. As a result, for most fee categories either no nonroutine inspections were conducted or a very small number of nonroutine inspections were completed. For these reasons, the NRC is proposing, for fee purposes, to establish a single inspection fee rather than separate fees for routine and nonroutine inspections.

This proposed inspection fee would be assessed for either a routine or a nonroutine inspection conducted by the NRC.

Third, a new fee category 4D is proposed to specifically segregate and identify licenses authorizing the receipt from other persons of byproduct material as defined in section 11.e.(2) of the Atomic Energy Act for possession and disposal. Section 11.e.(2) byproduct material is the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

Fourth, irradiator fee Categories 3F and 3G are being broadened to include underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.

Fifth, a new section, 170.8 is being added to comply with Office of Management and Budget (OMB) regulations that require agencies to give public notice, or a negative declaration, of the presence of information collection requirements contained in Federal regulations.

B. Amendments to 10 CFR Part 171: Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC

The NRC proposes six amendments to 10 CFR part 171. First, NRC proposes to amend §§ 171.15, and 171.16 to revise the annual fees for FY 1993 to recover approximately 100 percent of the FY 1993 budget authority less fees collected under 10 CFR part 170 and funds appropriated from the NWF.

Second, the NRC proposes to amend § 171.11 by revising paragraphs (a), (b), and (d). These proposed changes would incorporate the specific statutory exemption provided in the Energy Policy Act of 1992 for certain nonpower (research) reactors and make clarifying changes to the exemption provision for materials licensees in §§ 171.11(b) and (d). Section 2903(a)(4) of the Energy Policy Act, enacted October 24, 1992, amends Section 6101(c) of OBRA–90 to specifically exempt from 10 CFR Part 171 annual fees certain Federally owned research reactors if—

(1) The reactor is used primarily for educational training and academic research purposes and;

(2) The design of the research reactor satisfies certain technical specifications set forth in the legislation.

The NRC, in implementing this provision of the Energy Policy Act, intends to limit the exemption in 10 CFR part 171 only to Federally owned research reactors.

The NRC proposes to amend § 171.11(d) to clarify that the three factors for exemption for materials licensees should not be read as conjunctive requirements but rather should be read as independent considerations which can support an exemption request.

The NRC also notes that since the final FY 1992 rule was published in July 1992, licensees have continued to file requests for termination of their licenses or certificates with the NRC. Other licensees have either called or written to the NRC since the FY 1992 final rule became effective requesting further clarification and information concerning the annual fees assessed. The NRC is responding to these requests as quickly as possible but was unable to respond and take action on all of the requests prior to the end of the fiscal year on September 30, 1992. Footnote 1, of 10 CFR 171.16 provides that the annual fee is waived where a license is terminated prior to October 1 of each fiscal year. However, based on the number of requests filed, the Commission, for FY 1993, is proposing to exempt from the FY 1993 annual fees those licensees, and holders of certificates, registrations, and approvals who either filed for termination of their license or approval or filed for a possession only/storage license prior to October 1, 1992, and were capable of permanently ceasing licensed activities entirely by September 30, 1992. All other licensees and approval holders who held a license or approval on October 1, 1992, are subject to the FY 1993 annual fees.

Third, § 171.19 is amended to credit the quarterly partial payments made by certain licensees in FY 1993 toward their FY 1993 annual fees.

Fourth, a new category 4D is proposed to specifically segregate and identify licenses authorizing the receipt from other persons of byproduct material as defined in § 11.e.(2) of the Atomic Energy Act for possession and disposal. Section 11.e.(2) byproduct material is the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

Fifth, additional language is proposed for irradiator fee Categories 3F and 3G to clarify that those two fee categories include underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.

Sixth, a new § 171.8 is being added to comply with Office of Management and Budget (OMB) regulations that require agencies to give the public notice, or a negative declaration, of the presence of information collection requirements contained in Federal regulations.

The NRC notes that the impact of the proposed fees for FY 1993 on small entities has been evaluated in the Regulatory Flexibility Analysis (see Appendix A to this proposed rule). Based on this analysis, the NRC is proposing to continue for FY 1993 a maximum annual fee of $1,800 per licensed category for those licensees who qualify as a small entity under the NRC's size standards. The NRC is also proposing to continue for FY 1993 the lower tier small entity annual fee of $400 per licensed category for certain materials licensees, which was established by the NRC in FY 1992 (57 FR 13625; April 17, 1992).

The 10 CFR Part 171 annual fees have been determined using the same method used to determine the FY 1991 and FY 1992 annual fees. The amounts to be collected through annual fees in the amendments to 10 CFR Part 171 are based on the increased professional hourly rate. The proposed amendments to 10 CFR Part 171 do not change the underlying basis for 10 CFR Part 171; that is, charging a class of licensees for NRC costs attributable to that class of licensees. The charges are consistent with the Congressional guidance in the Conference Committee Report, which states that the "conferees contemplate that the NRC will continue to allocate generic costs that are attributable to a given class of licensee to such class" and the "conferees intend that the NRC assess the annual charge under the principle that licensees who require the greatest expenditures of the agency's resources should pay the greatest annual fee." 136 Cong. Rec., at H12692–93.

The NRC notes that many licensees have indicated during the past two years that although they held a valid NRC license authorizing the possession and use of special nuclear, source, or byproduct material, they were in fact either not using the material to conduct operations or had disposed of the material and no longer needed the license. In particular, this issue has been raised by certain uranium mill licensees who have mills not currently in operation. In responding to licensees about this matter, the NRC has stated that annual fees are assessed based on whether a licensee holds a valid NRC license that authorizes possession and use of radioactive material. Whether or not a licensee is actually conducting operations using the material is a matter of licensee discretion. The NRC cannot control whether a licensee elects to possess and use radioactive material once it receives a license from the NRC.

Therefore, the NRC reemphasizes that the annual fees will be assessed based on whether a licensee holds a valid license with the NRC that authorizes possession and use of radioactive material. To remove any uncertainty, the NRC is proposing minor clarifying amendments to 10 CFR 171.16, footnotes 1 and 7.

C. FY 1993 Budgeted Costs

The FY 1993 budgeted costs by major activity, to be recovered through 10 CFR Parts 170 and 171 fees are shown in Table I.

TABLE I.—RECOVERY OF NRC'S FY 1993 BUDGET AUTHORITY

[In millions of dollars]

Recovery method	Estimated amount
Nuclear Waste Fund	$21.1
Part 170 (license and inspection fees)	116.6
Other receipts	.1
Part 171 (annual fees):	
Power reactors	316.5
Nonpower reactors	.5
Fuel facilities	14.4
Spent fuel storage	.7
Uranium recovery	.5
Transportation	4.4
Material users	[1] 35.1
Subtotal	372.1
Costs remaining to be recovered not identified above	30.1
Total	540.0

[1] Includes $5.3 million that will not be recovered from small materials licensees because of the reduced small entity fees.

The NRC is proposing that the $30.1 million identified for those activities which are not identified as either 10 CFR parts 170 or 171 or the NWF in Table I be distributed among the NRC classes of licensees as follows:

$27.0 million to operating power reactors;

$1.4 million to fuel facilities; and

$1.7 million to other materials licensees.

In addition, approximately $5.3 million must be collected as a result of continuing the $1,800 maximum fee for small entities and the lower tier small entity fee of $400 for certain licensees. In order for the NRC to recover 100 percent of its FY 1993 budget authority in accordance with OBRA–90, the NRC is proposing to recover $4.5 million of the $5.3 million from operating power reactors and the remaining $0.8 million from large entities that are not reactor licensees.

This distribution results in an additional charge (surcharge) of approximately $289,000 per operating power reactor; $100,000 for each HEU, LEU, UF_6 and each other fuel facility license; $1,600 for each materials license in a category that generates a significant amount of low level waste; and $120 for other materials licenses. When added to the base annual fee of approximately $2.9 million per reactor, this will result in an annual fee of approximately $3.2 million per operating power reactor. The total fuel facility annual fee would be between approximately $710,000 and $3.3 million. The total annual fee for materials licenses would vary depending on the fee category(ies) assigned to the license.

The proposed additional charges not directly or solely attributable to a specific class of NRC licensees or costs not recovered from all NRC licensees on the basis of previous Commission policy decisions would be recovered from the designated classes of licensees previously identified. A further discussion and breakdown of the specific costs by major classes of licensees are shown in Section IV of this proposed rule.

The NRC notes that in prior litigation over NRC annual fees, the U.S. Court of Appeals for the District of Columbia Circuit concluded that the NRC "did not abuse its discretion by failing to impose the annual fee on all licensees," *Florida Power & Light Co.* v. *NRC*, 846 F.2d 765, 770 (D.C. Cir. 1988), *cert. denied*, 109 S. Ct. 1952 (1989). As noted earlier, the conferees on Public Law 101–508 have acknowledged the D.C. Circuit's holding that the Commission was within its legal discretion not to impose fees on all licensees.

IV. Section-by-Section Analysis

The following analysis of those sections that are affected under this proposed rule provides additional explanatory information. All references are to title 10, chapter I, U.S. Code of Federal Regulations.

Part 170

Section 170.8 Information Collection Requirements: OMB Approval

This section is being added to comply with Office of Management and Budget (OMB) regulations that require agencies to give the public notice, or a negative declaration, of the presence of information collection requirements contained in Federal regulations. These revisions are of a minor administrative nature and are made to comply with OMB regulations.

Section 170.20 Average Cost Per Professional Staff Hour

This section is amended to reflect an agency-wide professional staff-hour rate based on FY 1993 budgeted costs. Accordingly, the NRC professional staff-hour rate for FY 1993 for all fee categories that are based on full cost is $132 per hour, or $229,912 per direct FTE. The rate is based on the FY 1993 direct FTEs and NRC budgeted costs that are not recovered through the appropriation from the NWF. The rate is calculated using the identical method established for FY 1991 and FY 1992. The method is as follows:

1. All direct FTEs are identified in Table II by major program.

TABLE II.—ALLOCATION OF DIRECT FTE'S BY MAJOR PROGRAM

Major program	Number of direct FTEs [1]
Reactor safety and safeguards regulation	1,080.0
Reactor safety research	117.7
Nuclear material and low-level waste safety and safeguards regulation	334.4
Reactor special and independent reviews, investigations, and enforcement	69.0
Nuclear material management and support	18.0
Total direct FTE	[2] 1,619.1

[1] FTE (full time equivalent) is one person working for a full year. Regional employees are counted in the office of the program each supports.

[2] In FY 1993, 1,619.1 FTEs of the total 3,296 FTEs are considered to be in direct support of NRC non-NWF programs. The remaining 1,676.9 FTEs are considered overhead and general and administrative.

2. NRC FY 1993 budgeted costs are allocated, in Table III, to the following four major categories:

(a) Salaries and benefits.

(b) Administrative support.

(c) Travel.

(d) Program support.

3. Direct program support, the use of contract or other services in support of the line organization's direct program, is excluded because these costs are charged directly through the various categories of fees.

4. All other costs (i.e., Salaries and Benefits, Travel, Administrative Support, and Program Support contracts/services for G&A activities) represent "in-house" costs and are to be collected by allocating them uniformly over the total number of direct FTEs.

Using this method, which was described in the final rules published July 10, 1991 (56 FR 31472) and July 23,

1992 (57 FR 32691) and excluding direct Program Support funds, the remaining $372.3 million allocated uniformly to the direct FTEs (1,619.1) results in a rate of $229,912 per FTE for FY 1993. The Direct FTE Hourly Rate is $132 per hour (rounded to the nearest whole dollar). This rate is calculated by dividing $372.3 million by the number of direct FTEs (1,619.1 FTE) and the number of productive hours in one year (1,744 hours) as indicated in OMB Circular A-76, "Performance of Commercial Activities."

TABLE III.—FY 1993 BUDGET AUTHORITY BY MAJOR CATEGORY

[In millions of dollars]

Salaries and benefits	$254.1
Administrative support	83.8
Travel	14.1
Total nonprogram support obligations	352.0
Program support	166.9
Total budget authority	518.9
Less direct program support and offsetting receipts	146.6
Budget allocated to direct FTE	372.3
Professional hourly rate	$132

Section 170.21 Schedule of Fees for Production and Utilization Facilities, Review of Standard Reference Design Approvals, Special Projects, Inspections and Import and Export Licenses

The proposed licensing and inspection fees in this section, which are based on full-cost recovery, are revised to reflect the FY 1993 budgeted costs and to more completely recover costs incurred by the NRC in providing licensing and inspection services to identifiable recipients. The fees assessed for services provided under the schedule are based on the professional hourly rate as shown in § 170.20 and any direct program support (contractual services) cost expended by the NRC. Any professional hours expended on or after the effective date of this rule would be assessed at the FY 1993 rate shown in § 170.20. The NRC is proposing to revise the amount of the import and export licensing fees in § 170.21, facility Category K to provide for the proposed increase in the hourly rate from $123 per hour to $132 per hour.

Footnote 2 of § 170.21 is revised to provide that for those applications currently on file and pending completion, the professional hours expended up to the effective date of this rule will be assessed at the professional rates established for the June 20, 1984, January 30, 1989, July 2, 1990, July 10, 1991, and July 23, 1992, rules as appropriate. For topical report applications currently on file which are still pending completion of the review, and for which review costs have reached the applicable fee ceiling established by the July 2, 1990, rule, the costs incurred after any applicable ceiling was reached through August 8, 1991, will not be billed to the applicant. Any professional hours expended for the review of topical report applications, amendments, revisions or supplements to a topical report on or after August 9, 1991, are assessed at the applicable rate established by § 170.20.

Section 170.31 Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections and Import and Export Licenses

The licensing and inspection fees in this section would be revised to recover more completely the FY 1993 costs incurred by the Commission in providing licensing and inspection services to identifiable recipients. Those flat fees, which are based on the average time to review an application or conduct an inspection, have been adjusted to reflect both the proposed increase in the professional hourly rate from $123 per hour in FY 1992 to $132 per hour in FY 1993 and the revised average professional staff hours needed to process a licensing action (new license, renewal, and amendment) and to conduct inspections.

As previously indicated, the CFO Act requires that the NRC conduct a review, on a biennial basis, of fees and other charges imposed by the agency for its services and revise those charges to reflect the costs incurred in providing the services. Consistent with the CFO Act requirement, the NRC has completed its review of license and inspection fees assessed by the agency. The review focused on the flat fees that are charged nuclear materials users for licensing actions (new licenses, renewals, and amendments) and for inspections. The full cost license/inspection fees (e.g., for reactor and fuel facilities) and annual fees were not included in this biennial review because the hourly rate for full cost fees and the annual fees are reviewed and updated annually in order to recover 100 percent of the NRC budget authority.

To determine the licensing and inspection flat fees for materials licensees and applicants, the NRC uses historical data to determine the average number of professional hours required to perform a licensing action or inspection for each license category. These average hours are multiplied by the proposed professional hourly rate of $132 per hour for FY 1993. Because the professional hourly rate is updated annually, the biennial review examined only the average number of hours per licensing action and inspection. The review indicates that the NRC needs to modify the average number of hours on which the current licensing and inspection flat fees are based in order to recover the cost of providing the licensing and inspection services. The average number of hours required for licensing actions was last reviewed and modified in 1990 (55 FR 21173; May 23, 1990). Thus the revised hours used to determine the proposed fees for FY 1993 reflect the changes in the licensing program that have occurred since that time, for example, new initiatives underway for certain types of licenses and management guidance that reviewers conduct more detailed reviews of certain renewal applications based on historical enforcement actions in order to insure public health and safety. The average number of hours for materials licensing actions (new licenses, renewals and amendments) have not changed significantly for most categories. For new license applications, approximately 60 percent of the materials license population would have increases of less than 25 percent, with some having slight decreases. For license renewals, approximately 85 percent would have increases of less than 25 percent, with some having decreases; and for amendments, approximately 90 percent would have increases of less than 25 percent with some having decreases. Only 2 percent of the materials license population would have increases of 100 percent or greater, for example, in the renewal area, irradiator licenses (fee Categories 3F and 3G) and licenses authorizing distribution of items containing byproduct material to persons generally licensed under 10 CFR part 31 (fee Category 3J).

For materials inspections, a distribution of the changes to the inspection fees shows that inspection fees would increase by at least 100 percent for 19 percent of the licenses. The largest increases would be for inspections conducted of those licenses authorizing byproduct material for (1) broad scope processing or manufacturing of items for commercial distribution (fee category 3A); (2) broad scope research and development (fee category 3L); and (3) broad scope medical programs (fee category 7B). Over 50 percent of the licenses would have increases of more than 50 percent. The primary reason for these relatively large increases is that the average number of hours on which inspection

fees are based has not been updated since 1984 (49 FR 21293; May 21, 1984). As a result, the average number of professional hours used in the current fee schedule for inspections is outdated. During the past eight years, the NRC's inspection program has changed significantly. In some program areas, for example, NRC management guidance in recent years has emphasized that, based on historical enforcement actions, inspections be more thorough and in-depth so as to improve public health and safety.

The review of the inspection information also indicates that over 90 percent of the inspections conducted are routine inspections. As a result, for most fee categories either no nonroutine inspections were conducted or a very small number of nonroutine inspections were completed. For these reasons, the NRC is proposing for fee purposes to combine routine and nonroutine inspection fees into a single fee rather than separate fees for routine and nonroutine inspections. This proposed inspection fee will be assessed for either a routine or a nonroutine inspection conducted by the NRC.

The amounts of the licensing and inspection flat fees were rounded, as in FY 1991 and FY 1992, by applying standard rules of arithmetic so that the amounts rounded would be de minimus and convenient to the user. Fees that are greater than $1,000 are rounded to the nearest $100. Fees under $1,000 are rounded to the nearest $10.

The proposed fees are applicable to fee categories 1.C and 1.D; 2.B and 2.C; 3.A through 3.P; 4.B through 9.D, 10.B, 15A through 15E and 16. The proposed fees will be assessed for applications filed or inspections conducted on or after the effective date of this rule.

For those licensing, inspection, and review fees assessed that are based on full-cost recovery (cost for professional staff hours plus any contractual services), the revised hourly rate of $132, as shown in § 170.20, will apply to those professional staff hours expended on or after the effective date of this rule.

Additional language is proposed for irradiator fee Categories 3F and 3G to clarify that those two fee categories include underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Although the sources are not removed from their shielding for irradiation purposes, underwater irradiators are not self-shielded as are the small irradiators in fee Category 3E. The underwater irradiators are large irradiators, and possession limits of thousands of curies are authorized in the licenses. The design of the facility is important to the safe use of both exposed source irradiators and underwater irradiators, and 10 CFR part 36 applies the same requirements to the underwater irradiators where the source is not exposed for irradiation as to the exposed source irradiators. The average costs of conducting license reviews and performing inspections of the underwater irradiators where the source remains shielded during irradiation are similar to the costs for irradiators where the source is exposed during irradiation.

A new category 4D is proposed to specifically segregate and identify those licenses authorizing the receipt, from other persons, of byproduct material as defined in § 11.e.(2) of the Atomic Energy Act for possession and disposal. Section 11.e.(2) byproduct material is the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. This proposed change is based on the NRC's recognition of increased activity related to disposal of 11.e.(2) byproduct material and to better distinguish this unique category of license.

Part 171

Section 171.8 Information Collection Requirements: OMB Approval

This section is being added to comply with Office of Management and Budget (OMB) regulations that require agencies to give the public notice, or a negative declaration, of the presence of information collection requirements contained in Federal regulations. These revisions are of a minor administrative nature and are made to comply with OMB regulations.

Section 171.11 Exemptions

Paragraph (a) of this section is revised and renumbered as (a)(1). A new paragraph (a)(2) is added which incorporates the specific statutory exemption provided in the Energy Policy Act of 1992 for certain nonpower (research) reactors and paragraphs (b) and (d), the exemption section for materials licensees, have been revised. Section 2903(a)(4) of the Energy Policy Act amends section 6101(c) of OBRA–90 to specifically exempt from 10 CFR part 171 annual fees certain Federally owned research reactors if—

(1) The reactor is used primarily for educational training and academic research purposes; and

(2) The design of the research reactor satisfies certain technical specifications set forth in the legislation. For purposes of this exemption the term "research reactor" means a nuclear reactor that—

(i) Is licensed by the Nuclear Regulatory Commission under section 104 c. of the Atomic Energy Act of 1954 (42 U.S.C. 2134(c)) for operation at a thermal power level of 10 megawatts or less; and

(ii) If so licensed for operation at a thermal power level of more than 1 megawatt, does not contain—

(A) A circulating loop through the core in which the licensee conducts fuel experiments;

(B) A liquid fuel loading; or

(C) An experimental facility in the core in excess of 16 square inches in cross-section.

The NRC, in implementing this provision of the Energy Policy Act, intends to limit the exemption in 10 CFR part 171 only to Federally owned research reactors.

The NRC, in making this required change, is not intending to change its exemption policy. As in FY 1991 and FY 1992, the NRC plans to continue a very high eligibility threshold for exemption requests and reemphasizes its intent to grant exemptions sparingly. Therefore, the NRC strongly discourages the filing of exemption requests by licensees who have previously had exemption requests denied unless there are significantly changed circumstances.

Earlier in this notice, the NRC discussed its proposal to continue exempting nonprofit educational institutions from annual fees for FY 1993.

The NRC is proposing to revise § 171.11(b) to not only require that requests for exemptions be filed with the NRC within 90 days from the effective date of the final rule establishing the annual fees but also to require that clarification of or questions relating to annual fee bills must also be filed within 90 days from the date of the invoice.

Exemption requests, or any requests to clarify the bill, will not, per se, extend the interest-free period for payment of the bill. Bills are due on the effective date of the final rule. Therefore, only payment will ensure avoidance of interest, administrative, and penalty charges.

Experience in considering exemption requests under § 171.11 has indicated that § 171.11(d) is ambiguous regarding whether an applicant must fulfill all, or only one, of the three factors listed in the exemption provision in order to be considered for an exemption. The NRC is clarifying the section to indicate that the three factors should not be read as conjunctive requirements but rather as independent considerations which can support an exemption request.

The NRC notes that section 2903(c) of the Energy Policy Act requires the NRC to review its policy for assessment of annual fees, under section 6101(c) of OBRA–90, solicit comment on the need for changes to this policy, and recommend changes in existing law to the Congress the NRC finds are needed to prevent the placement of an unfair burden on certain NRC licensees, particularly those who hold licenses to operate Federally owned research reactors used primarily for educational training and academic research purposes. The NRC intends to solicit public comment on the need for changes to NRC fee policy in a separate notice that is expected to be published in the **Federal Register** in April 1993. The **Federal Register** notice for this action would allow for a 90-day public comment period.

The NRC also notes that since the FY 1992 final rule was published in July 1992, licensees have continued to file requests for termination with the NRC. Other licensees have either called or written to the NRC since the final rule became effective requesting further clarification and information concerning the annual fees assessed. The NRC is responding to these requests as quickly as possible but it was unable to respond and take appropriate action on all of the requests before the end of the fiscal year on September 30, 1992. Footnote 1 of 10 CFR 171.16 provides that the annual fee is waived where a license is terminated prior to October 1 of each fiscal year. However, based on the number of requests filed, the NRC is proposing to exempt from the FY 1993 annual fees those licensees, and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage only licenses prior to October 1, 1992, and were capable of permanently ceasing licensed activities entirely by September 30, 1992. All other licensees and approval holders who held a license or approval on October 1, 1992, are subject to the FY 1993 annual fees.

Section 171.15 Annual Fee: Reactor Operating Licenses

The annual fees in this section would be revised to reflect the FY 1993 budgeted costs. Paragraphs (a), (b)(3), (c)(2), (d), and (e) would be revised to comply with the requirement of OBRA–90 to recover approximately 100 percent of the NRC budget for FY 1993. Table IV shows the budgeted costs that have been allocated to operating power reactors. They have been expressed in terms of the NRC's FY 1993 programs and program elements. The resulting total base annual fee amount for power reactors is also shown. On the average, the power reactor base annual fees for FY 1993 have increased approximately 2.2 percent above the FY 1992 annual fees.

TABLE IV.—ALLOCATION OF NRC FY 1993 BUDGET TO POWER REACTORS BASE FEES[1]

[Dollars in thousands]

	Program element total		Allocated to power reactors	
	Propgram support	direct FTE	Program support	Direct FTE
Reactor Safety and Safeguards Regulation (RSSR)				
Standard reactor designs	$6,663	111.2	$6,363	103.5
Reactor license renewal	913	14.6	913	14.6
Reactor and site licensing	1,015	24.4	995	24.1
Resident inspections	.....	204.0	.....	204.0
Region-based inspections	4,628	245.5	4,628	240.3
Interns (HQ and regions)	.....	45.0	.....	45.0
Special inspections	3,157	60.7	3,157	60.7
License maintenance and safety evaluations	8,606	222.3	8,606	222.3
Plant performance	860	55.1	860	55.1
Human performance	6,920	61.0	6,470	56.4
Other safety reviews and assistance	988	36.1	658	29.7
RSSR Program total	.....	.....	32,650	1,055.7
Reactor Safety Research (RSR)				
Standard reactor designs	20,200	29.6	20,200	29.6
Reactor aging and license renewal	22,293	13.4	21,493	13.3
Plant performance	2,800	3.0	2,800	3.0
Human reliability	6,150	7.2	6,150	7.2
Reactor accident analysis	22,102	26.0	22,102	26.0
Safety issue resolution and regulatory improvements	11,590	38.5	11,590	38.5
RSR Program total	.....	.....	84,335	117.6
Nuclear Material and Low Level (NMLL)				
NMLL (NMSS):				
Safeguards licensing and inspection	440	19.4	.....	.1
Threat and event assess./international safeguards	1,600	12.7	1,275	6.1
Develop and implement inspection activities	0	2.3	0	1.3
Uranium recovery licensing and inspection	350	9.7	38	.2
Decommissioning	1,200	30.1	200	5.6
NMLL (RES):				
Environmental policy and decommissioning	1,925	9.0	825	3.8

TABLE IV.—ALLOCATION OF NRC FY 1993 BUDGET TO POWER REACTORS BASE FEES[1]—Continued

[Dollars in thousands]

	Program element total		Allocated to power reactors	
	Propgram support	direct FTE	Program support	Direct FTE
NMLL Program total	.....	.....	$2,338	17.1
Reactor Special and Independent Reviews, Investigations, and Enforcement				
Diagnostic evaluations	350	7.0	350	7.0
Incident investigations	25	1.0	25	1.0
NRC incident response	2,005	24.0	2,005	24.0
Operational experience evaluation	5,360	34.0	5,360	34.0
Committee on review generic requirements	.....	2.0	.....	2.0
RSIRIE Program Total	.....	.....	$7,740	68.0
Grand total	.....	.....	$127,063	1,258.4
Total base fee amount allocated to power reactors: $416.4 million[2]				
Less estimated Part 170 power reactor fees: $100.0 million				
Part 171 base fees for operating power reactors: $316.4 million.				

[1] Base annual fees include all costs attributable to the operating power reactor class of licensees. The base fees do not include costs allocated to power reactors for policy reasons.

[2] Amount is obtained by multiplying the direct FTE times the rate per FTE and adding the program support funds.

Based on the information in Table IV, the base annual fees to be assessed for FY 1993 are the amounts shown in Table V below for each nuclear power operating license.

TABLE V.—BASE ANNUAL FEES FOR OPERATING POWER REACTORS

Reactors	Containment type	Annual fee
Westinghouse:		
1. Beaver Valley 1	PWR large dry containment	$2,906,000
2. Beaver Valley 2	do	2,906,000
3. Braidwood 1	do	2,906,000
4. Braidwood 2	do	2,906,000
5. Byron 1	do	2,906,000
6. Bryon 2	do	2,906,000
7. Callaway 1	do	2,906,000
8. Comanche Peak 1	do	2,906,000
9. Diablo Canyon 1	do	2,906,000
10. Diablo Canyon 2	do	2,903,000
11. Farley 1	do	2,903,000
12. Farley 2	do	2,906,000
13. Ginna	do	2,906,000
14. Haddam Neck	do	2,906,000
15. Harris 1	do	2,906,000
16. Indian Point 2	do	2,906,000
17. Indian Point 3	do	2,906,000
18. Kewaunee	do	2,906,000
19. Millstone 3	do	2,906,000
20. North Anna 1	do	2,906,000
21. North Anna 2	do	2,906,000
22. Point Beach 1	do	2,906,000
23. Point Beach 2	do	2,906,000
24. Prairie Island 1	do	2,906,000
25. Prairie Island 2	do	2,906,000
26. Robinson 2	do	2,906,000
27. Salem 1	do	2,906,000
28. Salem 2	do	2,906,000
29. San Onofre 1	do	2,903,000
30. Seabrook 1	do	2,906,000
31. South Texas 1	do	2,906,000
32. South Texas 2	do	2,906,000
33. Summer 1	do	2,906,000
34. Surry 1	do	2,906,000
35. Surry 2	do	2,906,000
36. Trojan	do	2,903,000
37. Turkey Point 3	do	2,906,000
38. Turkey Point 4	do	2,906,000

TABLE V.—BASE ANNUAL FEES FOR OPERATING POWER REACTORS—Continued

Reactors	Containment type	Annual fee
39. Vogtle 1	do	2,906,000
40. Vogtle 2	do	2,906,000
41. Wolf Creek 1	do	2,906,000
42. Zion 1	do	2,906,000
43. Zion 2	do	2,906,000
44. Catawba 1	PWR—Ice Condenser	2,898,000
45. Catawba 2	do	2,898,000
46. Cook 1	do	2,898,000
47. Cook 2	do	2,898,000
48. McGuire 1	do	2,898,000
49. McGuire 2	do	2,898,000
50. Sequoyah 1	do	2,898,000
51. Sequoyah 2	do	2,898,000
Combustion Engineering:		
1. Arkansas 2	PWR Large dry containment	2,947,000
2. Calvert Cliffs 1	do	2,947,000
3. Calvert Cliffs 2	do	2,947,000
4. Ft. Calhoun 1	do	2,947,000
5. Maine Yankee	do	2,947,000
6. Millstone 2	do	2,947,000
7. Palisades	do	2,947,000
8. Palo Verde 1	do	2,943,000
9. Palo Verde 2	do	2,943,000
10. Palo Verde 3	do	2,943,000
11. San Onofre 2	do	2,943,000
12. San Onofre 3	do	2,943,000
13. St. Lucie 1	do	2,947,000
14. St. Lucie 2	do	2,947,000
15. Waterford 3	do	2,947,000
Babcock & Wilcox:		
1. Arkansas 1	do	2,898,000
2. Crystal River 3	do	2,898,000
3. Davis Besse 1	do	2,898,000
4. Oconee 1	do	2,898,000
5. Oconee 2	do	2,898,000
6. Oconee 3	do	2,898,000
7. Three Mile Island 1	do	2,898,000
General Electric:		
1. Browns Ferry 1	Mark I	2,873,000
2. Browns Ferry 2	do	2,873,000
3. Browns Ferry 3	do	2,873,000
4. Brunswick 1	do	2,873,000
5. Brunswick 2	do	2,873,000
6. Clinton 1	Mark III	2,965,000
7. Cooper	Mark I	2,873,000
8. Dresden 2	do	2,873,000
9. Dresden 3	do	2,873,000
10. Duane Arnold	do	2,873,000
11. Fermi 2	do	2,873,000
12. Fitzpatrick	do	2,873,000
13. Grand Gulf 1	Mark III	2,965,000
14. Hatch 1	Mark I	2,873,000
15. Hatch 2	do	2,873,000
16. Hope Creek 1	do	2,873,000
17. LaSalle 1	Mark II	2,873,000
18. LaSalle 2	do	2,873,000
19. Limerick 1	do	2,873,000
20. Limerick 2	do	2,873,000
21. Millstone 1	Mark I	2,873,000
22. Monticello	do	2,873,000
23. Nine Mile Point 1	do	2,873,000
24. Nine Mile Point 2	Mark II	2,873,000
25. Oyster Creek	Mark I	2,873,000
26. Peach Bottom 2	do	2,873,000
27. Peach Bottom 3	do	2,873,000
28. Perry 1	Mark III	2,965,000
29. Pilgrim	Mark I	2,873,000
30. Quad Cities 1	do	2,873,000
31. Quad Cities 2	do	2,873,000
32. River Bend 1	Mark III	2,965,000
33. Susquehanna 1	Mark II	2,873,000
34. Susquehanna 2	do	2,873,000

TABLE V.—BASE ANNUAL FEES FOR OPERATING POWER REACTORS—Continued

Reactors	Containment type	Annual fee
35. Vermont Yankee	Mark I	2,873,000
36. Washington Nuclear 2	Mark II	2,873,000
Other Reactors:		
1. Big Rock Point	GE dry containment	2,873,000
2. Three Mile Island 2	B&W PWR-Dry containment	2,898,000

The "Other Reactors" listed in Table V have not been included in the fee base because historically they have been granted either full or partial exemptions from the annual fees. The NRC proposes to grant a partial exemption in FY 1993 to Big Rock Point, a smaller older reactor, and grant a full exemption for Three Mile Island 2 because the authority to operate TMI–2 was revoked in 1979.

Paragraph (b)(3) would be revised to change the fiscal year references from FY 1992 to FY 1993. Paragraph (c)(2) would be amended to show the amount of the surcharge for FY 1993, which will be added to the base annual fee for each operating power reactor shown in Table V. This surcharge would recover those NRC budgeted costs that are not directly or solely attributable to operating power reactors, but nevertheless must be recovered to comply with the requirements of OBRA–90. The NRC has continued its previous policy decision to recover these costs from operating power reactors.

The FY 1993 budgeted costs related to the additional charge and the amount of the charge are calculated as follows:

Category of costs	FY 1993 budgeted costs ($ in millions)
1. Activities not attributable to an existing NRC licensee or class of licensee:	
a. reviews for DOE/DOD reactor projects, West Valley Demonstration Project, DOE Uranium Mill Tailing Radiation Control Act (UMTRCA) actions	$5.2
b. international cooperative safety program and international safeguards activities; and	8.4
c. 67% of low level waste disposal generic activities	6.3
2. Activities not assessed Part 170 licensing and inspection fees or Part 171 annual fees based on Commission policy:	
a. activities associated with nonprofit educational institutions; and	7.1
b. costs not recovered from Part 171 for small entities	4.5
Total Budgeted Costs	31.5

The annual additional charge is determined as follows:

Total budgeted costs÷Total number of operating reactors=$31.5 million÷109=$289,000 per operating power reactor.

On the basis of this calculation, an operating power reactor, Beaver Valley 1, for example, would pay a base annual fee of $2,906,000 and an additional charge of $289,000 for a total annual fee of $3,195,000 for FY 1993.

Paragraph (d) would be revised to show, in summary form, the amount of the total FY 1993 annual fee, including the surcharge, to be assessed for each major type of operating power reactor.

Paragraph (e) would be revised to show the amount of the FY 1993 annual fee for non-power (test and research) reactors. In FY 1993, $520,000 in costs are attributable to those commercial and non-exempt Federal government organizations that are licensed to operate test and research reactors. Applying these costs uniformly to those nonpower reactors which are not exempt from fees results in an annual fee of $65,000 per operating license. The Energy Policy Act provided for an exemption for certain Federally owned research reactors that are used primarily for educational training and academic research purposes where the design of the reactor satisfies certain technical specifications set forth in the legislation. The NRC has granted an exemption from annual fees for FY 1992 and FY 1993 to the Veterans Administration Medical Center, Omaha, Nebraska, for its research reactor.

Section 171.16 Annual Fees: Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC

Paragraph (d) would be revised to reflect the FY 1993 budgeted costs for materials licensees, including Government agencies licensed by the NRC. These fees are necessary to recover the FY 1993 generic costs totalling $55.1 million applicable to fuel facilities, uranium recovery facilities, holders of transportation certificates and QA program approvals, and other materials licensees, including holders of sealed source and device registrations.

Tables VI and VII show the NRC program elements and resources that are attributable to fuel facilities and materials users, respectively. The costs attributable to the uranium recovery class of licensees are those associated with uranium recovery licensing and inspection. For transportation, the costs are those budgeted for transportation research, licensing, and inspection. Similarly, the budgeted costs for spent fuel storage are those for spent fuel storage research, licensing, and inspection.

TABLE VI.—Allocation of NRC FY 1993 Budget to Fuel Facility Base Fees [1]

	Total program element		Allocated to fuel facility	
	Program support $,K	FTE	Program support $,K	FTE
NMLL (Research)	$1,640	5.3	$350	1.1
Radiation Protection/Health Effects:				
Environmental Policy and Decommissioning	1,925	9.0	100	.4
NMLL (Res) Program Total	.....	.....	450	1.5
NMLL (NMSS):				
Fuel Facilities Lic./Inspections	4,800	157.9	1,510	39.4
Event Evaluation	.....	15.3	.....	3.8
Safeguards Licensing/Inspection	440	19.4	440	17.3
Threat and Event Assessment	1,600	12.7	123	1.5
Decommissioning	1,050	21.8	190	5.1
Uranium Recovery (DAM SAFETY)	350	9.7	6	.....
NMLL (NMSS) Program Total	.....	.....	2,269	67.1
NMLL (MSIRIE)				
Incident Response	.....	3.0	.....	1.0
Total NMLL	.....	.....	2,719	69.6

Total Base Fee Amount Allocated to Fuel Facilities	$18.7 million.[2]
Less Part 170 Fuel Facility Fees	4.3 million.[2]
Part 171 Base Fees for Fuel Facilities	14.4 million.

[1] Base annual fee includes all costs attributable to the fuel facility class of licensees. The base fee does not include costs allocated to fuel facilities for policy reasons.
[2] Amount is obtained by multiplying the direct FTE times the rate per FTE and adding the program support funds.

TABLE VII.—ALLOCATION OF FY 1993 BUDGET TO MATERIAL USERS BASE FEES [1]

	Total		Allocated to materials users	
	Program support $,K	FTE	Program support $,K	FTE
NMLL (Research):				
Materials Licensee Performance	$550	.4	$495	.4
Materials Regulatory Standards	1,000	12.1	854	10.3
Radiation Protection/Health Effects	1,640	5.3	1,161	3.8
Environmental Policy and Decommissioning	1,925	9.0	900	4.3
Total NMLL (Res)	.....	.....	$3,410	18.8
NMLL (NMSS):				
Licensing/Inspection of Materials Users	$2,300	92.6	2,070	93.3
Event Evaluation	.....	15.3	.....	11.9
Threat and Event Assessment	1,600	12.7	89	.....
Decommissioning	1,050	21.8	684	16.6
Low level waste—on site disposal	850	17.0	225	1.9
Total NMLL (NMSS)	.....	.....	$3,068	123.7
NMLL (MSIRIE):				
Analysis and Evaluation of Operational Data	256	8.0	113	4.5
Total NMLL Program	.....	.....	$6,591	147.0

Base Amount Allocated to Materials Users ($,M)	$40.4 million.[2]
Less Part 170 Material Users Fees	$5.3 million.
Part 171 Base Fees for Material Users	$35.1 million.

[1] Base annual fee includes all costs attributable to the materials class of licensees. The base fee does not include costs allocated to materials licensees for policy reasons.
[2] Amount is obtained by multiplying the direct FTE times the rate per FTE and adding the program support funds.

The allocation of the NRC's $14.4 million in budgeted costs to the individual fuel facilities is based, as in FY 1991 and FY 1992, primarily on the conferees' guidance that licensees who require the greatest expenditure of NRC resources should pay the greatest annual fee. Because the two high-enriched fuel manufacturing facilities possess strategic quantities of nuclear materials, more NRC generic safety and safeguards costs (e.g., physical security) are attributable to these facilities.

Using this approach, the base annual fee for each facility is shown below.

	Annual fee—safeguards and safety
High Enriched Fuel:	
Nuclear Fuel Services	$3,196,000
Babcock and Wilcox	3,196,000
Subtotal	6,392,000
Low Enriched Fuel:	
Siemens Nuclear Power	1,219,000
Babcock and Wilcox	1,219,000
General Electric	1,219,000
Westinghouse	1,219,000
Combustion Engineering (Hematite)	1,219,000
Subtotal	6,095,000
UF_6 Conversion:	
Allied Signal Corp.	662,000
Sequoyah Fuels Corp.	662,000
Subtotal	1,324,000
Other fuel facilities (5 facilities at $122,000 each)	610,000
Total	14,421,000

One of the Combustion Engineering's (CE) low enriched uranium fuel facilities has not been included in the fee base because of the D.C. Circuit Court of Appeals decision of March 16, 1993, that directed the NRC to grant an exemption for FY 1991 to Combustion Engineering for one of its two facilities. As a result of the Court's decision, the NRC proposes to grant an exemption for one of CE's low enriched uranium fuel facilities for FY 1992 and FY 1993. The NRC will therefore calculate its FY 1993 annual fees for the low enriched fuel category by dividing its budgeted costs among five licenses rather than six licenses as done previously.

The allocation of the costs attributable to uranium recovery is also based on the conferees' guidance that licensees who require the greatest expenditure of NRC resources should pay the greatest annual fee. It is estimated that approximately 50 percent of the $465,000 for uranium recovery is attributable to uranium mills (Class I facilities). Approximately 27 percent of the $465,000 for uranium recovery is attributable to those solution mining licensees who do not generate uranium mill tailings (Class II facilities). The remaining 23 percent is allocated to the other uranium recovery facilities (e.g. extraction of metals and rare earths). The resulting annual fees for each class of licensee are:

Class I facilities	$58,100
Class II facilities	25,400
Other facilities	21,100

For spent fuel storage licenses, the generic costs of $733,000 have been spread uniformly among those licensees who hold specific or general licenses for receipt and storage of spent fuel at an ISFSI. This results in an annual fee of $146,600.

To equitably and fairly allocate the $35.1 million attributable to the approximately 6,800 diverse material users and registrants, the NRC has continued to base the annual fee on the Part 170 application and inspection fees. Because the application and inspection fees are indicative of the complexity of the license, this approach continues to provide a proxy for allocating the costs to the diverse categories of licensees based on how much it costs NRC to regulate each category. The fee calculation also continues to consider the inspection frequency because the inspection frequency is indicative of the safety risk and resulting regulatory costs associated with the categories of licensees. In summary, the annual fee for these categories of licenses is developed as follows:

Annual Fee = (Application Fee + Inspection Fee/Inspection Priority) × Constant + (Unique Category Costs).

The constant is the multiple necessary to recover $35.1 million and is 2.3 for FY 1993. The unique costs are any special costs that the NRC has budgeted for a specific category of licensees. For FY 1993, unique costs of approximately $1.9 million were identified for the medical improvement program which is attributable to medical licensees; about $115,000 in costs were identified as being attributable to radiography licensees; and about $115,000 was identified as being attributable to irradiator licensees. The changes to materials annual fees for FY 1993 varies compared to the FY 1992 annual fees. Some of the annual fees decrease while other annual fees increase. There are three reasons for the changes in the fees compared to FY 1992. First, the FY 1993 budgeted amount attributable to materials licensees is about 12 percent higher than the FY 1992 amount. Second, the number of licensees to be assessed annual fees in FY 1993 has decreased about 4 percent below the FY 1992 levels (from about 7,100 to about 6,800). Third, the changes in the 10 CFR Part 170 license application and inspection fees cause a redistribution of the costs on which the annual fees are based, since these Part 170 fees are used as a proxy to determine the annual fees. The materials fees must be established at the proposed levels in order to comply with the mandate of OBRA–90 to recover approximately 100 percent of the NRC's FY 1993 budget authority. A materials licensee may pay a reduced annual fee if the licensee qualifies as a small entity under the NRC's size standards and certifies that it is a small entity on NRC Form 526.

To recover the $4.4 million attributable to the transportation class of licensees, about $1.0 million will be assessed to the Department of Energy (DOE) to cover all of its transportation casks under Category 18. The remaining transportation costs for generic activities ($3.4 million) are allocated to holders of approved QA plans. The annual fee for approved QA plans is $67,400 for users and fabricators and $1,000 for users only.

The amount or range of the FY 1993 base annual fees for all materials licensees is summarized as follows:

MATERIALS LICENSES BASE ANNUAL FEE RANGES

Category of license	Annual fees
Part 70—High enriched fuel.	$3.2 million.
Part 70—Low enriched fuel.	1.2 million.
Part 40—UF_6 conversion.	0.6 million.
Part 40—Uranium recovery.	21,100 to 58,100.
Part 30—Byproduct Material.	680 to 26,4001.[1]
Part 71—Transportation of Radioactive Material.	1,000 to 67,400
Part 72—Independent Storage of Spent Nuclear Fuel.	146,600.

[1] Excludes the annual fee for a few military "master" materials licenses of broad-scope issued to Government agencies which is $358,400.

Irradiator fee categories 3F and 3G are being broadened to include underwater irradiators for irradiation of materials when the source is not exposed for irradiation purposes. Although the sources are not removed from their shielding for irradiation purposes, underwater irradiators are not self-shielded as are the small irradiators in fee Category 3E. The underwater irradiators are large irradiators, and possession limits of thousands of curies are authorized in the licenses. The design of the facility is important to the safe use of both exposed source irradiators and underwater irradiators, and 10 CFR 36 applies the same requirements to the underwater irradiators where the source is not exposed for irradiation as to the exposed source irradiators.

A new Category 4D is proposed to specifically segregate and identify those licenses which authorize the receipt, possession and disposal of byproduct

material, as defined by Section 11.e.(2) of the Atomic Energy Act, from other persons. This proposed change is based on the NRC's recognition of potential increased activity related to disposal of 11.e.(2) byproduct material and to better distinguish this unique category of license.

Paragraph (e) would be amended to establish the additional charge which is to be added to the base annual fees shown in paragraph (d) of this proposed rule. The alternatives the NRC is considering in this area are discussed at some length in Section II of this notice. This surcharge will continue to be shown, for convenience, with the applicable categories in paragraph (d). Although these NRC LLW disposal regulatory activities are not directly attributable to regulation of NRC materials licensees, the costs nevertheless must be recovered in order to comply with the requirements of OBRA-90. The NRC has continued the previous policy decision to use the volume of waste disposed of by materials licensees to determine the percent of these LLW costs to be recovered from materials licensees. The additional charge will recover approximately 33 percent of the NRC budgeted costs of $9.4 million relating to LLW disposal generic activities because these materials licensees disposed of 33 percent of the total LLW that was disposed of by NRC licensees in 1990–1991. This percentage calculation for FY 1993 differs from the calculation for FY 1991 and FY 1992 because LLW disposed by Agreement State licensees was subtracted from the total prior to calculation of the percentage. The FY 1993 budgeted costs related to the additional charge and the amount of the charge are calculated as follows:

Category of costs	FY 1993 budgeted costs ($ in millions)
1. Activities not attributable to an existing NRC licensee or class of licensee, i.e., 33% of LLW disposal generic activities.	$3.1

Of the $3.1 million in budgeted costs shown above for LLW activities, 45 percent of the amount ($1.4 million) would be allocated to fuel facilities included in Part 171 (14 facilities), as follows: $100,000 per HEU, LEU, UF6 facility and for each of the other 5 fuel facilities. The remaining 55 percent ($1.7 million) would be allocated to the material licensees in categories that generate low level waste (1,049 licensees) as follows: $1,600 per materials license except for those in Category 17. Those licensees that generate a significant amount of low level waste for purposes of the calculation of the $1,600 surcharge are in fee Categories 1.B, 1.D, 2.C, 3.A, 3.B, 3.C, 3.L, 3.M, 3.N, 4.A, 4.B, 4.C, 4.D, 5.B, 6.A, and 7.B. The surcharge for Category 17, which also generate and/or dispose of low level waste, is $23,700.

Of the $5.3 million not recovered from small entities, $0.8 million would be allocated to fuel facilities and other materials licensees. This results in a surcharge of $120 per category for each licensee that is not eligible for the small entity fee.

On the basis of this calculation, a fuel facility, a high enriched fuel fabrication licensee, for example, would pay a base annual fee of $3,196,000 and an additional charge of $289,000 for LLW activities and small entity costs. A medical center with a broad-scope program would pay a base annual fee of $26,400 and an additional charge of $1,720, for a total annual fee of $28,120 for FY 1993.

Section 171.19 Payment

This section would be revised to give credit for those partial payments made by certain licensees in FY 1993 toward their FY 1993 annual fees. The NRC anticipates that the first, second, and third quarterly payments for FY 1993 will have been made by operating power reactor licensees and some materials licensees before the final rule is effective. Therefore, NRC will credit payments received for those three quarters toward the total annual fee to be assessed. The NRC will adjust the fourth quarterly bill in order to recover the full amount of the revised annual fee. As in FY 1992, payment of the annual fee is due on the effective date of the rule and interest accrues from the effective date of the rule. However, interest will be waived if payment is received within 30 days from the effective date of the rule.

The NRC notes that many licensees have indicated during the past two years that although they held a valid NRC license authorizing the possession and use of special nuclear, source, or byproduct material, they were in fact either not using the material to conduct operations or had disposed of the material and no longer needed the license. In particular, this issue has been raised by certain uranium mill licensees who have mills not currently in operation. In responding to licensees about this matter, the NRC has stated that annual fees are assessed based on whether a licensee holds a valid NRC license that authorizes possession and use of radioactive material. Whether or not a licensee is actually conducting operations using the material is a matter of licensee discretion. The NRC cannot control whether a licensee elects to possess and use radioactive material once it receives a license from the NRC. Therefore, the NRC reemphasizes that the annual fees will be assessed based on whether a licensee holds a valid NRC license that authorizes possession and use of radioactive material. To remove any uncertainty, the NRC is proposing minor clarifying amendments to 10 CFR 171.16, footnotes 1 and 7.

V. Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental impact assessment has been prepared for the proposed regulation.

VI. Paperwork Reduction Act Statement

This proposed rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

VII. Regulatory Analysis

With respect to 10 CFR part 170, this proposed rule was developed pursuant to title V of the Independent Offices Appropriation Act of 1952 (IOAA) (31 U.S.C. 9701) and the Commission's fee guidelines. When developing these guidelines the Commission took into account guidance provided by the U.S. Supreme Court on March 4, 1974, in its decision of *National Cable Television Association, Inc.* v. *United States*, 415 U.S. 36 (1974) and *Federal Power Commission* v. *New England Power Company*, 415 U.S. 345 (1974). In these decisions, the Court held that the IOAA authorizes an agency to charge fees for special benefits rendered to identifiable persons measured by the "value to the recipient" of the agency service. The meaning of the IOAA was further clarified on December 16, 1976, by four decisions of the U.S. Court of Appeals for the District of Columbia, *National Cable Television Association* v. *Federal Communications Commission*, 554 F.2d 1094 (D.C. Cir. 1976); *National Association of Broadcasters* v. *Federal Communications Commission*, 554 F.2d 1118 (D.C. Cir. 1976); *Electronic Industries Association* v. *Federal Communications Commission*, 554 F.2d

1109 (D.C. Cir. 1976) and *Capital Cities Communication, Inc.* v. *Federal Communications Commission*, 554 F.2d 1135 (D.C. Cir. 1976). These decisions of the Courts enabled the Commission to develop fee guidelines that are still used for cost recovery and fee development purposes.

The Commission's fee guidelines were upheld on August 24, 1979, by the U.S. Court of Appeals for the Fifth Circuit in *Mississippi Power and Light Co.* v. *U.S. Nuclear Regulatory Commission*, 601 F.2d 223 (5th Cir. 1979), *cert. denied*, 444 U.S. 1102 (1980). The Court held that—

(1) The NRC had the authority to recover the full cost of providing services to identifiable beneficiaries;

(2) The NRC could properly assess a fee for the costs of providing routine inspections necessary to ensure a licensee's compliance with the Atomic Energy Act and with applicable regulations;

(3) The NRC could charge for costs incurred in conducting environmental reviews required by NEPA;

(4) The NRC properly included the costs of uncontested hearings and of administrative and technical support services in the fee schedule;

(5) The NRC could assess a fee for renewing a license to operate a low-level radioactive waste burial site; and

(6) The NRC's fees were not arbitrary or capricious.

With respect to 10 CFR part 171, on November 5, 1990, the Congress passed Public Law 101–508, the Omnibus Budget Reconciliation Act of 1990 (OBRA–90). For FYs 1991 through 1995, OBRA–90 requires that approximately 100 percent of the NRC budget authority be recovered through the assessment of fees. To accomplish this statutory requirement, the NRC, in accordance with § 171.13, is publishing the proposed amount of the FY 1993 annual fees for operating reactor licensees, fuel cycle licensees, materials licensees, and holders of Certificates of Compliance, registrations of sealed source and devices and QA program approvals, and Government agencies. OBRA–90 and the Conference Committee Report specifically state that—

(1) The annual fees be based on the Commission's FY 1993 budget of $540.0 million less the amounts collected from Part 170 fees and the funds directly appropriated from the NWF to cover the NRC's high level waste program;

(2) The annual fees shall, to the maximum extent practicable, have a reasonable relationship to the cost of regulatory services provided by the Commission; and

(3) The annual fees be assessed to those licensees the Commission, in its discretion, determines can fairly, equitably, and practicably contribute to their payment.

Therefore, when developing the annual fees for operating power reactors the NRC continued to consider the various reactor vendors, the types of containment, and the location of the operating power reactors. The annual fees for fuel cycle licensees, materials licensees, and holders of certificates, registrations and approvals and for licenses issued to Government agencies take into account the type of facility or approval and the classes of the licensees.

10 CFR part 171, which established annual fees for operating power reactors effective October 20, 1986 (51 FR 33224; September 18, 1986), was challenged and upheld in its entirety in *Florida Power and Light Company* v. *United States*, 846 F.2d 765 (D.C. Cir. 1988), *cert. denied*, 490 U.S. 1045 (1989).

10 CFR Parts 170 and 171, which established fees based on the FY 1989 budget, were also legally challenged. As a result of the Supreme Court decision in *Skinner* v. *Mid-American Pipeline Co.*, 109 S. Ct. 1726 (1989), and the denial of certiorari in *Florida Power and Light*, all of the lawsuits were withdrawn.

The NRC's FY 1991 annual fee rule was largely upheld recently by the D.C. Circuit Court of Appeals in *Allied Signal* v. *NRC*, discussed extensively earlier in this notice.

VIII. Regulatory Flexibility Analysis

The NRC is required by the Omnibus Budget Reconciliation Act of 1990 to recover approximately 100 percent of its budget authority through the assessment of user fees. OBRA–90 further requires that the NRC establish a schedule of charges that fairly and equitably allocates the aggregate amount of these charges among licensees.

This proposed rule establishes the schedules of fees that are necessary to implement the Congressional mandate for FY 1993. The proposed rule results in an increase in the fees charged to most licensees, and holders of certificates, registrations, and approvals, including those licensees who are classified as small entities under the Regulatory Flexibility Act. The Regulatory Flexibility Analysis, prepared in accordance with 5 U.S.C. 604, is included as appendix A to this proposed rule.

IX. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and that a backfit analysis is not required for this proposed rule. The backfit analysis is not required because these amendments do not require the modification of or additions to systems, structures, components, or design of a facility or the design approval or manufacturing license for a facility or the procedures or organization required to design, construct or operate a facility.

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Byproduct material, Holders of certificates, registrations, approvals, Intergovernmental relations, Non-payment penalties, Nuclear materials.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 170, and 171.

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

1. The authority citation for part 170 is revised to read as follows:

Authority: 31 U.S.C. 9701; sec. 301, Pub. L. 92–314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 205, Pub. L. 101–576, 104 Stat. 2842 (31 U.S.C. 902).

2. A new § 170.8 is added to read as follows:

§ 170.8 Information collection requirements: OMB approval.

This part contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

3. Section 170.20 is revised to read as follows:

§ 170.20 Average cost per professional staff-hour.

Fees for permits, licenses, amendments, renewals, special projects, Part 55 requalification and replacement examinations and tests, other required reviews, approvals, and inspections under §§ 170.21 and 170.31 that are

based upon the full costs for the review or inspection will be calculated using a professional staff-hour rate equivalent to the sum of the average cost to the agency for a professional staff member, including salary and benefits, administrative support, travel, and certain program support. The professional staff-hour rate for the NRC based on the FY 1993 budget is $132 per hour.

4. In § 170.21, the introductory paragraph, Category K, and footnotes 1 and 2 to the table are revised to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

Applicants for construction permits, manufacturing licenses, operating licenses, import and export licenses, approvals of facility standard reference designs, requalification and replacement examinations for reactor operators, and special projects and holders of construction permits, licenses, and other approvals shall pay fees for the following categories of services.

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility categories and type of	Fees [1, 2]
* * * * * * *	
K. Import and export licenses:	
Licenses for the import and export only of production and utilization facilities or the import and export only of components for production and utilization facilities issued pursuant to 10 CFR Part 110.	
1. Application for import or export of reactors and other facilities and components which must be reviewed by the Commission and the Executive Branch, for example, actions under 10 CFR 110.40(b).	
Application-new license	$8,600
Amendment	8,600
2. Application for import or export of reactor components and initial exports of other equipment requiring Executive Branch review only, for example, those actions under 10 CFR 110.41(a)(1) (8).	
Application-new license	5,300
Amendment	5,300
3. Application for export of components requiring foreign government assurances only.	
Application-new license	3,300
Amendment	3,300
4. Application for export or import of other facility components and equipment not requiring Commission review, Executive Branch review or foreign government assurances.	
Application-new license	1,300
Amendment	1,300
5. Minor amendment of any export or import license to extend the expiration date, change domestic information, or make other revisions which do not require analysis or review.	
Amendment	130

[1] Fees will not be charged for orders issued by the Commission pursuant to § 2.202 of this chapter or for amendments resulting specifically from the requirements of such Commission orders. Fees will be charged for approvals issued pursuant to a specific exemption provision of the Commission's regulations under Title 10 of the Code of Federal Regulations (e.g. §§ 50.12, 73.5) and any other sections now or hereafter in effect regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. Fees for licenses in this schedule that are initially issued for less than full power are based on review through the issuance of a full power license (generally full power is considered 100 percent of the facility's full rated power). Thus, if a licensee received a low power license or a temporary license for less than full power and subsequently receives full power authority (by way of license amendment or otherwise), the total costs for the license will be determined through that period when authority is granted for full power operation. If a situation arises in which the Commission determines that full operating power for a particular facility should be less than 100 percent of full rated power, the total costs for the license will be at that decided lower operating power level and not at the 100 percent capacity.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For those applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of this rule will be determined at the professional rates established for the June 20, 1984, January 30, 1989, July 2, 1990, July 10, 1991, and July 23, 1992 rules as appropriate. For those applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990, rules but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20. In no event will the total review costs be less than twice the hourly rate shown in § 170.20.

* * * * * * *

5. Section 170.31 is revised to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

Applicants for materials licenses, import and export licenses, and other regulatory services and holders of materials licenses, or import and export licenses shall pay fees for the following categories of services. This schedule includes fees for health and safety and safeguards inspections where applicable.

SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
1. Special nuclear material:	
A. Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U–235 in unsealed form or 200 grams or more of U–233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only:	
License, renewal, amendment	(6)
Inspections	(6)
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI):	
License, renewal, amendment	(6)
Inspections	(6)
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers: [4]	
Application—new license	$570
Renewal	670
Amendment	360
Inspections	660
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1A: [4]	
Application—new license	590
Renewal	420
Amendment	330
Inspections	1,100
E. Licenses for construction and operation of a uranium enrichment facility:	
Application	125,000
License, renewal, amendment	(6)
Inspections	(6)
2. Source material:	
A. Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode:	
License, renewal, amendment	(6)
Inspections	(6)
B. Licenses for possession and use of source material for shielding:	
Application—new license	220
Renewal	160
Amendment	260
Inspections	550
C. All other source material licenses:	
Application—new license	2,500
Renewal	1,300
Amendment	450
Inspections	2,500
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application—new license	2,600
Renewal	1,700
Amendment	460
Inspections	[5] 9,700
B. Other licenses for possession and use of byproduct material issued pursuant to Part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution:	
Application—new license	1,200
Renewal	2,200
Amendment	600
Inspections	[5] 3,000
C. Licenses issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material:	
Application—new license	3,500
Renewal	3,000
Amendment	490
Inspections	3,300
D. Licenses and approvals issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radio-pharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material:	
Application—new license	1,300
Renewal	540
Amendment	370
Inspections	3,000

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units):	
Application—new license	920
Renewal	750
Amendment	330
Inspections	1,200
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application—new license	1,300
Renewal	1,000
Amendment	330
Inspections	$1,300
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes.	
Application—new license	5,200
Renewal	4,700
Amendment	630
Inspections	4,100
H. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of Part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter:	
Application—new license	2,400
Renewal	2,300
Amendment	800
Inspections	1,100
I. Licenses issued pursuant to Subpart A of Part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of Part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of Part 30 of this chapter:	
Application—new license	4,600
Renewal	2,600
Amendment	1,100
Inspections	1,000
J. Licenses issued pursuant to Subpart B of Part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under Part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Part 31 of this chapter:	
Application—new license	2,100
Renewal	1,400
Amendment	370
Inspections	1,800
K. Licenses issued pursuant to Subpart B of Part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under Part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under Part 31 of this chapter:	
Application—new license	1,900
Renewal	1,400
Amendment	260
Inspections	1,000
L. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution:	
Application—new license	4,100
Renewal	2,200
Amendment	620
Inspections	4,700
M. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for research and development that do not authorize commercial distribution:	
Application—new license	1,400
Renewal	1,500
Amendment	690
Inspections	2,200
N. Licenses that authorize services for other licensees, except (1) licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P, and (2) licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, 4C, and 4D:	
Application—new license	1,700
Renewal	2,000
Amendment	670
Inspections	2,400

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
O. Licenses for possession and use of byproduct material issued pursuant to Part 34 of this chapter for industrial radiography operations:	
Application—new license	3,800
Renewal	2,800
Amendment	690
Inspections	[5] 3,500
P. All other specific byproduct material licenses, except those in Categories 4A through 9D:	
Application—new license	570
Renewal	670
Amendment	360
Inspections	1,500
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material:	
License, renewal, amendment	(6)
Inspections	(6)
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application—new license	3,900
Renewal	2,100
Amendment	420
Inspections	2,300
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material:	
Application—new license	1,500
Renewal	1,100
Amendment	250
Inspections	2,800
D. Licenses specifically authorizing the receipt from other persons of byproduct material as defined in section 11.e.(2) of the Atomic Energy Act for possession and disposal:	
License, renewal, amendment	(6)
Inspections	(6)
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies:	
Application—new license	3,700
Renewal	3,900
Amendment	650
Inspections	3,600
B. Licenses for possession and use of byproduct material for field flooding tracer studies:	
License, renewal, amendment	(6)
Inspections	1,300
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material:	
Application—new license	4,500
Renewal	2,900
Amendment	700
Inspections	4,500
7. Human use of byproduct, source, or special nuclear material:	
A. Licenses issued pursuant to Parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—new license	3,700
Renewal	1,200
Amendment	550
Inspections	2,200
B. Licenses of broad scope issued to medical institutions or two or more physicians pursuant to Parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—new license	2,600
Renewal	3,500
Amendment	500
Inspections	8,600

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
C. Other licenses issued pursuant to Parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices:	
Application—new license	1,100
Renewal	1,400
Amendment	500
Inspections	2,100
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities:	
Application—new license	660
Renewal	700
Amendment	480
Inspections	1,000
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution:	
Application—each device	3,700
Amendment—each device	1,300
Inspections	(6)
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices:	
Application—each device	1,800
Amendment—each device	660
Inspections	(6)
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution:	
Application—each source	790
Amendment—each source	260
Inspections	(6)
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel:	
Application—each source	400
Amendment—each source	130
Inspections	(6)
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers:	
Approval, Renewal, Amendment	(6)
Inspections	(6)
B. Evaluation of 10 CFR Part 71 quality assurance programs:	
Application—Approval	370
Renewal	280
Amendment	320
Inspections	(6)
11. Review of standardized spent fuel facilities:	
Approval, Renewal, Amendment	(6)
Inspections	(6)
12. Special projects:	
Approvals and preapplication/licensing activities	(6)
Inspections	(6)
13. A. Spent fuel storage cask Certificate of Compliance:	
Approvals	(6)
Amendments, revisions, and supplements	(6)
Reapproval	(6)
B. Inspections related to spent fuel storage cask Certificate of Compliance	(6)
C. Inspections related to storage of spent fuel under § 72.210 of this chapter	(6)
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities pursuant to 10 CFR Parts 30, 40, 70, and 72 of this chapter:	
Approval, Renewal, Amendment	(6)
Inspections	(6)
15. Import and Export licenses:	
Licenses issued pursuant to 10 CFR part 110 of this chapter for the import and export only of special nuclear material, source material, byproduct material, heavy water, tritium, or nuclear grade graphite.	
A. Application for import or export of HEU and other materials which must be reviewed by the Commission and the Executive Branch, for example, those actions under 10 CFR 110.40(b):	
Application—new license	8,600
Amendment	8,600
B. Application for import or export of special nuclear material, heavy water, nuclear grade graphite, tritium, and source material, and initial exports of materials requiring Executive Branch review only, for example, those actions under 10 CFR 110.41(a)(2)–(8).	
Application—new license	5,300

SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fee [2, 3]
Amendment	5,300
C. Application for export of routine reloads of LEU reactor fuel and exports of source material requiring foreign government assurances only.	
Application—new license	3,300
Amendment	3,300
D. Application for export or import of other materials not requiring Commission review, Executive Branch review or foreign government assurances.	
Application—new license	1,300
Amendment	1,300
E. Minor amendment of any export or import license to extend the expiration date, change domestic information or make other revisions which do not require analysis or review.	
Amendment	130
16. Reciprocity:	
Agreement State licensees who conduct activities in a non-Agreement State under the reciprocity provisions of 10 CFR 150.20.	
Application (each filing of Form 241)	700
Renewal	N/A
Amendment	N/A
Inspections	(7)

[1] *Types of fees*—Separate charges as shown in the schedule will be assessed for preapplication consultations and reviews and applications for new licenses and approvals, issuance of new licenses and approvals, amendments and renewals to existing licenses and approvals, safety evaluations of sealed sources and devices, and inspections. The following guidelines apply to these charges:

(a) *Application fees*—Applications for new materials licenses and approvals; applications to reinstate expired licenses and approvals except those subject to fees assessed at full cost; and applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20, must be accompanied by the prescribed application fee for each category, except that:

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category; and

(2) Applications for licenses under Category 1E must be accompanied by an application fee of $125,000.

(b) *License/approval/review fees*—Fees for applications for new licenses and approvals and for preapplication consultations and reviews subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 4D, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12 (b), (e), and (f).

(c) *Renewal/reapproval fees*—Applications for renewal of licenses and approvals must be accompanied by the prescribed renewal fee for each category, except that fees for applications for renewal of licenses and approvals subject to full cost fees (fee Categories 1A, 1B, 1E, 2A, 4A, 4D, 5B, 10A, 11, 12, 13A, and 14) are due upon notification by the Commission in accordance with § 170.12(d).

(d) *Amendment fees*—(1) Applications for amendments to licenses and approvals, except those subject to fees assessed at full costs, must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories in which case the amendment fee for the highest fee category would apply. For those licenses and approvals subject to full costs (fee Categories 1A, 1B, 1E, 2A, 4A, 4D, 5B, 10A, 11, 12, 13A, and 14), amendment fees are due upon notification by the Commission in accordance with § 170.12(c).

(2) An application for amendment to a materials license or approval that would place the license or approval in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for the new category.

(3) An application for amendment to a license or approval that would reduce the scope of a licensee's program to a lower fee category must be accompanied by the prescribed amendment fee for the lower fee category.

(4) Applications to terminate licenses authorizing small materials programs, when no dismantling or decontamination procedure is required, are not subject to fees.

(e) *Inspection fees*—Although a single inspection fee is shown in the regulation, separate charges will be assessed for each routine and nonroutine inspection performed, including inspections conducted by the NRC of Agreement State licensees who conduct activities in non-Agreement States under the reciprocity provisions of 10 CFR 150.20. Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. If a licensee holds more than one materials license at a single location, a fee equal to the highest fee category covered by the licenses will be assessed if the inspections are conducted at the same time, unless the inspection fees are based on the full cost to conduct the inspection. The fees assessed at full cost will be determined based on the professional staff time required to conduct the inspection multiplied by the rate established under § 170.20 to which any applicable contractual support services costs incurred will be added. Licenses covering more than one category will be charged a fee equal to the highest fee category covered by the license. Inspection fees are due upon notification by the Commission in accordance with § 170.12(g). See Footnote 5 for other inspection notes.

[2] Fees will not be charged for orders issued by the Commission pursuant to 10 CFR 2.202 or for amendments resulting specifically from the requirements of such Commission orders. However, fees will be charged for approvals issued pursuant to a specific exemption provision of the Commission's regulations under title 10 of the Code of Federal Regulations (e.g., 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections now or hereafter in effect) regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in Categories 9A through 9D.

[3] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For those applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of this rule will be determined at the professional rates established for the June 20, 1984, January 30, 1989, July 2, 1990, July 10, 1991, and July 23, 1992, rules, as appropriate. For those applications currently on file for which review costs have reached an applicable fee ceiling established by the June 20, 1984, and July 2, 1990 rules, but are still pending completion of the review, the cost incurred after any applicable ceiling was reached through January 29, 1989, will not be billed to the applicant. Any professional staff-hours expended above those ceilings on or after January 30, 1989, will be assessed at the applicable rates established by § 170.20, as appropriate, except for topical reports whose costs exceed $50,000. Costs which exceed $50,000 for each topical report, amendment, revision, or supplement to a topical report completed or under review from January 30, 1989, through August 8, 1991, will not be billed to the applicant. Any professional hours expended on or after August 9, 1991, will be assessed at the applicable rate established in § 170.20. In no event will the total review costs be less than twice the hourly rate shown in § 170.20.

[4] Licensees paying fees under Categories 1A, 1B, and 1E are not subject to fees under Categories 1C and 1D for sealed sources authorized in the same license except in those instances in which an application deals only with the sealed sources authorized by the license. Applicants for new licenses or renewal of existing licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application or renewal fee for fee Category 1C only.

[5] For a license authorizing shielded radiographic installations or manufacturing installations at more than one address, a separate fee will be assessed for inspection of each location, except that if the multiple installations are inspected during a single visit, a single inspection fee will be assessed.

[6] Full cost.

[7] Fees as specified in appropriate fee categories in this section.

PART 171—ANNUAL FEES FOR REACTOR OPERATING LICENSES, AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

6. The authority citation for part 171 is revised to read as follows:

Authority: Sec. 7601, Pub. L. 99–272, 100 Stat. 146, as amended by sec. 5601, Pub. L. 100–203, 101 Stat. 1330, as amended by Sec. 3201, Pub. L. 101–239, 103 Stat. 2106 as amended by sec. 6101, Pub. L. 101–508, 104 Stat. 1388, (42 U.S.C. 2213); sec. 301, Pub. L. 92–314, 86 Stat. 222 (42 U.S.C. 2201(w)); sec. 201, 88 Stat. 1242 as amended (42 U.S.C. 5841); sec. 2903, Pub. L. 102–486, 106 Stat. 3125, (42 U.S.C. 2214 note).

7. A new § 171.8 is added as follows:

§ 171.8 Information collection requirements: OMB approval.

This part contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3401 *et seq.*).

8. In § 171.11, paragraphs (a), (b), and (d) are revised to read as follows:

§ 171.11 Exemptions.

(a) An annual fee is not required for:

(1) A construction permit or license applied for by, or issued to, a nonprofit educational institution for a production or utilization facility, other than a power reactor, or for the possession and use of byproduct material, source material, or special nuclear material. This exemption does not apply to those byproduct, source, or special nuclear material licenses which authorize:

(i) Human use;

(ii) Remunerated services to other persons;

(iii) Distribution of byproduct material, source material, or special nuclear material or products containing byproduct material, source material, or special nuclear material; and

(iv) Activities performed under a Government contract.

(2) Federally owned research reactors used primarily for educational training and academic research purposes. For purposes of this exemption, the term research reactor means a nuclear reactor that—

(i) Is licensed by the Nuclear Regulatory Commission under Section 104 c. of the Atomic Energy Act of 1954 (42 U.S.C. 2134(c)) for operation at a thermal power level of 10 megawatts or less; and

(ii) If so licensed for operation at a thermal power level of more than 1 megawatt, does not contain—

(A) A circulating loop through the core in which the licensee conducts fuel experiments;

(B) A liquid fuel loading; or

(C) An experimental facility in the core in excess of 16 square inches in cross-section.

(b) The Commission may, upon application by an interested person or on its own initiative, grant an exemption from the requirements of this part that it determines is authorized by law or otherwise in the public interest. Requests for exemption must be filed with the NRC within 90 days from the effective date of the final rule establishing the annual fees for which the exemption is sought in order to be considered. Absent extraordinary circumstances, any exemption requests filed beyond that date will not be considered. The filing of an exemption request does not extend the date on which the bill is payable. Only timely payment in full ensures avoidance of interest and penalty charges. If a partial or full exemption is granted, any overpayment will be refunded. Requests for clarification of or questions relating to an annual fee bill must also be filed within 90 days from the date of the initial invoice to be considered.

* * * * *

(d) The Commission may grant a materials licensee an exemption from the annual fee only if it determines that the annual fee is not based on a fair and equitable allocation of the NRC costs. It is the intention of the Commission that such exemptions will be rarely granted. The following factors must be fulfilled as determined by the Commission for an exemption to be granted:

(1) There are data specifically indicating that the assessment of the annual fee will result in a significantly disproportionate allocation of costs to the licensee, or class of licensees; or

(2) There is clear and convincing evidence that the budgeted generic costs attributable to the class of licensees are neither directly or indirectly related to the specific class of licensee nor explicitly allocated to the licensee by Commission policy decisions; or

(3) Any other relevant matter that the licensee believes shows that the annual fee was not based on a fair and equitable allocation of NRC costs.

9. In § 171.15, paragraphs (a), (b)(3), (c)(2), (d), and (e) are revised to read as follows:

§ 171.15 Annual fees: Reactor operating licenses.

(a) Each person licensed to operate a power, test or research reactor shall pay the annual fee for each unit for which the person holds an operating license at any time during the Federal FY in which the fee is due, except for those test and research reactors exempted in § 171.11 (a)(1) and (a)(2).

(b) * * *

(3) Generic activities required largely for NRC to regulate power reactors, e.g., updating Part 50 of this chapter, or operating the Incident Response Center. The base FY 1993 annual fees for each operating power reactor subject to fees under this section and which must be collected before September 30, 1993, are shown in paragraph (d) of this section.

(c) * * *

(2) The FY 1993 surcharge to be added to each operating power reactor is $289,000. This amount is calculated by dividing the total cost for these activities ($31.5 million) by the number of operating power reactors (109).

(d) The FY 1993 Part 171 annual fees for operating power reactors are as follows:

PART 171 ANNUAL FEES BY REACTOR CATEGORY [1]

[Fees in Thousands]

Reactor vendor	Number	Base fee	Added charge	Total fee	Estimated collections
Babcock/Wilcox	7	$2,898	$289	$3,187	$22,309

PART 171 ANNUAL FEES BY REACTOR CATEGORY [1]—Continued

[Fees in Thousands]

Reactor vendor	Number	Base fee	Added charge	Total fee	Estimated collections
Combustion Eng.	15	2,947	289	3,236	48,540
GE Mark I	24	2,873	289	3,162	75,888
GE Mark II	8	2,873	289	3,162	25,296
GE Mark III	4	2,965	289	3,254	13,016
Westinghouse	51	2,906	289	3,195	162,945
Totals	109				347,994

[1] Fees assessed will vary for plants West of the Rocky Mountains and for Westinghouse plants with ice condensers.

(e) The annual fees for licensees authorized to operate a nonpower (test and research) reactor licensed under Part 50 of this chapter except for those reactors exempted from fees under § 171.11(a), are as follows:

Research reactor—$65,000
Test reactor—$65,000

* * * * *

10. In § 171.16, the introductory text of paragraph (c) and paragraphs (c)(4), (d), and (e) are revised to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals and government agencies licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification, the licensee may pay reduced annual fees for FY 1993 as follows:

	Maximum annual fee per licensed category
Small Businesses and Small Not-For-Profit Organizations (Gross Annual Receipts):	
$250,000 to $3.5 million	$1,800
Less than $250,000	400
Private Practice Physicians (Gross Annual Receipts):	
$250,000 to $1.0 million	1,800
Less than $250,000	400
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 50,000	1,800
Less than 20,000	400
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Less.	1,800

* * * * *

(4) The maximum annual fee (base annual fee plus surcharge) a small entity is required to pay for FY 1993 is $1,800 for each category applicable to the license(s).

(d) The FY 1993 annual fees for materials licensees and holders of certificates, registrations or approvals subject to fees under this section are as follows:

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses			Annual fees [1, 2, 3]
1. Special nuclear material:			
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.			
	License No.	Docket No.	
High enriched fuel:			
Babcock and Wilcox	SNM–42	70–27	$3,196,000
Nuclear Fuel Services	SNM–124	70–143	3,196,000
Low Enriched Fuel:			
B&W Fuel Company	SNM–1168	70–1201	1,219,000
Combustion Engineering (Hematite)	SNM–33	70–36	1,219,000
General Electric Company	SNM–1097	70–1113	1,219,000
Siemens Nuclear Power	SNM–1227	70–1257	1,219,000
Westinghouse Electric Co	SNM–1107	70–1151	1,219,000
Surcharge			100,000

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
(2) All other special nuclear materials licenses not included in category 1.A.(1) above for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of contained U–235 in unsealed form or 200 grams or more of U–233 in unsealed form	$122,000
Surcharge	100,000
B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI)	146,600
Surcharge	120
C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers	1,600
Surcharge	120
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in § 150.11 of this chapter, for which the licensee shall pay the same fees as those for Category 1.A.(2)	1,800
Surcharge	1,720
E. Licenses for the operation of a uranium enrichment facility	N/A[11]
2. Source material:	
A.(1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride	662,000
Surcharge	100,000
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ leaching, heap-leaching, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
Class I facilities[4]	58,100
Class II facilities[4]	25,400
Other facilities	21,100
Surcharge	120
B. Licenses which authorize only the possession, use and/or installation of source material for shielding	680
Surcharge	120
C. All other source material licenses	7,600
Surcharge	1,720
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued pursuant to Parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution	17,000
Surcharge	1,720
B. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution	5,000
Surcharge	1,720
C. Licenses issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized pursuant to part 40 of this chapter when included on the same license	10,500
Surcharge	1,720
D. Licenses and approvals issued pursuant to §§ 32.72, 32.73, and/or 32.74 of this chapter authorizing distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources or devices not involving processing of byproduct material. This category also includes the possession and use of source material for shielding authorized pursuant to part 40 of this chapter when included on the same license	5,200
Surcharge	120
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units)	3,700
Surcharge	120
F. Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes	4,700
Surcharge	120
G. Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes	21,900
Surcharge	120
H. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter	6,000
Surcharge	120
I. Licenses issued pursuant to subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter	10,900
Surcharge	120

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
J. Licenses issued pursuant to subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter	5,800
Surcharge	120
K. Licenses issued pursuant to subpart B of part 31 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter	5,100
Surcharge	120
L. Licenses of broad scope for possession and use of byproduct material issued pursuant to part 30 and 33 of this chapter for research and development that do not authorize commercial distribution	12,900
Surcharge	1,720
M. Other licenses for possession and use of byproduct material issued pursuant to part 30 of this chapter for research and development that do not authorize commercial distribution	4,400
Surcharge	1,720
N. Licenses that authorize services for other licensees, except:	
(1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3P, and	
(2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4A, 4B, 4C, and 4D	5,200
Surcharge	1,720
O. Licenses for possession and use of byproduct material issued pursuant to part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized pursuant to part 40 of this chapter when authorized on the same license	17,200
Surcharge	120
P. All other specific byproduct material licenses, except those in Categories 4A through 9D	2,000
Surcharge	120
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material	[5] 113,400
Surcharge	1,720
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material	14,100
Surcharge	1,720
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material	6,600
Surcharge	1,720
D. Licenses specifically authorizing the receipt, from other persons, of byproduct material as defined in section 11.e.(2) of the Atomic Energy Act for possession and disposal	7,600
Surcharge	1,720
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies	11,100
Surcharge	120
B. Licenses for possession and use of byproduct material for field flooding tracer studies	13,500
Surcharge	1,720
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material	13,700
Surcharge	1,720
7. Human use of byproduct, source, or special nuclear material:	
A. Licenses issued pursuant to parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license	14,400
Surcharge	120
B. Licenses of broad scope issued to medical institutions or two or more physicians pursuant to parts 30, 33, 35, 40 and 70 of this chapter authorizing research and development, including human use of byproduct material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license [9]	26,400
Surcharge	1,720
C. Other licenses issued pursuant to parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material and/or special nuclear material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license [9]	5,000

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1, 2, 3]
Surcharge	120
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities	1,800
Surcharge	120
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	8,400
Surcharge	120
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	4,100
Surcharge	120
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	1,800
Surcharge	120
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	910
Surcharge	120
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.	
Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
Other Casks	[6] N/A
B. Approvals issued of 10 CFR Part 71 quality assurance programs.	
Users and Fabricators	67,400
Users	1,000
Surcharge	120
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A
B. General licenses for storage of spent fuel under 10 CFR 72.210	146,600
Surcharge	120
14. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation or site restoration activities pursuant to 10 CFR parts 30, 40, 70, and 72.	[7] N/A
15. Import and Export licenses	[8] N/A
16. Reciprocity	[8] N/A
17. Master materials licenses of broad scope issued to Government agencies	358,400
Surcharge	23,820
18. DOE Certificates of Compliance	[10] 1,013,000
Surcharge	120

[1] Amendments based on applications filed after October 1 of each fiscal year that change the scope of a licensee's program or that cancel a license will not result in any refund or increase in the annual fee for that fiscal year or any portion thereof for the fiscal year filed. The annual fee will be waived where the license is terminated prior to October 1 of each fiscal year, and the amount of the annual fee will be increased or reduced where an amendment or revision is issued to increase or decrease the scope prior to October 1 of each fiscal year.

Annual fees will be assessed based on whether a licensee holds a valid license with the NRC which authorizes possession and use of radioactive material. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration or approval held by that person. For those licenses that authorize more than one activity on a single license (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license. Licensees paying annual fees under Category 1.A.(1). are not subject to the annual fees of category 1.C and 1.D for sealed sources authorized in the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of Parts 30, 40, 70, 71, or 72 of this chapter.

[3] For FYs 1994 and 1995, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the FEDERAL REGISTER for notice and comment.

[4] A Class I license includes mill licenses issued for the extraction of uranium from uranium ore. A Class II license includes solution mining licenses (in-situ and heap leach) issued for the extraction of uranium from uranium ores including research and development licenses. An "other" license includes licenses for extraction of metals, heavy metals, and rare earths.

[5] Two licenses have been issued by NRC for land disposal of special nuclear material. Once NRC issues a LLW disposal license for byproduct and source material, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, Part 71 and 72 Certificates of Compliance and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to the users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Categories 7B or 7C.

[10] This includes Certificates of Compliance issued to DOE that are not under the Nuclear Waste Fund.

[11] No annual fee has been established because there are currently no licensees in this particular fee category.

(e) A surcharge is proposed for each category, for which a base annual fee is required. The surcharge consists of the following:

(1) To recover costs relating to LLW disposal generic activities, an additional charge of $100,000 has been added to fee Categories 1.A.(1), 1.A.(2) and 2.A.(1); an additional charge of $1,600 has been added to fee Categories 1.D., 2.C., 3.A., 3.B., 3.C., 3.L., 3.M., 3.N., 4.A., 4.B., 4.C., 4.D., 5.B., 6.A., and 7.B.; and an additional charge of $23,700 has been added to fee Category 17.

(2) To recoup those costs not recovered from small entities, an additional charge of $120 has been added to each fee Category, except Categories 1E, 10.A., 11., 12., 13.A., 14., 15. and 16., since there is no annual fee for these categories. Licensees who qualify as small entities under the provisions of § 171.16(c) and who submit a completed NRC Form 526 are not subject to the $120 additional charge.

11. In § 171.19, paragraphs (b) and (c) are revised to read as follows:

§ 171.19 Payment.

* * * * *

(b) For FY 1993 through FY 1995, the Commission will adjust the fourth quarterly bill for operating power reactors and certain materials licensees to recover the full amount of the revised annual fee. All other licensees, or holders of a certificate, registration, or approval of a QA program will be sent a bill for the full amount of the annual fee upon publication of the final rule. Payment is due on the effective date of the final rule and interest shall accrue from the effective date of the final rule. However, interest will be waived if payment is received within 30 days from the effective date of the final rule.

(c) For FYs 1993 through 1995, annual fees in the amount of $100,000 or more and described in the **Federal Register** Notice pursuant to § 171.13, shall be paid in quarterly installments of 25 percent. A quarterly installment is due on October 1, January 1, April 1, and July 1 of each fiscal year. Annual fees of less than $100,000 shall be paid once a year.

Dated at Rockville, Maryland this 14th day of April, 1993.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

Appendix A to This Proposed Rule Regulatory Flexibility Analysis for the Amendments to 10 CFR Part 170 (License Fees) and 10 CFR Part 171 (Annual Fees)

I. Background

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.) establishes as a principle of regulatory practice that agencies endeavor to fit regulatory and informational requirements, consistent with applicable statutes, to a scale commensurate with the businesses, organizations, and government jurisdictions to which they apply. To achieve this principle, the Act requires that agencies consider the impact of their actions on small entities. If the agency cannot certify that a rule will not significantly impact a substantial number of small entities, then a regulatory flexibility analysis is required to examine the impacts on small entities and the alternatives to minimize these impacts.

To assist in considering these impacts under the Regulatory Flexibility Act, the NRC adopted size standards for determining which NRC licensees qualify as small entities (50 FR 50241; December 9, 1985). These size standards were clarified November 6, 1991 (56 FR 56672). The NRC size standards are as follows:

(1) A small business is a business with annual receipts of $3.5 million or less except private practice physicians for which the standard is annual receipts of $1 million or less.

(2) A small organization is a not-for-profit organization which is independently owned and operated and has annual receipts of $3.5 million or less.

(3) Small governmental jurisdictions are governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000.

(4) A small educational institution is one that is (1) supported by a qualifying small governmental jurisdiction, or (2) one that is not state or publicly supported and has 500 employees or less.

Public Law 101–508, the Omnibus Budget Reconciliation Act of 1990 (OBRA–90), requires that the NRC recover approximately 100 percent of its budget authority, less appropriations from the Nuclear Waste Fund, for Fiscal Years (FY) 1991 through 1995 by assessing license and annual fees. For FY 1991, the amount collected was approximately $445 million, and for FY 1992, the amount collected was approximately $492.5 million. The amount to be collected in FY 1993 is approximately $518.9 million.

To comply with OBRA–90, the Commission amended its fee regulations in 10 CFR Parts 170 and 171 in FY 1991 (56 FR 31472; July 10, 1991) and FY 1992, (57 FR 32691; July 23, 1992) based on a careful evaluation of over 500 comments. These final rules established the methodology used by NRC in identifying and determining the fees assessed and collected in FY 1991 and FY 1992. The NRC has used the same methodology established in the FY 1991 and FY 1992 rulemakings to establish the proposed fees to be assessed for FY 1993.

II. Impact on Small Entities

The comments received on the proposed FY 1991 and FY 1992 fee rule revisions and the small entity certifications received in response to the final FY 1991 and FY 1992 fee rules indicate that NRC licensees qualifying as small entities under the NRC's size standards are primarily those licensed under the NRC's materials program. Therefore, this analysis will focus on the economic impact of the annual fees on materials licensees.

The Commission's fee regulations result in substantial fees being charged to those individuals, organizations, and companies that are licensed under the NRC materials program. Of these materials licensees, the NRC estimates that about 18 percent (approximately 1,300 licensees) qualify as small entities. This estimate is based on the number of small entity certifications filed in response to the FY 1991 and FY 1992 fee rules.

The commenters on the FY 1991 and FY 1992 proposed fee rules indicated the following results if the proposed annual fees were not modified:

—Large firms would gain an unfair competitive advantage over small entities. One commenter noted that a small well-logging company (a "Mom and Pop" type of operation) would find it difficult to absorb the annual fee, while a large corporation would find it easier. Another commenter noted that the fee increase could be more easily absorbed by a high-volume nuclear medicine clinic. A gauge licensee noted that, in the very competitive soils testing market, the annual fees would put it at an extreme disadvantage with its much larger competitors because the proposed fees would be the same for a two-person licensee as for a large firm with thousands of employees.

—Some firms would be forced to cancel their licenses. One commenter, with receipts of less than $500,000 per year, stated that the proposed rule would, in effect, force it to relinquish its soil density gauge and license, thereby reducing its ability to do its work effectively. Another commenter noted that the rule would force the company and many other small businesses to get rid of the materials license altogether. Commenters stated that the proposed rule would result in about 10 percent of the well logging licensees terminating their licenses immediately and approximately 25 percent terminating their licenses before the next annual assessment.

—Some companies would go out of business. One commenter noted that the proposal would put it, and several other small companies, out of business or, at the very least, make it hard to survive.

—Some companies would have budget problems. Many medical licensees commented that, in these times of slashed reimbursements, the proposed increase of the existing fees and the introduction of additional fees would significantly affect their budgets. Another noted that, in view of the cuts by Medicare and other third party carriers, the fees would produce a hardship and some facilities would experience a great deal of difficulty in meeting this additional burden.

Over the past two years, approximately 2,300 license, approval, and registration terminations have been requested. Although some of these terminations were requested because the license was no longer needed or licenses or registrations could be combined, indications are that other termination requests were due to the economic impact of the fees.

The NRC continues to receive written and oral comments from small materials licensees. These comments indicate that the $3.5 million threshold for small entities is not representative of small businesses with gross receipts in the thousands of dollars. These commenters believe that the $1,800 maximum annual fee represents a relatively high percentage of gross annual receipts for these "Mom and Pop" type businesses. Therefore, even the reduced annual fee could have a significant impact on the ability of these types of businesses to continue to operate.

To alleviate the continuing significant impact of the annual fees on a substantial number of small entities, the NRC considered alternatives, in accordance with the RFA. These alternatives were evaluated in the FY 1991 rule (56 FR 31472; July 10, 1991) and the FY 1992 rule (57 FR 32691; July 23, 1992). The alternatives considered by the NRC can be summarized as follows:

—Base fees on some measure of the amount of radioactivity possessed by the licensee (e.g., number of sources).

—Base fees on the frequency of use of the licensed radioactive material (e.g., volume of patients).

—Base fees on the NRC size standards for small entities.

The NRC has reexamined the FY 1991 and FY 1992 evaluation of the above alternatives. Based on that reexamination, the NRC continues to support the previous conclusion. That is, the NRC continues to believe that establishment of a maximum fee for small entities is the most appropriate option to reduce the impact on small entities.

The NRC established, and is proposing to continue for FY 1993, a maximum annual fee for small entities. The RFA and its implementing guidance do not provide specific guidelines on what constitutes a significant economic impact on a small entity. Therefore, the NRC has no benchmark to assist it in determining the amount or the percent of gross receipts that should be charged to a small entity. For FY 1993, the NRC proposes to rely on the analysis previously completed that established a maximum annual fee for a small entity by comparing NRC license and inspection fees under 10 CFR Part 170 with Agreement State fees for those fee categories that are expected to have a substantial number of small entities. Because these fees have been charged to small entities, the NRC continues to believe that these fees or any adjustments to these fees during the past year do not have a significant impact on them. In issuing this proposed rule for FY 1993, the NRC concludes that the proposed materials license and inspection fees do not have a significant impact on a substantial number of small entities and that the maximum small entity fee of $1,800 be maintained to alleviate the impact of the fees on small entities.

By maintaining the maximum annual fee for small entities at $1,800, the annual fee for many small entities will be reduced while at the same time materials licensees, including small entities, pay for most of the FY 1993 costs ($29.8 million of the total $35.1 million) attributable to them. Therefore, the NRC is proposing to continue, for FY 1993, the maximum annual fee (base annual fee plus surcharge) for certain small entities at $1,800 for each fee category covered by each license issued to a small entity. Note that the costs not recovered from small entities are allocated to other materials licensees and to operating power reactors.

While reducing the impact on many small entities, the Commission agrees that the current maximum annual fee of $1,800 for small entities, when added to the part 170 license and inspection fees, may continue to have a significant impact on materials licensees with annual gross receipts in the thousands of dollars. Therefore, as in FY 1992, the NRC will continue for FY 1993 the lower-tier small entity fee of $400 for small entities with relatively low gross annual receipts established in the final rule dated April 17, 1992 (57 FR 13625).

In establishing the annual fee for lower tier small entities, the NRC continues to retain a balance between the objectives of the RFA and OBRA–90. This balance can be measured by (1) the amount of costs attributable to small entities that is transferred to larger entities (the small entity subsidy); (2) the total annual fee small entities pay, relative to this subsidy; and (3) how much the annual fee is for a lower tier small entity. Nuclear gauge users were used to measure the reduction in fees because they represent about 40 percent of the materials licensees and most likely would include a larger percentage of lower tier small entities than would other classes of materials licensees. The Commission is continuing an annual fee of $400 for the lower tier small entities to ensure that the lower tier small entities receive a reduction (75 percent for small gauge users) substantial enough to mitigate any severe impact. Although other reduced fees would result in lower subsidies, the Commission believes that the amount of the associated annual fees, when added to the license and inspection fees, would still be considerable for small businesses and organizations with gross receipts of less than $250,000 or for governmental entities in jurisdictions with a population of less than 20,000.

III. Summary

The NRC has determined the annual fee significantly impacts a substantial number of small entities. A maximum fee for small entities strikes a balance between the requirement to collect 100 percent of the NRC budget and the requirement to consider means of reducing the impact of the proposed fee on small entities. On the basis of its regulatory flexibility analyses, the NRC concludes that a maximum annual fee of $1,800 for small entities and a lower tier small entity annual fee of $400 for small businesses and non-profit organizations

with gross annual receipts of less than $250,000, and small governmental entities with a population of less than 20,000, will reduce the impact on small entities. At the same time, these reduced annual fees are consistent with the objectives of OBRA–90. Thus, the revised fees for small entities maintain a balance between the objectives of OBRA–90 and the RFA. The NRC has used the methodology and procedures developed for the FY 1991 and FY 1992 fee rules in this proposed rule establishing the FY 1993 fees. Therefore, the analysis and conclusions established in the FY 1991 and FY 1992 rules remain valid for this proposed rule for FY 1993.

[FR Doc. 93–9296 Filed 4–22–93; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91–NM–257–AD]

Airworthiness Directives; Boeing Model 727 and 737 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: This action withdraws a notice of proposed rulemaking (NPRM) that proposed a new airworthiness directive (AD), applicable to all Boeing Model 727 series airplanes and certain Boeing Model 737 series airplanes. That action would have required inspection of the input shaft in the auxiliary (standby) rudder Power Control Unit (PCU), and reporting to the Federal Aviation Administration (FAA) of units that failed the inspection test procedure that was outlined in the proposed AD. Since the issuance of the NPRM, the FAA has re-evaluated the design data and has determined that the condition addressed in the NPRM is not an unsafe condition warranting issuance of an AD. Accordingly, the proposed rule is withdrawn.

FOR FURTHER INFORMATION CONTACT: Kenneth W. Frey, Aerospace Engineer, Seattle Aircraft Certification Office, Systems and Equipment Branch, ANM–130S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2673; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to add a new airworthiness directive (AD), applicable to all Boeing Model 727 series airplanes and certain Boeing Model 737 series airplanes, was published in the **Federal Register** on February 12, 1992 (57 FR 5093). The proposed rule would have required inspection of the input shaft in the auxiliary (standby) rudder Power Control Unit (PCU), and reporting to the FAA of units that failed the inspection test procedure that was outlined in the proposed AD. That action was prompted by a report that the input shaft of the PCU of one airplane showed evidence of galling which may have greatly increased the force necessary to move the input shaft. The proposed actions were intended to prevent an uncommanded rudder input and reduced controllability of the airplane.

Since the issuance of that NPRM, the FAA has re-evaluated the design of the rudder control system on the Model 727 and 737 series airplanes and has determined that the flight crew would be capable of detecting the galling condition before it causes any rudder control problems. The galling condition would be detectable by:

(1) Increased force necessary to move the rudder pedal,

(2) Erratic nose gear steering with the yaw damper engaged,

(3) Rudder yaw damper kick back or yaw damper back drives on the rudder pedals during flight, and

(4) Erratic operation of the rudder yaw damper or erratic rudder oscillations with the yaw damper engaged.

None of these indications of galling represent a safety hazard.

Furthermore, the design of the control system on the Model 727 and 737 series airplanes ensures that the flight crew would be capable of continued safe flight and landing after any input shaft galling, up to and including a totally "welded" condition. If the input lever of the standby PCU suddenly became "welded" to the PCU housing while deflected to the most extreme off-neutral position due to yaw damper activity, the flight crew would be capable of returning the rudder almost to neutral, or all the way to neutral, through normal use of the rudder pedals. Additionally, on the Model 727 series airplanes, a rudder system shear-out provision will disconnect the galled standby PCU input linkage; and on the Model 737 series airplanes, the control system linkage between the main PCU and standby PCU is designed to allow enough deflection to occur to move the input lever to the main PCU. Further, on the Model 737 series airplanes, full rudder can be compensated with lateral controls in the majority of flight envelopes. Finally, Boeing Commercial Airplane Group has revised the Model 727 and 737 Maintenance Manuals to emphasize the indications of input lever binding in the standby rudder PCU, which would facilitate an operator's ability to determine the proper maintenance action.

Upon further consideration and re-evaluation of the design data, the FAA has determined that the condition addressed in the NPRM is not an unsafe condition warranting issuance of an AD. Accordingly, the proposed rule is hereby withdrawn.

Withdrawal of this notice of proposed rulemaking constitutes only such action, and does not preclude the agency from issuing another notice in the future, nor does it commit the agency to any course of action in the future.

Since this action only withdraws a notice of proposed rulemaking, it is neither a proposed nor a final rule and therefore, is not covered under Executive Order 12291, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Withdrawal

Accordingly, the notice of proposed rulemaking, Docket 91–NM–257–AD, published in the **Federal Register** on February 12, 1992 (57 FR 5093) is withdrawn.

Issued in Renton, Washington, on April 19, 1993.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–9495 Filed 4–22–93; 8:45am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[FI–189–84]

RIN 1545–AH48

Debt Instruments With Original Issue Discount; Imputed Interest on Deferred Payment Sales or Exchages of Property; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to [FI–189–84], which was

published in the **Federal Register** for Tuesday, December 22, 1992 (57 FR 60750). The proposed regulations relate to the tax treatment of debt instruments with original issue discount and the imputation of interest on deferred payments under certain contracts for the sale or exchange of property.

FOR FURTHER INFORMATION CONTACT: Frederick S. Campbell-Mohn, (202) 622-3940 (not a toll-free number), William E. Blanchard, (202) 622-3950 (not a toll-free number), or Andrew C. Kittler, (202) 622-3940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The proposed regulations that are the subject of these corrections simplify rules proposed in 1986 under sections 163, 483, 1271, 1272, 1273, 1274, 1275.

Need for Correction

As published, FI-189-84 contains errors which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of proposed regulations FI-189-84 which was the subject of FR Doc. 92-30431, is corrected as follows:

1. On page 60750, column 2, in the preamble under the heading "*Paperwork Reduction Act*", first full paragraph, third line, the language "§§ 1.1272-(d)(2)(iii), 1.1272-3, 1.1273-" is corrected to read "§§ 1.1272-1(d)(2)(iii), 1.1272-3, 1.1273-".

2. On page 60753, column 1, in the preamble under the heading § "*Sections 1.1274-1 Through 1.1274-5 Determination of Issue Price in the Case of Certain Debt Instruments Issued for Property*", first paragraph, third line, the language "sections 1.1274-1 through 1.1274-7 of" is corrected to read "§§ 1.1274-1 through 1.1274-7 of".

§1.483-1 [Amended]

3. On page 60757, column 3, § 1.483-1(c)(3)(v), the paragraph heading "*Options subject to section 1234.*" is corrected to read "*Options.*".

§1.1272-1 [Amended]

4. On page 60762, column 1, § 1.1272-1(j), the last line of paragraph (v) of *Example 3*, the language "(11.31 percent/6)." is corrected to read "(11.31 percent/6)).".

§1.1274A-1 [Amended]

5. On page 60772, column 3, § 1.1274A-1(b)(3)(ii), the fourth line from the bottom of *Example 1*, the language "These sales or exchanges are part of a series" is corrected to read "These sales are part of a series".

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93-9454 Filed 4-22-93; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Regulatory Program Amendment

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

ACTION: Proposed rule.

SUMMARY: OSM is announcing receipt of a proposed amendment submitted by Indiana as a modification to the State's regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment (Program Amendment 93-3) consists of proposed changes to the Indiana Surface Mining Rules concerning delegation of authority, ultimate authority, conduct of certain proceedings and record keeping by the Administrative Law Judge (ALJ). The amendment is intended to revise the Indiana Administrative Code (IAC) rules to implement statutory changes contained in the 1992 Senate Enrolled Act (SEA) 154.

This document sets forth the times and locations that the Indiana program and the proposed amendment to that program will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed for a public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on May 24, 1993; if requested, a public hearing on the proposed amendment is scheduled for 1 p.m. on May 18, 1993; and, requests to present oral testimony at the hearing must be received on or before 4 p.m. on May 10, 1993.

ADDRESSES: Written comments and request to testify at the hearing should be directed to Mr. Roger W. Calhoun, Director, Indianapolis Field Office, at the address listed below. If a hearing is requested, it will be held at the same address

Copies of the Indiana program, the amendment, a listing of any scheduled public meetings, and all written comments received in response to this document will be available for public review at the following locations, during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Indianapolis Field Office, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204. Telephone: (317)226-6166.

Indiana Department of Natural Resources, 402 West Washington Street, room 295, Indianapolis, IN 46204. Telephone: (317)232-1547.

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Indianapolis Field Office.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Telephone (317) 226-6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982, **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

II. Discussion of the Proposed Amendment

By letter dated June 4, 1991 (Administrative Record Number IND-0894), the Indiana Department of Natural Resources (IDNR) submitted a proposed amendment to the Indiana program concerning statutes enacted by Indiana under SEA 154 from the 1991 Indiana Legislative Session. The amendments included provisions concerning requirements for hearings, and changes in the responsibilities of the director of the IDNR and the Natural Resources Commission (NRC). OSM approved the proposed amendments on June 23, 1992 (57 FR 27928).

By letter dated April 2, 1993 (Administrative Record Number IND-1217), Indiana submitted proposed program amendment number 93-3. Program amendment 93-3 consists of proposed changes to the Indiana rules concerning delegation of authority,

ultimate authority, conduct of certain proceedings, and record keeping by the ALJ. The proposed changes to the Indiana rules reflect statutory changes contained in the 1992 SEA 154.

The proposed amendments are summarized below.

1. 310 IAC 0.6–1–2 Applicability of Rule

New subsection 2(c) is added to provide that 310 IAC 0.6–1–12 does not apply if IC 4–21.5–4 or if 310 IAC 0.6–1–2.5(b) or 2.5(c) apply. Also, a party may seek judicial review under IC 4–21.5–5 of a final order made by an ALJ under this subsection.

2. 310 IAC 0.6–1–2.5 Ultimate Authority for the IDNR

This new section is added to provide in subsection 2.5(a) that the NRC is the ultimate authority for the IDNR for proceedings under 310 IAC 0.6–1, except as provided in subsections 310 IAC 0.6–1–2.5 (b) and (c).

Subsection 2.5(b) provides that the ALJ is the ultimate authority for the IDNR for any administrative review under IC 13–4.1 or 310 IAC 12, except for proceedings concerning the approval or disapproval of a permit application, permit revision application or permit renewal under IC 13–4.1–4–5, and proceedings for suspension or revocation of a permit under IC 13–4.1–11–6.

New subsection 2.5(c) provides that an order made by an ALJ granting or denying temporary relief from a decision of the director of the IDNR is a final order of the IDNR.

3. 310 IAC 0.6–1–17 Record of Proceedings

This new section is added to provide (in subsection 17(a)) that the record required to be kept by an ALJ under IC 4–21.5–3–14 commences with the filing of one of the following with the director of the IDNR: (1) A petition for administrative review under IC 4–21.5–3–7; (2) a complaint under IC 4–21.5–3–8; (3) a proceeding before an ALJ under IC 4–21.5–4.

New subsection 17(b) provides that the record required to be kept by an ALJ consists of the official record as set forth in IC 4–21.5–3–33.

New subsection 17(c) provides that in addition to subsections 17 (a) and (b), subsection 17(c) applies to proceedings concerning the approval or disapproval of a permit application, permit revision application, or permit renewal under IC 13–4.1–4–5. Upon a timely objection made at hearing, the ALJ shall exclude testimony or exhibits which are offered but which identify matters which were not part of the "record before the director" under IC 13–4.1–4–5. The "record before the director" includes each of the following: (1) The permit; (2) the permit application; (3) documentation tendered or referenced in writing by the applicant or an interested person for the purposes of evaluating, or used by the IDNR to evaluate the application; (4) the analyses of the IDNR in considering the application, including the expertise of the IDNR's employees and references used to evaluate the application; (5) documentation received under IC 13–4.1–4–2, including the conduct and results of any informal conference or public hearing under IC 13–4.1–4–2(c); (6) correspondence received or generated by the department relative to the application, including letters of notification, proofs of filing newspaper advertisements, and timely written comments from an interested person.

4. 310 IAC 0.6–1–9 Defaults, Dismissals, Agreed Orders, and Consent Decrees

Subsection 9(a) has been amended to provide that an ALJ may, on its own motion or the motion of a party, enter a nonfinal order of default or dismissal, as appropriate, and submit the nonfinal order to the secretary of the NRC for final action if any of the described conditions are met. Prior to this amendment, the rule only provided for nonfinal orders of dismissal by the ALJ. In addition, new subsection 9(a)(4) is added to provide that a default or dismissal could be entered in a civil action.

Subsection 9(c) is amended by the addition and deletion of language. As revised, subsection 9(c) provides that an ALJ may enter a nonfinal order of default or a nonfinal order of involuntary dismissal only following the issuance of a proposed order of default or proposed order of dismissal under IC 4–21.5–3–24.

Subsection 9(d) is amended to provide that the secretary (of the NRC), as the designee of the NRC under IC 4–21.5–3–28(b), may affirm the entry of a nonfinal default order, dismissal order, or consent decree. The secretary of the NRC has exclusive authority to approve, remand, or submit to the commission for final action, any nonfinal order or decree entered by an ALJ under section 310 IAC 0.6–1–9. A party which opposes the entry of a final order by the secretary of the NRC must file a written objection, and the ALJ and any other party may file a written response to the objection. Prior to the proposed amendment, the director of the IDNR was the designee of the NRC under IC 4–21.5–3–28(b).

Subsection 9(e) is amended to provide that an order of default, order of dismissal, agreed order, or consent decree made by the secretary of the NRC is a final order of the IDNR and is made with prejudice, unless otherwise specified in the order of decree. Prior to the proposed amendment, the rule did not specify an order of default, nor did it specify the secretary of the NRC.

New subsection 9(f) provides that an order of default, order of dismissal, agreed order, or consent decree made by an ALJ, where acting as the ultimate authority for the IDNR under section 310 IAC 0.6–1–2.5(b), is a final order of the department unless otherwise specified in the order or decree. A person may seek judicial review of a final order entered under 310 IAC 0.6–1–9(f) as provided in IC 4–21.5–5.

The full text of the proposed program amendment submitted by Indiana is available for public inspection at the addresses listed above. The Director now seeks public comment on whether the proposed amendment is no less effective than the Federal regulations. If approved, the amendment will become part of the Indiana program.

III. Public Comment Procedures

In accordance with provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Indiana satisfies the requirements of 30 CFR 732.15 for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Indiana program.

Written Comments

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

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by the close of business on May 10, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in

advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

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

Public Meeting

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

IV. Procedural Determinations

Executive Order 12291

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

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.13 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

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

Paperwork Reduction Act

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

Regulatory Flexibility Act

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

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: April 15, 1993.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93-9496 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 675

[Docket No. 930487-3087]

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule; proposed revision to Final 1993 Specifications of Groundfish; request for comments.

SUMMARY: NMFS proposes regulations to implement Amendment 28 to the Fishery Management Plan (FMP) for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI). These regulations are proposed to establish three new management districts in the Aleutian Islands subarea (AI). This action also proposes to: (1) Amend the Final 1993 Initial Specifications of Groundfish and Prohibited Species Catch Allowances for the BSAI (1993 Specifications), and (2) implement amendments to clarify existing regulations. These actions are intended by the North Pacific Fishery Management Council (Council) to promote management and conservation of groundfish and other fish resources and to further the goals and objectives contained in the FMP that governs these fisheries.

DATES: Comments are invited until June 4, 1993.

ADDRESSES: Comments may be sent to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, Alaska 99802 (Attn. Lori Gravel). The proposed rule was analyzed as part of the environmental assessment/regulatory impact review (EA/RIR) prepared for Amendment 28. Individual copies of Amendment 28 and the EA/RIR may be obtained from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, Alaska 99510 (telephone 907-271-2809).

FOR FURTHER INFORMATION CONTACT: Jessica A. Gharrett, Fisheries Management Biologist, Alaska Region, NMFS, 907-586-7228.

SUPPLEMENTARY INFORMATION:

Background

The domestic groundfish fisheries in the Exclusive Economic Zone (EEZ) of the BSAI are managed by the Secretary of Commerce (Secretary) in accordance with the FMP. The FMP was prepared by the Council under the authority of

the Magnuson Fishery Conservation and Management Act (Magnuson Act) and is implemented by regulations appearing at 50 CFR 611.93 and 50 CFR part 675 for the U.S. fishery. General regulations that also pertain to the U.S. fishery appear at 50 CFR part 620.

At times, amendments to the FMP and/or its implementing regulations are necessary to resolve problems pertaining to management of the groundfish fisheries. This proposed rule would implement Amendment 28 to the FMP. This amendment would establish three new management districts within the AI of the BSAI. Amendment 28 was recommended to the Secretary by the Council at its January 1993 meeting.

In addition to the FMP amendment, a revision to the Final 1993 Initial Specifications of Groundfish and Prohibited Species Catch Allowances as published in the **Federal Register** (58 FR 8703, February 17, 1993) and amendments to clarify existing regulations are proposed.

A description of, and the reasons for, each measure follows.

Establishment of the Eastern, Central, and Western Districts of the Aleutian Islands Subarea

A groundfish species or species group may be apportioned to the entire BSAI, or to smaller area units defined in the FMP or implementing regulations, provided that sufficient biological information exists with which to establish acceptable biological catches (ABCs) for the areas of interest. The AI is currently not subdivided under the FMP. Therefore, groundfish may not be apportioned to smaller areas within the AI.

In the BSAI, the entire total allowable catch (TAC) specified for each groundfish species, except pollock, sablefish, and rockfishes, is apportioned to the entire BSAI. For some species, particularly Atka mackerel, fishing effort has occurred in a relatively small area within the AI. This can result in undesirable effects of highly concentrated effort, such as the potential for localized depletion of groundfish, intensified competition with marine predators for fishery resources, and greater possibility of habitat degradation.

At its September 1992 meeting, the Council recommended initiation of an FMP amendment to divide the AI. This request developed from concerns of the Council's Scientific and Statistical Committee (SSC) and Plan Team, that in recent years the commercial catches of groundfish in the AI, particularly of Atka mackerel, have become spatially concentrated in relatively small portions of the subarea. A division of the AI was desirable to: (1) Provide increased flexibility in TAC management, (2) enhance the Council's ability to disperse fishing effort, and (3) minimize the potential for undesirable effects of concentrated fishing effort.

At the same time, representatives of the fishing industry requested that increased harvest amounts be made available for Atka mackerel. This increase was opposed by the SSC unless Atka mackerel TAC apportionments and fishing effort more closely reflected distribution of Atka mackerel biomass and unless the potential for localized depletion could be minimized. An FMP amendment to divide the AI, thereby providing a mechanism to apportion groundfish TACs, could benefit many groundfish fisheries, but is particularly critical for the Atka mackerel fishery in 1993.

A draft analysis was prepared under guidance of the National Environmental Policy Act (NEPA) of 1969, E.O. 12291, and NOAA policy. Three alternatives were considered in the EA/RIR: The status quo, under which no subdivision of the AI would be made; Alternative 2, under which the AI would be divided into two districts by dividing the subarea at 177° E. longitude; and, Alternative 3, under which the AI would be divided into three districts by dividing the subarea at 177° W. longitude and 177° E. longitude.

At its January 18–20, 1993, meeting, the Council considered the testimony and recommendations of its Plan Team, SSC, Advisory Panel (AP), and the public, including fishing industry representatives, on the amendment proposal and the EA/RIR analysis. The Council then approved Amendment 28 that would establish Eastern, Central, and Western AI management districts so that the harvest of Atka mackerel or other groundfish TAC amounts specified for the AI could be controlled independently in the new districts. Groundfish TACs that are so apportioned could be more effectively managed, and other biological and environmental effects of concentrated fishing effort could be minimized. This amendment might also increase value realized from groundfish fishery, if greater amounts of more valued species are made available.

Revision of Final 1993 Initial Specifications for Atka Mackerel

A restructured AI under Amendment 28 would provide a management tool to improve management and conservation of all groundfish stocks, and to control interactions between fishing activities and other aspects of the environment. The EA analyzed only the potential apportionment of Atka mackerel because of current industry demand for that species, the ready availability of biomass data with which to establish Atka mackerel ABCs, and the immediate need to implement revised ABC and TAC amounts for the 1993 Atka mackerel fishery.

NMFS is proposing to revise the 1993 Specifications to facilitate an increase in the TAC for Atka mackerel during 1993, should Amendment 28 be implemented during the fishing year. Currently, the Atka mackerel TAC is apportioned to the entire BSAI, and fishing can occur at any location within that area. In recent years, fishing effort for Atka mackerel has been concentrated in the eastern portion of the AI, resulting in fishing effort and removals that were disproportionate to the distribution of Atka mackerel biomass. For example, 66 percent of the 1992 Atka mackerel harvest came from the proposed Eastern Aleutian District, an area that contains only 11 percent of the biomass.

At its September 1992 meeting, the SSC recommended an overall preliminary ABC of 117,100 metric tons (mt) for Atka mackerel if the TAC could be apportioned among districts within the AI, noting the need to distribute this harvest level in proportion to the distribution of Atka mackerel biomass. Absent further subdivision of the AI, the SSC recommended a 1993 ABC for Atka mackerel of 32,100 mt, the amount the SSC believed could safely be harvested from the portion of the AI fished in recent years. At its December 1992 meeting, the Council adopted an ABC for Atka mackerel of 117,100 mt, and a TAC of 32,000 mt, providing a means to increase the Atka mackerel TAC if the AI is divided during 1993.

NMFS has specified final 1993 ABCs and TACs for groundfish fisheries in the BSAI under § 675.20(a)(7)(ii) (58 FR 8703, February 17, 1993). Contingent upon approval of Amendment 28 and its implementing regulations, NMFS proposes to alter the ABC and TAC for Atka mackerel by amending Table 1 of the Final 1993 Specifications (Table 1, amended). This proposed rule would divide the 1993 ABC and TAC specified for Atka mackerel into three separate apportionments for the Eastern Aleutian District and the Bering Sea Subarea, Central Aleutian District, and Western Aleutian District according to the distribution of Atka mackerel biomass in those areas found in the 1991 stock assessment survey, 10.8 percent, 44.7 percent, and 44.5 percent, respectively. For the purpose of allocating Atka mackerel, the Bering Sea subarea is combined with the Eastern Aleutian

district because, although insufficient information exists to establish a separate TAC for the Bering Sea subarea, inclusion under an established TAC will allow retention of incidental catches. One or more of the Atka mackerel TACs could then be independently increased by apportionment from the nonspecific operational reserve during the 1993 fishing year under § 675.20(a)(3). If this proposed rule is approved by the Secretary and implemented during 1993, the Council may recommend an increase of the 1993 Atka mackerel TAC from the operational reserve at a future meeting, after considering market effects and other socioeconomic factors.

The Atka mackerel TAC could be increased through apportionments of the operational reserve from 32,000 mt up to the ABC, or 117,100 mt. Public testimony presented to the Council in December 1992 indicated that only a moderate increase should be recommended because of the potentially undesirable market effects that would ensue from a 3–4 fold increase in TAC. Although amounts of reserve apportioned to Atka mackerel would be unavailable to other fisheries, the total TAC of groundfish specified for 1993, 1,998,620 mt, would not change.

TABLE 1, AMENDED.—FINAL 1993 ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), AND ITAC APPORTIONMENTS OF GROUNDFISH IN THE BERING SEA AND ALEUTIAN ISLANDS AREA[1 2]

Species	ABC	TAC	Initial TAC (ITAC) = DAP [3 4]
Pollock:			
Bering Sea (BS)	1,340,000	1,300,000	1,105,000
Aleutian Islands (AI)	58,700	51,600	43,860
Bogoslof District	42,000	1,000	850
Pacific cod	164,500	164,500	139,825
Sablefish:			
BS	1,500	1,500	1,275
AI	2,600	2,600	2,210
Atka mackerel:			
Eastern AI District/BS	12,670	3,456	2,938
Central AI District	52,344	14,304	12,158
Western AI District	52,086	14,240	12,104
Yellowfin sole	238,000	220,000	187,000
Rock sole	185,000	75,000	63,750
Greenland turbot	7,000	7,000	5,950
Arrowtooth flounder	72,000	10,000	8,500
Other flatfish [5]	191,000	79,000	67,150
Pacific ocean perch:			
BS	3,330	3,330	2,831
AI	13,900	13,900	11,815
Other red rockfish: [6] BS	1,400	1,200	1,020
Sharpchin/Northern: AI	5,670	5,100	4,335
Shortraker/Rougheye: AI	1,220	1,100	935
Other rockfish: [7]			
BS	400	360	306
AI	925	830	706
Squid	3,400	2,000	1,700
Other Species [8]	26,600	26,600	22,610
Totals	2,476,245	1,998,620	1,698,827

[1] Amounts are in metric tons. These amounts apply to the entire BS and AI area unless otherwise specified.
[2] Zero amounts of groundfish are specified for Joint Venture Processing (JVP) and Total Allowable Level of Foreign Fishing (TALFF).
[3] Initial TAC (ITAC) = 0.85 of TAC; initial reserve = TAC − ITAC = 299,793 mt.
[4] DAP = domestic annual processing = ITAC.
[5] "Other flatfish" includes all flatfish species except for Pacific halibut (a prohibited species) and all other flatfish species that have a separate specified TAC amount.
[6] "Other red rockfish" includes shortraker, rougheye, northern and sharpchin.
[7] "Other rockfish" includes Sebastes and Sebastolobus species except for Pacific ocean perch and the "other red rockfish" species.
[8] "Other species" includes sculpins, sharks, skates, eulachon, smelts, capelin, and octopus.

Technical Amendments to Existing Regulations

NMFS proposes several amendments to clarify or correct existing regulations. These changes and the reasons for them are as follows:

1. In the list of figures, Figure 1 is removed and Figures 2 through 5 are redesignated as Figures 1 through 4 as follows:

Figure 1—Reporting areas and bycatch limitation zones in Bering Sea and Aleutian Islands Management Area;

Figure 2—Length overall of a vessel;

Figure 3—Pelagic trawl; and

Figure 4—Pelagic trawl.

This change is necessary because the original Figure 1 is archaic and no longer useful for describing management area units. All references to the original Figures 1 through 5 are altered to refer to redesignated Figures 1 through 4, as appropriate. Those references are found in § 675.2 in definitions of "Bycatch limitation Zone 1," "Bycatch limitation Zone 2," "Bycatch limitation Zone 2H." "Length overall," "Pelagic trawl," "Statistical area," and in § 675.22(a).

2. In § 675.2, the definition of "Bering Sea and Aleutian Islands Management Area" is amended by redesignating paragraphs (a) through (c) as paragraphs (1) through (3) to conform with the current format used by the Office of the Federal Register, and in paragraph (3) the words "subarea" and "management unit" are changed to "District" and "Bering Sea subarea" to clarify that the Bogoslof District is a district within the

Bering Sea subarea and to facilitate future additions of districts numbered between 500 and 539; the definition of "Fishery" is amended by removing paragraphs (a) and (b), which refer to the removed Figure 1; and the definition of "Statistical Area" is amended by redesignating paragraphs (a) through (l) as paragraphs (1) through (12), to conform with the current format used by the Office of the Federal Register, to remove references to the removed Figure 1, to remove Statistical area 540, and to add Statistical areas 541, 542, and 543, the three new AI management districts proposed under this rule.

3. In § 675.2, the definition of "Community Development Quota Reserve (CDQ reserve"); and in § 675.20, paragraphs (a)(2)(ii), (a)(2)(iii), (a)(3)(ii), (a)(3)(iii), (a)(8), and (j)(4) are amended to refer to the newly added AI Districts in addition to BSAI subareas in references to Community Development Quota Reserves; pollock allocations to seasons, inshore and offshore components, and Community Development Quotas (CDQs); closures to directed fishing and closures to retention of groundfish; and the definition of a fishing trip for purposes of calculating allowable amounts of pollock roe. Also, paragraphs (j)(1) and (j)(4) are clarified to refer to the entire paragraph (j).

4. In § 675.24, the section heading is changed to "Gear Limitations" to clarify the content of the section, the introductory text is removed as obsolete, paragraphs (c)(1)(i) and (f) are changed by removing reference to the Bogoslof subarea to clarify that the Bogoslof District is part of the Bering Sea subarea, and paragraph (c)(1)(ii) is revised to indicate that the harvest restriction by gear type refers to each individual TAC, to accommodate any future apportionment of sablefish TAC to new AI Districts established under this proposed FMP amendment. Paragraphs (d)(1) and (d)(2) are revised to refer to districts in addition to subareas for purposes of closures to directed fishing or to retention of groundfish, and are further clarified to refer to allocations made under paragraph (c).

5. In § 675.27, paragraphs (b)(1)(ii) and (c)(1) are revised to refer to districts in addition to subareas for pollock specified for nonspecific operational reserve and for allocation to CDQs.

The Council recommended that the AI be divided into three districts for purposes of specifying and managing allowable levels of groundfish harvest. The proposed regulations would establish the Eastern, Central, and Western Aleutian Districts, eliminate Statistical area 540, and add Statistical areas 541, 542, and 543, designating them the Eastern, Central, and Western Aleutian Districts, respectively. To facilitate an inseason increase in Atka mackerel TAC, the 1993 ABC and TAC specified for Atka mackerel are proposed to be reallocated among the revised BSAI statistical areas. Amendments to existing regulations are proposed to improve accuracy and consistency.

Classification

Section 304(a)(1)(D) of the Magnuson Act, as amended, requires the Secretary to publish regulations proposed by a Council within 15 days of receipt of the FMP amendment and regulations. At this time the Secretary has not determined that the FMP amendment these regulations would implement is consistent with the national standards, other provisions of the Magnuson Act, and other applicable law. The Secretary, in making final determinations, will take into account the data, views, and comments received during the comment period.

NMFS prepared an EA for this FMP amendment that discusses the impact on the environment as a result of this rule. A copy of the EA may be obtained from the Council (see ADDRESSES).

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has initially determined that the proposed rule is not a "major rule" requiring a regulatory impact analysis under E.O. 12291. This rule does not impose significant economic costs, does not cause redistribution of costs and benefits, and would not have significant adverse effects on competition, employment, investment, productivity, innovation, or on markets. The rule should not lead to a substantial increase in prices paid by consumers, local governments, or geographic regions because the rule only establishes management district boundaries, a mechanism by which the Council may more effectively manage groundfish resources of the AI.

This proposed rule is exempt from the procedures of E.O. 12292 under section 8(a)(2) of that order. Deadlines imposed under the Magnuson Act, as amended, require the Secretary to publish this proposed rule 15 days after its receipt. The proposed rule is being reported to the Director, Office of Management and Budget, with an explanation of why it is not subject to E.O. 12291.

The General Counsel of the Department of Commerce certified to the Small Business Administration that this proposed rule, if adopted, will not have significant economic impacts on a substantial number of small entities because the rule creates new management districts, a management tool the Council may subsequently use to geographically apportion TACs, but would not directly alter apportionments of groundfish, or change participation in groundfish fisheries. This action would result in slight changes in recordkeeping and reporting for fishing and processing vessels electing to operate in the new districts, but would not differentially affect small entities or increase the reporting burden. The Atka mackerel fishery is conducted primarily by large catcher/processors and motherships; in 1991 and 1992, fewer than 29 factory trawlers, and two mothership processors with attendant harvesting vessels, participated in that fishery. The change in participation that might accompany any TAC increase is not predictable, but any increase facilitated by this rule in the 1993 Atka Mackerel TAC is not expected to have significant impacts on a substantial number of small harvesters.

Future apportionments of TAC in the new districts could eventually result in changes to (1) total amounts of each groundfish available, (2) spatial distribution of TACs, (3) participation by small harvesting vessels, and (4) the proportion of BSAI groundfish allocated to higher-valued species. Whether or not TACs will be so allocated in the future is not predictable or quantifiable. A copy of this analysis is available from the Council (see ADDRESSES).

This proposed rule involves a collection-of-information requirement which has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The reporting requirements and liable respondents under this proposed rule remain unchanged from that under an information budget (ICB) currently authorized under OMB 0648–0213. Currently, all information about groundfish harvests and vessel activities must be accounted for under that information budget. The addition of two additional reporting area boundaries would require a qualitative reporting change for operators of vessels that operate in the new areas. The resultant annual reporting burden for those vessels would not change from that currently estimated under the ICB.

The Council determined that this rule, if adopted, will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management program of Alaska. This determination has been submitted for review by the responsible State agency under section 307 of the Coastal Zone Management Act.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

An informal consultation pursuant to section 7 of the Endangered Species Act (ESA) for this proposed rule concluded that adoption of either alternative to the status quo would not affect endangered or threatened species under NMFS jurisdiction, including the Steller sea lion and listed species of Pacific salmon, in a manner or to an extent not already considered in prior consultations. NMFS has initiated consultation for 1993 groundfish TACs in regard to listed salmonids, although the conclusion is not expected to change because of a general reduction of salmon bycatch anticipated to result from this proposed rule. Additionally, pursuant to section 7 of the ESA, NMFS has initiated consultation with the U.S. Fish and Wildlife Service regarding the short-tailed albatross and other seabirds that are proposed or candidates for listing under the ESA.

The Regional Director determined that fishing activities conducted under this rule would have no significant adverse impacts on marine mammals not listed under the ESA.

List of Subjects in 50 CFR Part 675

Fisheries, Reporting and recordkeeping requirements.

Dated: April 19, 1993.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 675 is proposed to be amended as follows:

PART 675—GROUNDFISH OF THE BERING SEA AND ALEUTIAN ISLANDS AREA

1. The authority citation for part 675 continues to read as follows:

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

2. In § 675.2, the definitions of "Bycatch limitation zone 1", "Bycatch limitation zone 2", and "Bycatch limitation zone 2H" are amended by removing the words "Figure 2" and adding in their place the words "Figure 1"; the definition of "Length overall" is amended by removing the words "Figure 1" and adding in their place the words "Figure 2"; in the definition of "Pelagic trawl" paragraph (1) is amended by removing the words "Figure 4" and adding in their place the words "Figure 3"; in the definition of "Pelagic trawl" paragraph (2) is amended by removing the words "Figure 5" and adding in their place the words "Figure 4"; the definitions of "Bering Sea and Aleutian Islands management area," and "Fishery" are revised; and the definition of "Statistical Area" is amended by redesignating paragraphs (a) through (l) as paragraphs (1) through (12), revising the introductory text and redesignated paragraph (12), and adding paragraphs (13) and (14) to read as follows:

§ 675.2 Definitions.

* * * * *

Bering Sea and Aleutian Islands management area means the exclusive economic zone (EEZ) in the Bering Sea, and that portion of the EEZ in the North Pacific Ocean that is adjacent to the Aleutian Islands and west of 170°00′ W. longitude.

(1) The Bering Sea subarea of the Bering Sea and Aleutian Islands management area means that portion of the EEZ contained in Statistical areas 500–539 as defined in this section.

(i) The Bogoslof District of the Bering Sea subarea means that part of the Bering Sea subarea contained in Statistical area 518 as defined in this section.

(2) The Aleutian Islands subarea of the Bering Sea and Aleutian Islands management area means that portion of the EEZ contained in Statistical areas 541–543 as defined in this section.

(i) The Eastern Aleutian District means that part of the Aleutian Islands subarea contained in Statistical area 541 as defined in this section.

(ii) The Central Aleutian District means that part of the Aleutian Islands subarea contained in Statistical area 542 as defined in this section.

(iii) The Western Aleutian District means that part of the Aleutian Islands subarea contained in Statistical area 543 as defined in this section.

* * * * *

Fishery, for the purposes of this part, means all fishing for groundfish that is conducted in the Bering Sea and Aleutian Islands management area and adjacent territorial waters.

* * * * *

Statistical area means any one of the 14 geographical units of the Bering Sea and Aleutian Islands management area defined as follows (Figure 1):

* * * * *

(12) Statistical area 541—south of 55°00′ N. latitude, west of 170°00′ W. longitude and east of 177°00′ W. longitude.

(13) Statistical area 542—south of 55°00′ N. latitude, west of 177°00′ W. longitude and east of 177°00′ E. longitude.

(14) Statistical area 543—south of 55°00′ N. latitude, west of 177°00′ E. longitude.

* * * * *

3. In § 675.20, paragraph (j)(1) is amended by revising the first sentence, and paragraph (j)(4) is revised to read as follows:

§ 675.20 General limitations.

* * * * *

(j) * * *

(1) For purposes of this paragraph (j), only one primary product per fish, other than roe, may be used to calculate the round-weight equivalent. * * *

* * * * *

(4) *Fishing trip.* For purposes of this paragraph (j), a vessel is engaged in a fishing trip when commencing or resuming the harvesting, receiving, or processing of pollock until the transfer or offloading of any pollock or pollock product or until the vessel leaves the subarea or district where fishing activity commenced, whichever comes first.

* * * * *

4. In § 675.24, the section heading is revised, the introductory text of the section is removed, and paragraphs (c)(1)(i), (c)(1)(ii), (d)(1), (d)(2) and the introductory text of paragraph (f)(1) are revised to read as follows:

§ 675.24 Gear limitations.

* * * * *

(c) * * *

(1) * * *

(i) In the Bering Sea subarea, hook-and-line and pot gear may be used to take up to 50 percent of each TAC for sablefish; trawl gear may be used to take up to 50 percent of each TAC for sablefish.

(ii) In the Aleutian Islands subarea, hook-and-line and pot gear may be used to take up to 75 percent of each TAC for sablefish; trawl gear may be used to take up to 25 percent of each TAC for sablefish.

* * * * *

(d) * * *

(1) When the Regional Director determines that the share of each sablefish TAC assigned to any type of gear for any year and any subarea or district under paragraph (c) may be taken before the end of that year, the Regional Director, in order to provide adequate bycatch amounts to ensure continued groundfish fishing activity by that gear group, will, by publication in the **Federal Register**, prohibit directed fishing for sablefish by persons using that type of gear in that subarea or district for the remainder of the year.

(2) When the Regional Director determines that the share of each

sablefish TAC assigned to any type of gear for any year and any subarea or district under paragraph (c) is or will be reached, the Regional Director will, by publication in the **Federal Register**, require that sablefish be treated as a prohibited species by persons using that type of gear in that subarea or district for the remainder of that year.

* * * * *

(f) * * *

(1) Bering Sea subarea.

* * * * *

§§ 675.2, 675.20, and 675.27 [Amended]

5. In addition to the amendments set forth above, in 50 CFR part 675 remove the word "subarea" and add, in its place, the words "subarea or district" in the following places:

a. Section 675.2, in the definition of "Community Development Quota Reserve (CDQ reserve)";

b. Section 675.20 (a)(2)(ii), (a)(2)(iii), (a)(3)(ii) [2 times], (a)(3)(iii), and (a)(8) [3 times]; and

c. Section 675.27 (b)(1)(ii), and (c)(1).

§ 675.22 [Amended]

6. In § 675.22, paragraph (a) is amended by removing the words "figure 2" and adding in their place the words "figure 1".

7. Figure 1 of the part is removed; Figures 2 through 5 of the part are redesignated Figures 1 through 4 of the part; and redesignated Figure 1 is revised to read as follows:

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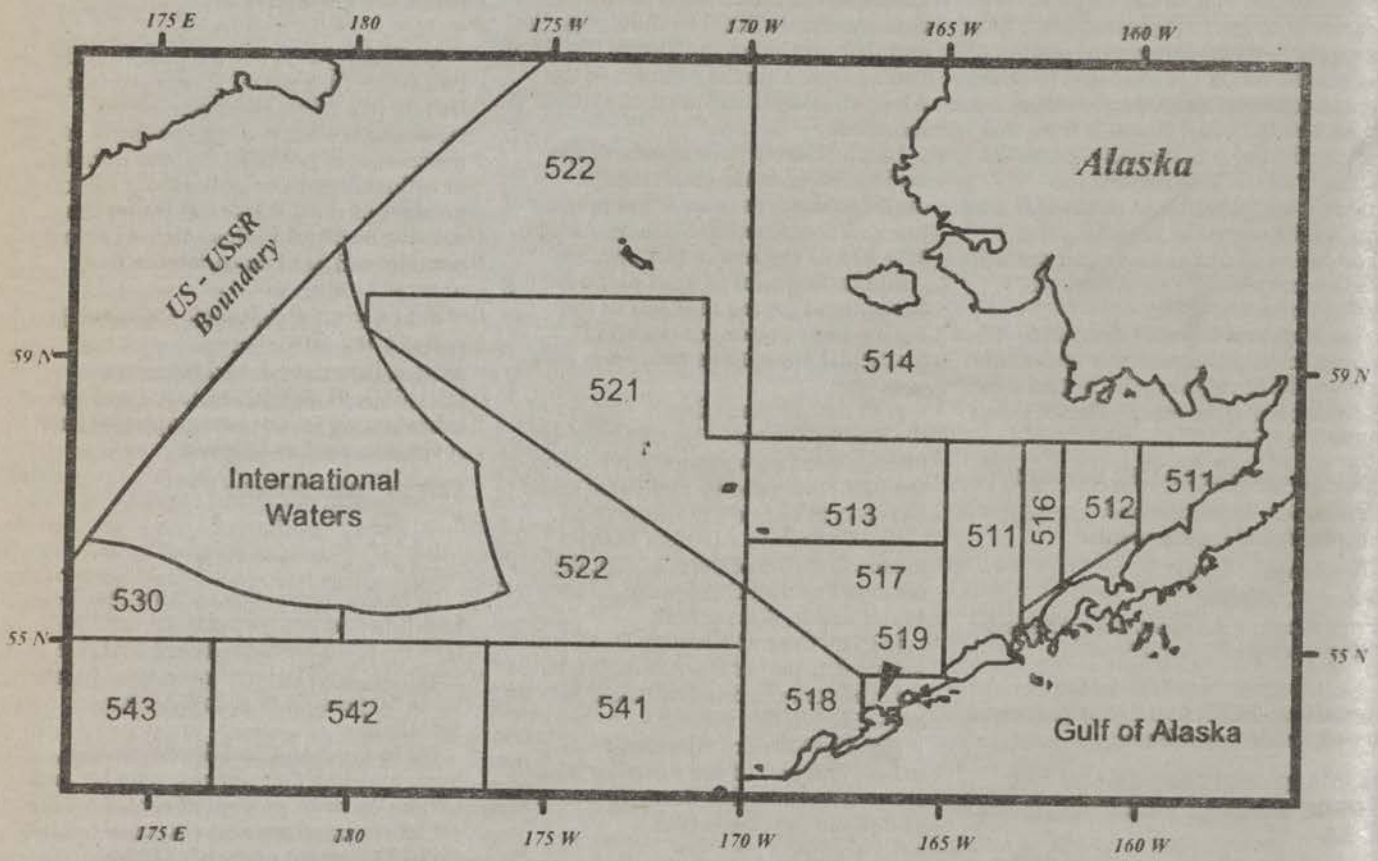

Figure 1. Reporting areas and bycatch limitation zones in the Bering Sea and Aleutian Islands Management Area.

Zone 1 = 511+512+516;

Zone 2 = 513+517+521; and

Zone 2H = 517.

[FR Doc. 93-9536 Filed 4-20-93; 2:44 pm]

BILLING CODE 3510-22-C

Notices

Federal Register
Vol. 58, No. 77
Friday, April 23, 1993

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 93-046-1]

Receipt of Permit Applications for Release Into the Environment of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that four applications for permits to release genetically engineered organisms into the environment are being reviewed by the Animal and Plant Health Inspection Service. The applications have been submitted in accordance with 7 CFR part 340, which regulates the introduction of certain genetically engineered organisms and products.

ADDRESSES: Copies of the applications referenced in this notice, with any confidential business information deleted, are available for public inspection in room 1141, South Building, U.S. Department of Agriculture, 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 an application are encouraged to call ahead on (202) 690-2817 to facilitate entry into the reading room. You may obtain copies of the documents by writing to the person listed under "FOR FURTHER INFORMATION CONTACT."

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, BBEP, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7612.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," require a person to obtain a permit before introducing (importing, moving interstate, or releasing into the environment) into the United States certain genetically engineered organisms and products that are considered "regulated articles." The regulations set forth procedures for obtaining a permit for the release into the environment of a regulated article, and for obtaining a limited permit for the importation or interstate movement of a regulated article.

Pursuant to these regulations, the Animal and Plant Health Inspection Service has received and is reviewing the following applications for permits to release genetically engineered organisms into the environment:

Application No.	Applicant	Date received	Organisms	Field test location
93-078-01, renewal of permit 92-037-05, issued on 05-01-92.	Monsanto Agricultural Company	03-19-93	Soybean plants genetically engineered to express tolerance to the herbicide glyphosate.	Delaware.
93-085-01, renewal of permit 91-078-01, issued on 06-05-91.	DNA Plant Technology Corporation	03-26-93	Tomato plants genetically engineered to express the chitinase (*chiA*) gene for resistance to fungal plant pathogens.	California.
93-085-02	Upjohn Company	03-26-93	Lettuce plants genetically engineered to express resistance to tomato spotted wilt virus.	Georgia.
93-085-03	Upjohn Company	03-26-93	Squash plants genetically engineered to express resistance to certain fungal plant pathogens.	Georgia.

Done in Washington, DC, this 20th day of April 1993.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93-9548 Filed 4-22-93; 8:45 am]

BILLING CODE 3410-34-P

Agricultural Research Service

Intent to Grant Exclusive License

AGENCY: Agricultural Research Service, USDA

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to Monell Chemical Senses Center, a nonprofit organization with headquarters in Philadelphia, Pennsylvania, an exclusive license on its share of U.S. Patent No. 5,187,196, issued February 16, 1993 (S.N. 07/322,039), "Grazing Repellent for Geese and Swans."

DATES: Comments must be received by July 22, 1993.

ADDRESSES: Send comments to: USDA-ARS-Office of Technology Transfer, Beltsville Agricultural Research Center, Baltimore Boulevard, Building 005, Room 403, BARC-W, Beltsville, Maryland 20705-2350.

FOR FURTHER INFORMATION CONTACT: M. Ann Whitehead of the Office of Technology Transfer at the Beltsville address given above; telephone: COMM: 301-504-6786.

SUPPLEMENTARY INFORMATION: The Federal Government's share of patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as said company has submitted a complete and sufficient application for a license, promising therein to bring the benefits of said invention to the U.S. public.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within ninety days from the date of this published Notice, Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

W.H. Tallent,

Assistant Administrator.

[FR Doc. 93–9539 Filed 4–22–93; 8:45 am]

BILLING CODE 3410–03–M

Forest Service

Environmental Impact Statement for Oil and Gas Leasing on Lands Administered by the Dixie National Forest; Iron, Garfield, Kane, Piute, Washington, and Wayne Counties, UT

AGENCY: USDA, Forest Service is the lead agency. USDI, Bureau of Land Management is a cooperating agency.

ACTION: Notice of intent to prepare environmental impact statement (EIS).

SUMMARY: The Forest Service, along with the Bureau of Land Management as a cooperating agency, will prepare an environmental impact statement for oil and gas leasing on lands administered by the Dixie National Forest. The EIS will be tiered to the current Final Environmental Impact Statement for the Dixie National Forest Land and Resource Management Plan.

DATES: Comments concerning the scope of the analysis should be received in writing by June 1, 1993.

ADDRESSES: Send written comments to Hugh C. Thompson, Forest Supervisor, Dixie National Forest, P.O. Box 580, 82 North 100 East, Cedar City, UT 84721–0580.

FOR FURTHER INFORMATION CONTACT: John Shochat, Dixie National Forest, 82 North 100 East, P.O. Box 580, Cedar City, UT 84721–0580, telephone number (801) 865–3700.

SUPPLEMENTARY INFORMATION: The Forest Service will prepare an EIS for oil and gas leasing on the entire Dixie National Forest. The preparation of an EIS is needed to comply with the National Environmental Policy Act in making the decision as to which lands are administratively available for leasing and the leasing decision for specific lands. The Forest Plan will also be amended to incorporate the availability decision once it is made. With the passage of the Federal Onshore Oil and Gas Leasing Reform Act (FOOGLRA), the Forest Service was given the authority to object or not object to leasing of National Forest System lands and to prescribe lease stipulations deemed necessary to mitigate potential resource impacts and reduce conflicts with other National Forest uses. The final decision and issuance of leases is the authority of the Bureau of Land Management.

The decisions to be made involve the leasing of federal minerals within the National Forest administrative boundary. Reasonably foreseeable oil and gas activities within the area will provide the basis for the evaluation of environmental consequences. However, approval of any subsequent activities will require additional NEPA analysis at the time they are actually proposed. The EIS and leasing decisions will be appealable under Forest Service Regulations 36 CFR part 217.

Issues to be addressed in the EIS will be determined through public scoping. For this purpose, the Forest is requesting written comments. Additionally, public meetings will be held in Cedar City and Salt Lake City, Utah. The Cedar City meeting will be held at the Holiday Inn, 1575 West 200 North, on May 25, 1993 at 7 p.m. The Salt Lake City meeting will be held at the Department of Natural Resources Building, Main Conference Room, 1636 West North Temple, on May 27, 1993 at 7 p.m.

Hugh C. Thompson, Forest Supervisor of the Dixie National Forest is the responsible official. The Bureau of Land Management has been identified as a cooperating agency. The Forest Service anticipates release of the Draft EIS for public comment by June 30, 1994, and completion of the Final EIS by December 31, 1994.

Preliminary issues for this project include: (1) Conformance with the Forest Plan, (2) Threatened, Endangered, Sensitive, and Proposed Species, (3) Big game habitat, (4) Roadless area management, (5) Water quality, (6) Visual resources, (7) Recreation management, (8) Riparian values, and (9) Access management.

Preliminary alternatives to be considered in the analysis include: (1) No Action/No Lease, (2) Forest Plan intent as reflected by Appendix C of the Forest Plan, and (3) Leasing with standard lease terms (no special stipulations).

The comment period on the draft EIS will be 45 days from the date the notice of availability appears in the **Federal Register**. It is very important that those interested in the proposed action participate at that time.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of a Draft EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers' position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could have been raised at the draft stage but are not raised until after completion of the final EIS may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, (9th Circuit, 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45 day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider then and respond to them in the Final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the Draft EIS or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.)

Dated: April 16, 1993.

Robert H. Meinrod,

Acting Forest Supervisor, Dixie National Forest.

[FR Doc. 93–9529 Filed 4–22–93; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Office of the Secretary

Advisory Committee; Availability of Report on Closed Meetings

AGENCY: Department of Commerce.

ACTION: Announcing public availability of report on closed meetings of advisory committees.

SUMMARY: The Department of Commerce has prepared its report on the activities of closed or partially closed meetings of advisory committees as required by the Federal Advisory Committee Act.

ADDRESSES: Copies of the reports have been filed and are available for public inspection at two locations:

Library of Congress, Newspaper and Current Periodicals Reading Room, room LM133, Madison Building, 1st and Independence Avenues, SE., Washington, DC 20540

Department of Commerce, Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th and Constitution Avenue, NW., Washington, DC 20230. Telephone (202) 377–4115.

SUPPLEMENTARY INFORMATION: The reports cover the closed and partially closed meetings held in 1992 of 45 committees and their subcommittees, the names of which are listed below:

Automated Manufacturing Equipment Technical Advisory Committee
Biotechnology Technical Advisory Committee
Board of Overseers of the Malcolm Baldrige National Quality Award
Committee of Chairs of Industry Advisory Committees for Trade Policy Matters (TPM)
Computer Systems Security and Privacy Advisory Board
Computer Systems Technical Advisory Committee
—Licensing Procedures Subcommittee
Electronics Technical Advisory Committee
Electronic Instrumentation Technical Advisory Committee
Industry Sector Advisory Committee (ISAC) on Aerospace Equipment for Trade Policy Matters (TPM)
—Subcommittee on Space
—Subcommittee on Finance
ISAC on Building Products and Other Materials for TPM
ISAC on Capital Goods for TPM
ISAC on Chemicals and Allied Products for TPM
ISAC on Consumer Goods for TPM
—North American Free Trade Agreement (NAFTA) Task Force
ISAC on Electronics and Instrumentation for TPM
ISAC on Energy for TPM
ISAC on Ferrous Ores and Metals for TPM
ISAC on Footwear, Leather, and Leather Products for TPM
ISAC on Lumber and Wood Products for TPM
ISAC on Nonferrous Ores and Metals for TPM
ISAC on Paper and Paper Products for TPM
ISAC on Services for TPM
ISAC on Small and Minority Business for TPM
ISAC on Textiles and Apparel for TPM
ISAC on Transportation, Construction, and Agricultural Equipment for TPM
ISAC on Wholesaling and Retailing for TPM
Importers and Retailers' Textile Advisory Committee
Industry Functional Advisory Committee on Customs Matters for TPM
Industry Functional Advisory Committee on Intellectual Property Rights for TPM
Industry Functional Advisory Committee on Standards for TPM
—North American Free Trade Agreement (NAFTA) Task Force
—Subcommittee on Conformity Assessment
Industry Policy Advisory Committee for Trade Policy Matters
Management-Labor Textile Advisory Committee
Materials Technical Advisory Committee
Materials Processing Equipment Technical Advisory Committee
Militarily Critical Technologies List Technical Advisory Committee
National Medal of Technology Nomination Evaluation Committee
National Technical Information Service Advisory Board
Panel of Judges of the Malcolm Baldrige National Quality Award
President's Export Council
Semiconductor Technical Advisory Committee
Sensors Technical Advisory Committee
—Subcommittee on Export Administration
Telecommunications Equipment Technical Advisory Committee
Transportation and Related Equipment Technical Advisory Committee
U.S. Automotive Parts Advisory Committee
Visiting Committee and Advanced Technology

FOR FURTHER INFORMATION CONTACT: Jan Witter, Program Analyst, Office of the Secretary, Department of Commerce, Washington, DC 20230, Telephone (202) 482–4115.

Dated: April 15, 1993.

Jan Witter,

Office of Management Support, Office of Federal Assistance and Management Support.

[FR Doc. 93–9528 Filed 4–22–93; 8:45 am]

BILLING CODE 3510–FA–M

Bureau of Export Administration

Action Affecting Export Privileges; Pan Aviation, Inc.

Order Denying Permission To Apply for or Use Export Licenses

In the Matter of: Pan Aviation, Inc., 305 N. Hibiscus Drive, Miami Beach, Florida 33135.

On January 23, 1992, Pan Aviation, Inc. (hereinafter referred to as Pan Aviation) was convicted in the U.S. District Court for the Southern District of Florida on two counts of violating section 38 of the Arms Export Control Act, as amended (22 U.S.C. 2778 (1988 & Supp. III 1991)) (AECA). The counts were part of a multiple-count criminal indictment charging Pan Aviation, *inter alia*, with attempting to export certain arms/military equipment from the United States to Iraq without having obtained the required export license from the Department of State. Section 11(h) of the Export Administration Act of 1979, as amended (50 U.S.C.A. app. 2401–2420 (1991, Supp. 1992, and Pub. L. No. 103–10, March 27, 1993)) (EAA), provides that, at the discretion of the Secretary of Commerce,[1] no person convicted of violating section 38 of the AECA, or certain other provisions of the United States Code, shall be eligible to apply for or use any export license issued pursuant to, or provided by, the EAA or the Export Administration Regulations (currently codified at 15 CFR parts 768–799 (1992)) (the Regulations), for a period of up to 10 years from the date of the conviction. In addition, any export license issued pursuant to the EAA in which such a person had any interest at the time of conviction may be revoked.

Pursuant to §§ 770.15 and 772.1(g) of the Regulations, upon notification that a person has been convicted of violating section 38 of the AECA, the Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, shall determine whether to deny that person permission to apply for or use any export license issued pursuant to, or provided by, the EAA and the Regulations and shall also determine whether to revoke any export license previously issued to such a person. Having received notice of Pan Aviation's conviction for violating section 38 of the AECA, and following consultations with the Director, Office of Export Enforcement, I have decided to deny Pan Aviation permission to

[1] Pursuant to appropriate delegations of authority that are reflected in the Regulations, the Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by section 11(h) of the EAA.

apply for or use any export license, including any general license, issued pursuant to, or provided by, the EAA and the Regulations, for a period of 10 years from the date of its conviction. The 10-year period ends on January 23, 2002. I have also decided to revoke all export licenses issued pursuant to the EAA in which Pan Aviation had an interest at the time of its conviction.

According, *it is hereby Ordered,*

I. All outstanding individual validated licenses in which Pan Aviation appears or participates, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation. Further, all of Pan Aviation's privileges of participating, in any manner or capacity, in any special licensing procedure, including, but not limited to, distribution licenses, are hereby revoked.

II. Until January 23, 2002, Pan Aviation, Inc., 305 N. Hibiscus Drive, Miami Beach, Florida 33135, hereby is denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction in the United States or abroad involving any commodity or technical data exported or to be exported from the United States, in whole or in part, and subject to the Regulations. Without limiting the generality of the foregoing, participation, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (i) As a party or as a representative of a party to any export license application submitted to the Department; (ii) in preparing or filing with the Department any export license application or request for reexport authorization, or any document to be submitted therewith; (iii) in obtaining from the Department or using any validated or general export license, reexport authorization or other export control document; (iv) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported or to be exported from the United States, and subject to the Regulations; and (v) in financing, forwarding, transporting, or other servicing of such commodities or technical data.

III. After notice and opportunity for comment as provided in § 770.15(h) of the Regulations, any person, firm, corporation, or business organization related to Pan Aviation by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

IV. As provided in § 787.12(a) of the Regulations, without prior disclosure of the facts to and specific authorization of the Office of Export Licensing, in consultation with the Office of Export Enforcement, no person may directly or indirectly, in any manner or capacity: (i) Apply for, obtain, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to an export or reexport of commodities or technical data by, to, or for another person then subject to an order revoking or denying his export privileges or then excluded from practice before the Bureau of Export Administration; or (ii) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate: (a) In any transaction which may involve any commodity or technical data exported or to be exported from the United States; (b) in any reexport thereof; or (c) in any other transaction which is subject to the Export Administration Regulations, if the person denied export privileges may obtain any benefit or have any interest in, directly or indirectly, any of these transactions.

V. This Order is effective immediately and shall remain in effect until January 23, 2002.

VI. A copy of this Order shall be delivered to Pan Aviation. This Order shall be published in the **Federal Register.**

Dated: April 12, 1993.

Eileen Albanese,

Acting Director, Office of Export Licensing.

[FR Doc. 93-9526 Filed 4-22-93; 8:45 am]

BILLING CODE 3510-DT-M

Action Affecting Export Privileges; Sarkis G. Soghanalian

Order Denying Permission To Apply for or Use Export Licenses

In the Matter of: Sarkis G. Soghanalian, with addresses at: 5745 NW. 38 Street, Virginia Gardens, Florida 33161, and Inmate Number 32995-004, Metropolitan Correctional Facility, 15801 SW. 137 Avenue, Miami, Florida 33177.

On January 29, 1992, Sarkis G. Soghanalian (hereinafter referred to as Soghanalian) was convicted in the U.S. District Court for the Southern District of Florida on two counts of violating section 38 of the Arms Export Control Act, as amended (22 U.S.C. 2778 (1988 & Supp. III 1991)) (AECA). The convictions were part of a multiple-count criminal indictment charging Soghanalian, *inter alia,* with attempting to export certain arms/military equipment from the United States to Iraq without having obtained the required export license from the Department of State. Section 11(h) of the Export Administration Act of 1979, as amended (50 U.S.C.A. app. 2401-2420 (1991, Supp. 1992, and Pub. L. No. 103-10, March 27, 1993)) (EAA), provides that, at the discretion of the Secretary of Commerce,[1] no person convicted of violating section 38 of the AECA, or certain other provisions of the United States Code, shall be eligible to apply for or use any export license issued pursuant to, or provided by, the EAA or the Export Administration Regulations (currently codified at 15 CFR parts 768-799 (1992)) (the Regulations), for a period of up to 10 years from the date of the conviction. In addition, any export license issued pursuant to the EAA in which such a person had any interest at the time of conviction may be revoked.

Pursuant to §§ 770.15 and 772.1(g) of the Regulations, upon notification that a person has been convicted of violating section 38 of the AECA, the Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, shall determine whether to deny that person permission to apply for or use any export license issued pursuant to, or provided by, the EAA and the Regulations and shall also determine whether to revoke any export license previously issued to such a person. Having received notice of Soghanalian's conviction for violating section 38 of the AECA, and following consultations with the Director, Office of Export Enforcement, I have decided to deny Soghanalian permission to apply for or use any export license, including any general license, issued pursuant to, or provided by, the EAA and the Regulations, for a period of 10 years from the date of his conviction. The 10-year period ends on January 29, 2002. I have also decided to revoke all export licenses issued pursuant to the EAA in which Soghanalian had an interest at the time of his conviction.

Accordingly, *it is hereby Ordered,*

I. All outstanding individual validated licenses in which Soghanalian appears or participates, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation. Further, all of Soghanalian's privileges of participating, in any manner or capacity, in any special licensing procedure, including, but not limited to,

[1] Pursuant to appropriate delegations of authority that are reflected in the Regulations, the Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by section 11(h) of the EAA.

distribution licenses, are hereby revoked.

II. Until January 29, 2002, Sarkis G. Soghanalian, with addresses at 5745 NW 38 Street, Virginia Gardens, Florida 33161, and Inmate Number 32995–004, Metropolitan Correctional Center, 15801 SW 137 Avenue, Miami, Florida 33177, hereby is denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction in the United States or abroad involving any commodity or technical data exported or to be exported from the United States, in whole or in part, and subject to the Regulations. Without limiting the generality of the foregoing, participation, either in the Untied States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (i) As a party or as a representative of a party of any export license application submitted to the Department; (ii) in preparing or filing with the Department any export license application or request for reexport authorization, or any document to be submitted therewith; (iii) in obtaining from the Department or using any validated or general export license, reexport authorization or other export control document; (iv) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using or disposing of, in whole or in part, any commodities or technical data exported or to be exported from the United States, and subject to the Regulations; and (v) in financing, forwarding, transporting, or other servicing of such commodities or technical data.

III. After notice and opportunity for comment as provided in § 770.15(h) of the Regulations, any person, firm, corporation, or business organization related to Soghanalian by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

IV. As provided in § 787.12(a) of the Regulations, without prior disclosure of the facts to and specific authorization of the Office of Export Licensing, in consultation with the Office of Export Enforcement, no person may directly or indirectly, in any manner or capacity: (i) Apply for, obtain, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to an export or reexport of commodities or technical data by, to, or for another person then subject to an order revoking or denying his export privileges or then excluded from practice before the Bureau of Export Administration; or (ii) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate: (a) in any transaction which may involve any commodity or technical data exported or to be exported from the United States; (b) in any reexport thereof; or (c) in any other transaction which is subject to the Export Administration Regulations, if the person denied export privileges may obtain any benefit or have any interest in, directly or indirectly, any of these transactions.

V. This Order is effective immediately and shall remain in effect until January 29, 2002.

VI. A copy of this Order shall be delivered to Soghanalian. This Order shall be published in the **Federal Register**.

Dated: April 12, 1993.

Eileen Albanese,

Acting Director, Office of Export Licensing.

[FR Doc. 93–9527 Filed 4–22–93; 8:45 am]

BILLING CODE 3510–DT–M

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Programs and Estuarine Reserves

AGENCY: Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), DOC.

ACTION: Notice of intent to evaluate.

SUMMARY: The NOAA Office of Ocean and Coastal Resource Management (OCRM) announces its intent to evaluate the performance of the California and Maine Coastal Management Programs and the Rookery Bay National Estuarine Research Reserve.

These evaluations will be conducted pursuant to section 312 of the Coastal Zone Management Act of 1972 (CZMA), as amended. The CZMA requires a continuing review of the performance of coastal states with respect to coastal management. Evaluation of coastal management programs and estuarine reserves require findings concerning the extent to which a state has adhered to the CZM program or estuarine reserve management plan approved by the Secretary of Commerce, and adhered to the terms of financial assistance awards funded under the CZMA. These reviews include a site visit, consideration of public comments, and consultations with interested Federal, state, and local agencies and members of the public. Public meetings are held as part of the site visits.

Notice is hereby given of the dates of the site visits for the listed evaluations, and the dates, local times, and locations of public meetings during the site visits.

The California Coastal Management Program site visit will be June 8–17, 1993. Public meetings will be held Wednesday, June 9, 1993, at 7 p.m. at the Marin County Civic Center, Board of Supervisors Chambers (Administrative Building, room 322), San Rafael, California 94903; and Tuesday, June 15, 1993, at 7 p.m., at the Airport Marine Hotel, 8601 Lincoln Boulevard, Los Angeles, California 90045.

The Maine Coastal Management Program site visit will be June 14–18, 1993. Public meetings will be held Tuesday, June 15, 1993, at 4 p.m., at the Customs House, 312 Fore Street, 3rd Floor, Portland, Maine; and Thursday, June 17, 1993, at 6 p.m. at the Marine Museum, Church Street, Searsport, Maine.

The Rookery Bay National Estuarine Research Reserve site visit will be July 26–30, 1993, A public meeting will be held Wednesday, July 28, 1993, at 7 p.m., at the Collier County Commissioner's Chambers, 3rd Floor Building F, 3301 Tamiami Trail E, Naples, Florida 33962.

The States will issue notices of the public meetings in local newspapers at least 45 days prior to the public meetings being held and will issue other timely notices appropriate.

Copies of the state's most recent performance reports, as well as OCRM's notifications and supplemental request letters to the states, are available upon request from OCRM. Written comments from interested parties regarding these programs are encouraged at this time and will be accepted until 15 days after the site visit. Please direct written comments to the Vickie A. Allin, Chief, Policy Coordination Division, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1825 Connecticut Avenue, NW. Washington, DC 20235. When the final evaluation findings are completed, OCRM will place a notice in the **Federal Register** announcing their availability.

FOR FURTHER INFORMATION CONTACT:

Vickie A. Allin, Chief, Policy Coordination Division, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1825 Connecticut Avenue, NW., Washington, DC 20235, (202) 606–4100.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

W. Stanley Wilson,

Assistant Administrator for Ocean Service and Coastal Zone Management.

[FR Doc. 93-9568 Filed 4-22-93; 8:45 am]

BILLING CODE 3510-08-M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: May 24, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202-3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603-7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following actions will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46 - 48c) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following services to the Procurement List for production by the nonprofit agencies listed:

Food Service Attendant, Naval Weapons Station, Building 306, Charleston, South Carolina, Nonprofit Agency: Goodwill Industries of Lower South Carolina, Inc. Charleston, South Carolina

Janitorial/Custodial, Federal Building Fairbanks, Alaska Nonprofit Agency: Fairbanks Rehabilitation Association Fairbanks, Alaska

Janitorial/Custodial, Joseph D. Addabbo Federal Building, Jamaica Avenue & Parsons Blvd., Jamaica, New York, Nonprofit Agency: FEDCAP Rehabilitation Services, Inc., New York, New York

Janitorial/Custodial (Excluding Commissary and Base Exchange), Grand Forks, North Dakota, Nonprofit Agency: Minot Vocational Adjustment Workshop, Inc., Minot, North Dakota

Repair of Small Hand Tools, Fleet and Industrial Supply Center, Jacksonville, Florida, Nonprofit Agency: Tampa Lighthouse for the Blind, Tampa, Florida

Beverly L. Milkman,

Executive Director.

[FR Doc. 93-9569 Filed 4-22-93; 8:45 am]

BILLING CODE 6820-33-P

Procurement List; Proposed Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: May 24, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202-3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603-7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed action.

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following actions will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46 - 48c) in connection with the service proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following service to the Procurement List for production by the nonprofit agency listed: Grounds Maintenance, at Various Off-base Locations within a 50-Mile Radius of the Navy Public Works Center, Norfolk, Virginia, Nonprofit Agency: Diversified Industrial Concepts, Inc. Virginia Beach, Virginia.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93-9570 Filed 4-22-93; 8:45 am]

BILLING CODE 6820-33-P

Procurement List Additions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to procurement list.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: May 24, 1993.

ADDRESSES: Committee for Purchase from People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On January 4, 25, February 12, 26 and March 5, 1993, the Committee for Purchase from People Who Are Blind or Severely Disabled published notices (58 F.R. 91, 5959, 8261, 11590 and 12580) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and services, fair market price, and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

Towel, Machinery Wiping
7920–01–370–1364

Compound, Corrosion Preventive
8030–00–524–9487
8030–00–213–3279
8030–00–251–5048
8030–00–251–5049

Services

Janitorial/Custodial, U.S. Army Engineer District, Waterway Project Office, Peoria, Illinois

Janitorial/Custodial, Automated Flight Service Station and Air Traffic Control Tower, Bowman Field, Louisville, Kentucky

Janitorial/Custodial, U.S. Army Reserve Center, 2501 Fraiser, Conroe, Texas

Janitorial/Custodial, U.S. Army Reserve Center, 920 S. Sam Houston, Huntsville, Texas

Janitorial/Custodial, U.S. Army Reserve Center, 2414 Winddecker Street, Midland, Texas

Janitorial/Custodial, Franconia Warehouse Complex, 6810 Loisdale Road, Springfield, Virginia.

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–9571 Filed 4–22–93; 8:45 am]

BILLING CODE 6820–33–P

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to procurement list.

SUMMARY: This action adds to the Procurement List men's gloves to be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: May 24, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On February 5, 1993, the Committee for Purchase From People Who Are Blind or Severely Disabled published a notice (58 FR 7216) of the proposed addition of these gloves to the Procurement List. Comments were received from the current contractor for the gloves in response to a Committee request for sales information. The contractor noted in some detail that these gloves are made under very exacting conditions, such as tight sewing tolerances and a need for extreme cleanliness in manufacturing the gloves. The contractor stated that it had taken a long time to learn to make the gloves efficiently. The contractor believes that loss of the opportunity to produce half the Government requirement for the gloves would have a severe impact on its employees and its overhead.

The Committee's decision that the nonprofit agency proposed to produce the gloves is capable of doing so is based in part on a plant inspection report by the Government agency that buys the gloves. The report addressed the exacting production conditions which the contractor noted in its comments and concluded that the nonprofit agency is capable of producing the gloves under those conditions. The nonprofit agency is experienced in producing gloves and is currently producing gloves on a commercial contract under the direction of a production manager with 14 years of glove experience.

The value of the 50% of the Government requirement for the gloves which is being added to the Procurement List represents a very small portion of the contractor's sales. The Committee does not believe that loss of these sales and the attendant increase in overhead together constitute severe adverse impact on the contractor. Even if the contractor is unable to employ the workers displaced by the Committee's action in its other business with the Government and the commercial market, the Committee considers that the possible loss of jobs is outweighed by the creation of jobs for people with severe disabilities, whose unemployment rate exceeds 65%.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to produce the commodities, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in

connection with the commodities proposed for addition to the Procurement List. Accordingly, the following commodities are hereby added to the Procurement List:

Gloves, Men's/
8440–00–160–0770
8440–00–160–0874
8440–00–160–0875

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–9572 Filed 4–22–93; 8:45 am]

BILLING CODE 6820–33–P

DEPARTMENT OF DEFENSE

Department of the Army

Preparation of an Environmental Impact Statement (EIS) for Projects and Activities Associated With Future Programs at White Sands Missile Range (WSMR)

AGENCY: Department of Defense, Department of Army.

ACTION: Notice of intent.

SUMMARY: The EIS will address the potential impacts of several categories of future test projects being planned at WSMR and categories of expanded range mission. The future testing categories include: Missile Testing (i.e. THAAD and Standard Missile) and High Altitude Testing (i.e. HABE and Research Rockets). The expanded missions include: Nuclear Effects Testing (i.e. Linear Accelerator and Gamma Range) and the launching of missiles from off-post with a final impact on WSMR.

In the past, WSMR has incorporated the National Environmental Policy Act in planning and evaluating new actions on a case-by-case basis. To better evaluate the cumulative effects of unrelated actions being planned at the same time the EIS will incorporate all known and future programs. The analysis will address potential impacts, cumulative effects and mitigation of these effects. If future projects are not within the scope of this analysis they will be incorporated through tiering as defined in the National Environmental Policy Act.

Alternatives to be considered include:

a. No action. Current level of testing is maintained. No testing of future programs or mission expansion on WSMR is considered.

b. Testing of future systems but not expanding the mission capabilities of the range.

c. Testing of future systems and expansion of the mission into Nuclear Effects Testing and launches into WSMR from off-post.

The Army will conduct scoping meetings prior to preparing the EIS. The first step is to determine the appropriate issues, activities and alternatives to be addressed. Among the anticipated areas to be evaluated are water quality and quantity, air quality, hazardous materials management and disposal, human health and safety, historic and archaeological resources, and biological resources. Comments regarding additional issues, activities and alternatives, as well as their relative importance, are welcome. Additionally, other Federal agencies, which are major users of WSMR, will be requested to act as cooperating agencies.

ADDRESSES: Anyone wishing to receive current information and future newsletters may send a postcard with their name and address to Advance Sciences Inc., 555 Telshor, suite 310, ATTN: Mr. Lewis Michaelson, Las Cruces, NM 88001.

This notice announces the beginning of the public comment period and scoping process. Scoping comments should be received within 15 days following the public scoping meetings. Scoping input will be used during the preparation of the EIS. Public scoping meetings will be held within the next four weeks in Las Cruces, Alamogordo, Socorro, and Albuquerque, New Mexico, and El Paso, Texas. Exact dates and locations will be advertised in the local media.

FOR FURTHER INFORMATION CONTACT: Persons and organizations wishing to comment on the proposed actions may attend these meetings or may send written comments to Commander, White Sands Missile Range, ATTN: STEWS–ES–E/Mr. Robert Andreoli, White Sands Missile Range, NM 88002–5048.

Dated: April 15, 1993.

Lewis D. Walker,

Deputy Assistant Secretary of Defense (Environment, Safety and Occupational Health), OASA (I,L&E).

[FR Doc. 93–9455 Filed 4–22–93; 8:45 am]

BILLING CODE 3710–08–M

Army Science Board; Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 10–12 May 1993.

Time of Meeting: 0800–1700 hours daily.

Place: Micom RD&E Center, Redstone Arsenal, the SSDC Building, and ATMD Building, Huntsville, AL.

Agenda: The Army Science Board's 1993 Summer Study on "Missile Defense Programs" will meet to continue work on the study. The ASB will receive briefings on Hardware-in-the-Loop (HWIL) Simulations, SDIO/Army Systems Development Programs, Interceptor Technology, System Lethality, and Tech Transfer Issues. This meeting will be closed to the public in accordance with section 552b.(c) of title 5, U.S.C., specifically subparagraph (1) thereof and title 5, U.S.C. appendix 2, subsection 10(d). The classified and unclassified information to be discussed will be so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Sally Warner, may be contacted for further information (703) 695–0781.

Sally A. Warner,

Administrative Officer, Army Science Board.

[FR Doc. 93–9580 Filed 4–22–93; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Office of Elementary and Secondary Education; Intent to Repay to the Illinois State Board of Education Funds Recovered as a Result of Final Audit Determinations

AGENCY: Department of Education.

ACTION: Notice of intent to award grantback funds.

SUMMARY: Under section 456 of the General Education Provisions Act (GEPA), 20 U.S.C. 1234e (1982), the U.S. Secretary of Education (Secretary) intends to repay to the Illinois State Board of Education, the State educational agency (SEA), an amount equal to 75 percent of the principal amount of funds recovered by the U.S. Department of Education (Department) as a result of a settlement of final audit determinations. This notice describes the SEA's plan for the use of the repaid funds and the terms and conditions under which the Secretary intends to make those funds available. The notice invites comments on the proposed grantback.

DATES: All comments must be received on or before May 24, 1993.

ADDRESSES: Comments concerning the grantback should be addressed to Dr. Bruce Gaarder, Director, Division of Program Development and Support, Compensatory Education Programs, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, SW.

(room 2043), Washington, DC 20202–6132.

FOR FURTHER INFORMATION CONTACT: Dr. Bruce Gaarder, Telephone: (202) 401–1695. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION:

A. Background

The Department recovered $1,000,000, plus interest, from the Illinois SEA in settlement of all claims arising from an audit of programs of the Board of Education of the City of Chicago, the local educational agency (LEA), covering the period September 1, 1972, through August 31, 1977.

The claims involved the SEA's administration of Title I of the Elementary and Secondary Education Act of 1965 (Title I), a program that addressed the special educational needs of educationally deprived children. Specifically, the April 16, 1980, final audit determinations of the then Deputy Commissioner for Elementary and Secondary Education (Deputy Commissioner) found that Title I funds had been expended in the LEA's Family Living Centers in violation of Title I requirements that funds be expended only for projects designed to meet the special educational needs of educationally deprived children, and that title I funds be used to supplement and not supplant non-Federal funds that would have been made available in the absence of Title I funds. The Deputy Commissioner also found that Title I funds had been expended in two Upper Grade Centers in violation of the Title I requirement that services provided with State and local funds in Title I project areas be at least comparable to services provided with State and local funds in areas not designated as Title I project areas. In addition, the Deputy Commissioner found that Title I funds were misexpended, in violation of the then Office of Education's general provisions regulations, because the LEA had included the costs of the district superintendents in determining indirect costs and because the costs of capital expenditures had been included in the total direct costs to which cost rates were applied. As a result of these findings, the Deputy Commissioner determined that $3,335,680 of Title I funds were misexpended for unallowable costs. The SEA appealed the determinations of the Deputy Commissioner to the Education Appeal Board. On April 26, 1990, the SEA, LEA (the intervenor in the appeal), and Department entered into a settlement agreement under which the SEA agreed to pay to the Department $1,000,000, plus accrued interest, in three installment payments. The SEA submitted two payments of $300,000, plus interest, in May 1990 and May 1991, respectively, and made the final payment of $400,000, plus interest, in May 1992.

B. Authority for Awarding a Grantback

Section 456(a) of GEPA, 20 U.S.C. 1234e(a) (1982), provides that whenever the Secretary has recovered funds following a final audit determination with respect to an applicable program, the Secretary may consider those funds to be additional funds available for the program and may arrange to repay to the SEA or LEA affected by that determination an amount not to exceed 75 percent of the recovered funds. The Secretary may enter into this grantback arrangement if the Secretary determines that the—

(1) Practices and procedures of the SEA or LEA that resulted in the audit determination have been corrected, and the SEA or LEA is, in all other respects, in compliance with the requirements of the applicable program;

(2) SEA has submitted to the Secretary a plan for the use of the funds to be awarded under the grantback arrangement that meets the requirements of the program, and, to the extent possible, benefits the population that was affected by the failure to comply or by the misexpenditures that resulted in the audit exception; and

(3) Use of funds to be awarded under the grantback arrangement in accordance with the SEA's plan would serve to achieve the purposes of the program under which the funds were originally granted.

C. Plan for Use of Funds Awarded Under a Grantback Arrangement

Pursuant to section 456(a)(2) of GEPA, the SEA has applied for a grantback of $750,000 and has submitted a plan for use of the grantback funds in the LEA's schools to meet the special educational needs of educationally deprived children in programs administered under Chapter 1 of Title I of the Elementary and Secondary Education Act of 1965, as amended (Chapter 1).

According to the plan, the LEA would use the grantback funds to supplement Chapter 1 program improvement activities in the 168 schools (grades 1 through 8) that were identified first for program improvement based on 1988–89 evaluation data. Because these schools still have not shown a gain in aggregate performance, they will implement joint program improvement plans that were developed with the SEA. Each of the 168 schools would be assigned an education expert from a local university, college, or other educational institution to advise a team of administrators, teachers, and parents from that school in implementing the joint plan. Further, the consultants would provide a training program for teachers and other Chapter 1 staff at each school in areas where additional training is needed. The consultants' services would also be provided to Chapter 1 personnel serving nonpublic school students and parents of those children. Approximately 1,680 teachers, aides, and parents would participate in the program improvement effort.

In addition, the LEA would develop two school/community resource centers to (1) facilitate the development of new programs and practices to improve the quality of Chapter 1 instruction; (2) serve as training locations for teachers, parents, and administrators of Chapter 1 schools; and (3) provide facilities for the production or selection of Chapter 1 materials for dissemination. School program improvement teams from the 168 schools implementing joint program improvement plans would be scheduled for training at the centers on a rotating basis. The centers would also provide special assistance to schools that plan to implement a schoolwide project as a strategy for improving the achievement of educationally deprived children.

Of the $750,000, $560,621 would be used for salaries and fringe benefits for 168 consultants, two teacher/writers, one evaluator, and two clerical staff persons. The remaining funds would be used to purchase resource center equipment and materials and for other operational expenses.

D. The Secretary's Determinations

The Secretary has carefully reviewed the plan submitted by the SEA. Based upon that review, the Secretary has determined that the conditions under section 456 of GEPA have been met.

These determinations are based upon the best information available to the Secretary at the present time. If this information is not accurate or complete, the Secretary is not precluded from taking appropriate administrative action. In finding that the conditions of section 456 of GEPA have been met, the Secretary makes no determination concerning any pending audit recommendations or final audit determinations.

E. Notice of the Secretary's Intent to Enter Into a Grantback Arrangement

Section 456(d) of GEPA requires that, at least 30 days before entering into an arrangement to award funds under a grantback, the Secretary must publish in the **Federal Register** a notice of intent to do so, and the terms and conditions under which the payment will be made.

In accordance with section 456(d) of GEPA, notice is hereby given that the Secretary intends to make funds available to the Illinois SEA under a grantback arrangement. The grantback award would be in the amount of $750,000, which is 75 percent of the principal amount recovered by the Department as a result of the audit.

F. Terms and Conditions Under Which Payments Under a Grantback Arrangement Would Be Made

The SEA and LEA agree to comply with the following terms and conditions under which payment under a grantback arrangement would be made:

(1) The funds awarded under the grantback must be spent in the—

(a) All applicable statutory and regulatory requirements;

(b) The plan that the SEA submitted and any amendments to that plan that are approved in advance by the Secretary; and

(c) The budget that was submitted with the plan and any amendments to the budget that are approved in advance by the Secretary.

(2) All funds received under the grantback arrangement must be obligated by September 30, 1993, in accordance with section 456(c) of GEPA and the SEA's plan.

(3) The SEA will, not later than January 1, 1994, submit a report to the Secretary that—

(a) Indicates that the funds awarded under the grantback have been spent in accordance with the proposed plan and approved budget, and

(b) Describes the results and effectiveness of the project for which the funds were spent.

(4) Separate accounting records must be maintained documenting the expenditures of funds awarded under the grantback arrangement.

(5) Before funds will be repaid pursuant to this notice, the SEA must repay to the Department any debts that become overdue or enter into a repayment agreement for those debts.

(Catalog of Federal Domestic Assistance Number 84.010, Educationally Deprived Children—Local Educational Agencies)

Dated: April 19, 1993.

Richard W. Riley,

Secretary of Education.

[FR Doc. 93-9486 Filed 4-22-93; 8:45 am]

BILLING CODE 4000-01-U

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, DOE.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Pub. L. 96-511, 44 U.S.C. 3501 et seq.). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component, which term includes the Federal Energy Regulatory Commission); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public; (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed on or before may 24, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395-3084. (Also, please notify the EIA contact listed below.).

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.)

FOR FURTHER INFORMATION CONTACT: Jay Casselberry, Office of Statistical Standards, (EI-73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254-5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Energy Information Administration
2. EIA-1, 3, 3A, 4, 5, 5A, 6, 7A, and 20
3. 1905-0167
4. Coal Program Package
5. New—OMB approved the Coal Program Package (OMB No. 1905-0167) on March 8, 1993; however, Forms EIA-3A, "Annual Coal Quality Report—Manufacturing Plants," and EIA-5A, "Annual Coal Quality Report—Coke Plants," were disapproved. EIA has provided additional justification and is requesting OMB approval of the EIA-3A and EIA-5A.
6. Quarterly (EIA-3, 5, and 6), Annually (EIA-3A, 5A, and 7A), Other (Standby) (EIA-1, 4, and are used in the event of a coal supply disruption.)
7. Mandatory
8. Businesses or other for-profit
9. 6,133 respondents
10. 2.06 responses per respondent
11. 1.53 hours per response
12. 19,390 hours
13. The coal surveys collect data on coal production, consumption, stock prices, imports and exports. Data are published in various EIA publications. Respondents are manufacturing plants, producers of coke, purchasers and distributors of coal, coal mining operators, and coal-consuming electric utilities.

The EIA-3A and EIA-5A will collect data on coal origin and coal quality. Data from the EIA-3A and EIA-5A will be used to report to Congress on the Clean Air Act Amendments as required by the Energy Policy Act of 1992. Data from the EIA-3A and EIA-5A will also be used by EIA's National Energy Modeling System (NEMS) which provides the primary technical and analytical support for the Department's National Energy Strategy. Respondents to the EIA-3A are manufacturing plants and to the EIA-5A, coke plants.

Statutory Authority: Sec. 2(a) of the Paperwork Reduction Act of 1980, (Pub. L.

96–511) which amended chapter 35 of title 44 United States Code. [See U.S.C. 3506(a) and (c)(1)]

Issued in Washington, DC, April 12, 1993.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–9544 Filed 4–22–93; 8:45 am]

BILLING CODE 6450–01–M

Residential Transportation Energy Consumption Survey; Forms

AGENCY: Energy Information Administration, Department of Energy.

ACTION: Notice of the proposed revision and extension of the Forms EIA–876A,B,C, and fuel purchase logs for the Residential Transportation Energy Consumption Survey (RTECS), and solicitation of comments.

SUMMARY: The Energy Information Administration (EIA), as part of its continuing effort to reduce paperwork and respondent burden (required by the Paperwork Reduction Act of 1980, Pub. L. 96–511, 44 U.S.C. 3501 et seq.), conducts a presurvey consultation program to provide the general public and other Federal agencies with an opportunity to comment on proposed and/or continuing reporting forms. This program helps to ensure that requested data can be provided in the desired format, reporting burden is minimized, reporting forms are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, EIA is soliciting comments concerning the proposed revision and extension to the Forms EIA–876A–C, "Residential Transportation Energy Consumption Survey." Also, a question has been added to the standard list of questions for potential data users to solicit comments on preferences as to whether EIA should publish data measured in metric units.

DATES: Written comments must be submitted on or before May 24, 1993. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below of your intention to do so as soon as possible.

ADDRESSES: Send comments to Ronald Lambrecht, EI–632, Energy Information Administration, Mail Stop 2F–090, Forrestal Building, U.S. Department of Energy, Washington, DC 20585, Telephone (202) 586–4962.

FOR FURTHER INFORMATION OR TO OBTAIN COPIES OF THE PROPOSED FORM AND INSTRUCTIONS: Requests for additional information or copies of the form and instructions should be directed to Ronald Lambrecht at the address listed above.

SUPPLEMENTARY INFORMATION:

I. Background

In order to fulfill its responsibilities under the Federal Energy Administration Act of 1974 (Pub. L. 93–275) and the Department of Energy Organization Act (Pub. L. 95–91), the Energy Information Administration is obliged to carry out a central, comprehensive, and unified energy data and information program which will collect, evaluate, assemble, analyze, and disseminate data and information related to energy resource reserves, production, demand, and technology, and related economic and statistical information relevant to the adequacy of energy resources to meet demands in the near and longer term future for the Nation's economic and social needs.

To meet this responsibility, as well as internal DOE requirements that are dependent on accurate data, the EIA has developed an ongoing program of national sample surveys on energy consumption in the residential transportation, manufacturing, commercial, and residential sectors.

The RTECS has been designed by the EIA to collect data on how energy is used by households for personal transportation. The RTECS sample of approximately 3,000 households is drawn from the larger sample selected for participation in the Residential Energy Consumption Survey (RECS). Data are collected primarily during telephone interviews. Households that cannot be reached by telephone are contacted by mail. The survey provides data on the number and types of vehicles used regularly by household members for personal transportation. For each vehicle, data are collected on the vehicle characteristics, the annual vehicle miles traveled, type of fuel purchased, vehicle fuel efficiency, and vehicle fuel price. The RTECS was conducted in 1983, 1985, 1988, and 1991.

Data from the survey will be published in the report "Household Vehicles Energy Consumption 1994", in the same format as the 1991 and 1988 surveys. Prior to 1988, the publication was called "Consumption Patterns of Household Vehicles". The data will be used as input for transportation studies and modeling by Congress, DOE and other Federal and non-federal agencies, groups and individuals

II. Current Actions

The EIA is proposing an extension of three years with minor changes. Changes will include an update of Forms EIA–876A–C to collect information for calendar year 1994. Also, the EIA is considering reinstating fuel purchase logs, records of actual fuel purchases and expenditures which were used in the 1983 and 1985 RTECS. Respondents would maintain the log for a maximun of one month. Questions contained on the log consist of (1) initial and final fuel gauge readings for the period; and (2) for each purchase of fuel during the period: The purchase date, number of gallons of motor fuel purchased, total cost of fuel, price per gallon, whether the tank was filled, and a fuel tank reading.

III. Request for Comments

Prospective respondents and other interested parties should comment on the proposed extension and revisions. The following general guidelines are provided to assist in the preparation of responses. Please indicate to which form your comments apply.

As a potential respondent:

A. Are the instructions and definitions clear and sufficient? If not, which instructions require clarification?

B. Can the data be submitted using the definitions included in the instructions?

C. Can data be submitted in accordance with the response time specified in the instructions?

D. Public reporting burden for this collection is estimated to average .25 hours response. (If fuel purchase logs are reinstated, the response burden will increase. Previously when logs were used, the response burden increased by .7 hours per response.) How much time, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, do you estimate it will require you to complete and submit the required form?

E. What is the estimated cost of completing this form, including the direct and indirect costs associated with the data collection? Direct costs should include all costs, such as administrative costs, directly attributable to providing this information.

F. How can the form be improved?

G. Do you know of any other Federal, State, or local agency that collects similar data? If you do, specify the agency, the data element(s), and the means of collection.

As a potential user:

A. Can you use data at the levels of detail indicated on the form?

B. For what purpose would you use the data? Be specific.

C. How could the form be improved to better meet your specific needs?

D. Are there alternate sources of data and do you see them? What are their deficiencies and/or strengths?

E. For the most part, information is published by EIA in U.S. customary units, e.g., cubic feet of natural gas, short tons of coal, and barrels of oil. Would you prefer to see EIA publish more information in metric units, e.g., cubic meters, metric tons, and kilograms? If yes, please specify what information (e.g., coal production, natural gas consumption, and crude oil imports), the metric unit(s) of measurement preferred, and in which EIA publication(s) you would like to see such information.

EIA is also interested in receiving comments from persons regarding their views on the need for the information contained in the Residential Transportation Energy Consumption Survey.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the form; they also will become a matter of public record.

Statutory Authorities: Section 2(a) of the Paperwork Reduction Act of 1980, Public Law 96–511, which amended chapter 35 of title 44, United States Code, (see 44 U.S.C. 3506(a) and (c)(1).

Issued in Washington, DC April 19, 1993.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–9543 Filed 4–22–93; 8:45 am]

BILLING CODE 6450–01–M

Office of Hearings and Appeals

Cases Filed During Week of April 2 Through April 9, 1993

During the Week of April 2 through April 9, 1993, the appeals and applications for other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of April 2 through April 9, 1993]

Date	Name and location of applicant	Case No.	Type of submission
Apr. 5, 1993	Albuquerque Tribune, Cleveland, OH	LFA–0278	Appeal of an Information Request Denial. *If Granted:* The March 1, 1993 Freedom of Information Request Denial issued by the Office of Inspector General would be rescinded, and the Albuquerque Tribune would receive access to documents pertaining to experiments conducted from 1945 through 1947 in which plutonium was injected into human subjects.
Apr. 5, 1993	Arco/K&B Service Station, Ansonia, CT	RR304–59	Request for Modification/Rescission in the Arco Refund Proceeding. *If Granted:* The March 27, 1989 Dismissal Letter (Case No. RF304–3746) issued to K & B Service Station would be modified regarding the firm's application for refund submitted in the Arco refund proceeding.
Apr. 6, 1993	Federation of American Scientists, Washington, DC.	LFA–0279	Appeal of an Information Request Denial. *If Granted:* The January 12, 1993 Freedom of Information Request Denial issued by the Office of Classification would be rescinded, and the Federation of American Scientists would receive access to a copy of a document identified as "Classification Policy Study."
Apr. 8, 1993	John Lohrenz, Ruston, LA	LFA–0280	Appeal of an Information Request Denial. *If Granted:* The March 30, 1993 Freedom of Information Request Denial issued by the FOI Office would be rescinded, and John Lohrenz would receive access to names and resumes of professional personnel who work on a DOE contract to study the recovery of by-passed oil in reservoirs in the Gulf of Mexico.
Apr. 8, 1993	Texaco/Big Three Truck Plaza, Washington, DC.	RR321–126	Request for Modification/Rescission in the Texaco Refund Proceeding. *If Granted:* The March 3, 1993 Decision and Order (Case No. RF321–17030) issued to Big Three Truck Plaza would be modified regarding the firm's application for refund submitted in the Texaco Refund Proceeding.

REFUND APPLICATIONS RECEIVED

Date received	Name of refund proceeding/ name of refund application	Case number
4/2/93 thru 4/9/93	Crude Oil Refund Applications Received.	RF272–94616 thru RF272–94632
4/2/93 thru 4/9/93	Atlantic Richfield Applications Received.	RF304–13780 thru RF304–13808
4/2/93 thru 4/9/93	Texaco Refund Applications Received.	RF321–19681 thru RF321–19691
4/5/93	Smith-Sheppard Concrete Co.	RC272–185
4/5/93	Monfort of Colorado, Inc.	RC272–1865
4/5/93	Thru-Way Canal	RF346–47
4/5/93	Seago Enterprises, Inc.	RF346–48

REFUND APPLICATIONS RECEIVED—Continued

Date received	Name of refund proceeding/ name of refund application	Case number
4/5/93	Don's Sechriever Canal.	RF346–49
4/6/93	Newport Yellow Cab. Co.	RC272–187
4/7/93	Westside Cab Company.	RC272–188
4/8/93	Arlen & Eunice Rude.	RC272–189
4/8/93	Cardox Oil of Liquid Air Corp.	RC272–190

[FR Doc. 93–9545 Filed 4–22–93; 8:45 am]

BILLING CODE 6450–01–M

Cases Filed During the Week of March 26 Through April 2, 1993

During the Week of March 26 through April 2, the applications for relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: April 19, 1993.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of Mar. 26 through Apr. 2, 1993]

Date	Name and location of applicant	Case No.	Type of submission
Mar. 29, 1993	Gulf/Jet Gas Corporation, St. Louis, MO	RR300–249	Request for modification/rescission in the Gulf refund proceeding. If Granted: The March 23, 1993 Dismissal Letter (Case No. RF300–17196) issued to Jet Gas Corporation regarding the firm's Application for Refund submitted in the Gulf Refund Proceeding would be modified.
Apr. 1, 1993	Gulf/Raleigh Plaza Gulf, Atlantic Beach, FL.	RR300–250	Request for modification/rescission in the Gulf refund proceeding. If Granted: The October 25, 1991 Dismissal Letter (Case No. RF300–12936) issued to Raleigh Plaza Gulf regarding the firm's Application for Refund submitted in the Gulf refund proceeding would be modified.

REFUND APPLICATIONS RECEIVED

Date received	Name of refund proceeding/name of refund applicant	Case No.
03/26/93 thru 04/02/93.	Crude Oil Refund applications received.	RF272–94588 thru RF272–94615
03/26/93 thru 04/02/93.	Atlantic Richfield applications received.	RF304–13758 thru RF304–13779
03/29/93	West Hills Texaco Service Stat.	RF321–19673
03/29/93	Coastal Texaco Service Stat.	RF321–19674
03/29/93	Huskill Texaco #1.	RF321–19675
03/29/93	Bob Horbacz Texaco.	RF321–19676
03/29/93	Teel's Texaco	RF321–19672

REFUND APPLICATIONS RECEIVED—Continued

Date received	Name of refund proceeding/name of refund applicant	Case No.
03/30/93	Center Street Canal.	RF346–45
03/30/93	12th Street Canal Station.	RF346–46
03/30/93	Fairoaks Texaco.	RF331–19677
03/30/93	Fife's Texaco Service.	RF331–19678
03/30/93	Star Inn Truck Stop.	RF321–19679
03/31/93	Walter Wronski.	RC272–184
03/31/93	Donald E. Riggle.	RF321–19680

[FR Doc. 93–9547 Filed 4–22–93; 8:45 am]

BILLING CODE 6450–01–P

Issuance of Proposed Decision and Order During the Week of March 29, Through April 2, 1993

During the Week of March 29 through April 2, 1993, the proposed decision and order summarized below was issued by the Office of Hearings and Appeals of the Department of Energy with regard to an application for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR part 205, subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purposes of the procedural regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of this proposed decision and order are available in the Public Reference Room of the Office of Hearings and Appeals, room 1E-234, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, Monday through Friday, between the hours of 1 p.m. and 5 p.m., except federal holidays.

Dated: April 19, 1993.

George B. Breznay,

Director, Office of Hearing and Appeals.

Proposed Decision and Order

Cunningham, West Helena, AK, LEE-0038, Reporting Requirements

Cunningham filed an Application for Exception from the requirement that it prepare and file Form EIA-782B ("Reseller/Retailer's Monthly Petroleum Product Sales Report"). The exception request, if granted, would exempt Cunningham from filing form EIA-782B. On March 31, 1993, a Proposed Decision and Order was issued which tentatively concluded that the exception request should be denied.

[FR Doc. 93-9546 Filed 4-22-93; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER93-542-000, et al.]

San Diego Gas & Electric Co, et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings have been made with the Commission:

1. San Diego Gas & Electric Company

April 16, 1993.

[Docket No. ER93-542-000]

Take notice that on April 5, 1993, San Diego Gas & Electric Company (SDG&E) tendered for filing a change of rates for firm transmission service, Rate Schedule FERC No. 60, as embodied in the Firm Transmission Service Agreement with Southern California Edison Company (Edison). Such change of rates reflects a decrease in the rate of return authorized by the California Public Utilities Commission (CPUC) to 9.94% from 10.75% for 1993, effective January 1, 1993.

SDG&E respectfully requests, pursuant to § 35.11, waiver of prior notice requirements specified in § 35.3 of the Commission's regulations, and an effective date of January 1, 1993.

Copies of this filing were served upon the Public Utilities Commission of the State of California and Edison.

Comment date: April 30, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Southern Company Services, Inc.

April 16, 1993.

[Docket Nos. ER91-150-003 and ER91-570-003]

Take notice that on January 21, 1993, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, and Savannah Electric and Power Company submitted, under protest, revisions to the transmission components of the formula rates in the above-referenced dockets in response to the Commission's order.

Comment date: April 28, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Northeast Utilities Service Company

April 15, 1993.

[Docket No. ER93-415-000]

Take notice that on March 31, 1993, Northeast Utilities Service Company (NUSCO), on behalf of Public Service Company of New Hampshire (PSNH), tendered for filing a Supplemental Agreement and information regarding the sale to UNITIL Power Corporation (UNITIL Power) of unit capacity and associated energy.

NUSCO states that the Supplement was filed in response to a request from the Commission.

NUSCO states that copies of this information have been mailed or delivered to each of the parties.

Comment date: April 29, 1993, in accordance with Standard Paragraph E end of this notice.

4. San Diego Gas & Electric Company

April 15, 1993.

[Docket No. ER93-543-000]

Take notice that on April 5, 1993, San Diego Gas & Electric Company (SDG&E) tendered for filing a change of rates for transmission service as embodied in SDG&E's agreements with the following entities which reflects a decrease in the rate of return to 9.94% from 10.75% authorized by the California Public Utilities Commission (CPUC), effective January 1, 1993, and changes in pricing structure. The change in pricing structure allows SDG&E to respond quickly to service requests and to charge market efficient rates at or below the embedded cost of the transmission facilities used to provide the service.

	Rate schedule FERC No.
1. City of Burbank (Burbank) ...	066
2. El Paso Electric Company (EPE) ...	074
3. Imperial Irrigation District (IID) ...	067
4. Southern California Edison Company (Edison) ...	058, 059

Copies of this filing were served upon the CPUC of the State of California, Burbank, EPE, IID and Edison.

Comment date: April 29, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Northeast Utilities Service Company

April 15, 1993.

[Docket No. ER93-524-000]

Take notice that on March 31, 1993, Northeast Utilities Service Company (NUSCO) on behalf of The Connecticut Light and Power Company (CL&P) and Public Service Company of New Hampshire tendered for filing a letter agreement that extend the term of a previously filed and accepted sales agreement between CL&P, PSNH and the New York Power Authority.

NUSCO states that a copy of this filing has been mailed to NYPA.

NUSCO requests that the Commission waive its regulations to the extent necessary.

Comment date: April 29, 1993, in accordance with Standard Paragraph E end of this notice.

6. Montaup Electric Company

April 15, 1993.

[Docket No. ER93-548-000]

Take notice that on April 6, 1993, Montaup Electric Company (Montaup) tendered for filing a letter agreement between itself and MASSPOWER under which Montaup will provide non-firm transmission service for the transmission of test power from MASSPOWER's generating unit located in Springfield, Massachusetts, from (a) the point of interconnection between Montaup's system and that of Northeast Utilities and (b) Montaup's points of interconnection with Commonwealth

Electric Company and/or Boston Edison Company. Montaup will provide the service at the same formula rates and under the same terms and conditions contained in the non-firm transmission tariff, FERC Electric Tariff Original Volume No. 2, on file with the Commission. Montaup has been informed by MASSPOWER that MASSPOWER is about to begin generating test power. Montaup requests waiver of the notice requirement in order to permit the filing to become effective April 7, 1993.

Comment date: April 29, 1993, in accordance with Standard Paragraph E end of this notice.

7. Louisville Gas and Electric Company

April 15, 1993.

[Docket No. ER92-533-000]

Take notice that Louisville Gas and Electric Company (LG&E), by letter dated April 7, 1993, tendered for filing the following revised rate schedules: (1) Generation Sales Service (Rate Schedule GSS) and (2) Coordination Transmission Service (Rate Schedule CT).

In the filing, Rate Schedule GSS is modified to make the interest rate used for the determination of late payment charges (paragraph 6.1) consistent with Rate Schedules CT and T, pursuant to the Commission's Order dated January 14, 1993, and Rate Schedule CT is modified to clarify the use of an umbrella agreement.

A copy of the filing was served upon the Kentucky Public Service Commission and the Indiana Utility Regulatory Commission.

Comment date: April 29, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. Union Electric Company

April 15, 1993.

[Docket No. ER93-555-000]

Take notice that on April 9, 1993, Union Electric Company (UE) tendered for filing a First Amendment dated March 22, 1993 to the Wholesale Electric Service Agreement dated November 18, 1988, between UE and Citizens Electric Corporation. UE asserts that the purpose of the First Amendment is to revise the kW and kWh meter correction factors at two delivery points.

Comment date: April 29, 1993, in accordance with Standard Paragraph E at the end of this notice

9. Pacific Gas and Electric Company

April 15, 1993.

[Docket No. ER93-556-000]

Take notice that on April 12, 1993, Pacific Gas and Electric Company (PG&E) tendered for filing a letter agreement containing proposed supplements to the Interconnection Agreements with Northern California Power Agency (NCPA) (Rate Schedule FERC No. 142) and the City of Santa Clara (Santa Clara) (Rate Schedule FERC No. 85). The procedures, contained in this letter agreement between the parties dated March 3, 1993, pertain to a flexible scheduling practice for the transmission of the power output of NCPA's and Santa Clara's Combustion Turbine Project No. 1. There are no changes to rates in this filing.

Copies of this filing have been served upon NCPA, Santa Clara, and the California Public Utilities Commission.

Comment date: April 29, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. United States Department of Energy—Western Area Power Administration (Central Valley Project)

April 15, 1993.

[Docket No. EF93-5011-000]

Take notice that on April 13, 1993, the Acting Assistant Secretary of Energy tendered for filing proposed rates for sales by the Western Area Power Administration from the Central Valley Project. The Acting Assistant Secretary of Energy approved these rates on an interim basis pursuant to a delegation of authority from the Secretary of Energy. The rates were filed with the Commission for requested approval on a final basis.

Comment date: April 30, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Public Service Company of New Mexico

April 16, 1993.

[Docket Nos. ER93-375-000 and ER93-378-000]

Take notice that on March 31, 1993, Public Service Company of New Mexico (PNM) submitted for filing a letter supplementing its earlier filing of the Contract for Electric Service between PNM and the City of Gallup, New Mexico. Under the Contract, PNM will sell firm power and energy to Gallup. The letter supplements the cost-of-service data provided with the original filing. Additionally, the letter requests that the notice of termination filed in Docket No. ER93-375-000 (concerning the termination of the previous PNM/Gallup electric service arrangement) be consolidated with Docket No. ER93-378-000. PNM states that copies of this filing have been served upon Gallup and the New Mexico Public Service Commission.

Comment date: April 26, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-9468 Filed 4-22-93; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2389-012—Maine]

Edwards Manufacturing Co.; Intent to Prepare an Environmental Impact Statement

April 29, 1993

The Federal Energy Regulatory Commission (FERC) has received an application for new license for the Edwards Dam Project No. 2389, situated on the Kennebec River in Kennebec County, Maine.

The FERC staff has determined that issuing a new license for this project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, the staff intends to prepare an environmental impact statement (EIS) on the hydroelectric project in accordance with the National Environmental Policy Act. The staff's EIS will objectively consider both site specific and cumulative environmental effects of the project and reasonable alternatives, and will include an economic, financial and engineering analysis.

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 the staff and considered in a final EIS. The staff's conclusions and recommendations will then be presented for the consideration of the Commission in reaching its final licensing decision. Public and agency

scoping meetings will be held at a future date to be announced.

For further information, please contact Robert Bell at (202) 219–2806.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9467 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

Application Tendered for Filing With the Commission

April 19, 1993

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. *Type of Application:* Minor License.

b. *Project No.:* 11395–000.

c. *Date Filed:* March 22, 1993.

d. *Applicant:* Mansfield Hydro Corporation.

e. *Name of Project:* Mansfield Hollow Water Power Project.

f. *Location:* On the Natchaug River, in the Town of Willimanctic, Tolland and Windham Counties, Connecticut.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Richard D. Ely, President, Mansfield Hollow Corporation, 140 Brookside Lane, Mansfield Center, CT 06250, (203) 487–1395.

i. *FERC Contact:* Mary C. Golato (tag) (202) 219–2804.

j. *Comment Date:* 60 days from the filing date in paragraph C. (May 21, 1993).

k. *Description of Project:* The proposed project would utilize an existing dam owned by the Department of the Army, Corps of Engineers, and consist of (1) an existing 630-foot-long penstock; (2) an existing powerhouse containing four turbine-generating units having a total generating capacity of 1,440 kilowatts; (3) a proposed 23-kilovolt transmission line; and (4) appurtenant facilities. The applicant estimates that the total average annual generation would be 3,600 megawatthours.

l. With this notice, we are initiating consultation with the Connecticut State Historic Preservation Officer (SHPO), as required by section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR at § 800.4.

m. Pursuant to § 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, 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 the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the filing date and serve a copy of the request on the applicant.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9466 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. CP93–286–000, et al.]

ANR Pipeline Co., et al.; Natural Gas Certificate Filings

April 15, 1993.

Take notice that the following filings have been made with the Commission:

1. ANR Pipeline Company

[Docket No. CP93–286–000]

Take notice that on April 5, 1993, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP93–286–000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon an exchange service on an emergency basis with Panhandle Eastern Pipe Line Company (Panhandle) all as more fully set forth in the application which is on file with the Commission and open to public inspection.

ANR (formerly Michigan Wisconsin Pipe Line Company) states that by Commission order issued January 18, 1977, in Docket Nos. CP76–538 and CP77–2 (57 FPC 258), ANR and Panhandle were authorized, pursuant to a letter agreement dated September 20, 1976, to exchange up to 100,000 Mcf of natural gas per day on an emergency basis at a point of interconnection of their facilities in Dewey County, Oklahoma. ANR states that Panhandle has notified ANR that it wished to terminate this service effective November 30, 1992, and that Panhandle has filed to abandon its related part of the service in Docket No. CP93–109–000. Accordingly, ANR requests permission to abandon the service it was authorized to provide in Docket No. CP76–538.

No facilities are proposed to be abandoned herein.

Comment date: May 6, 1993, in accordance with Standard Paragraph F at the end of this notice.

2. Ozark Gas Transmission System

[Docket No. CP93–287–000]

Take notice that on April 5, 1993, Ozark Gas Transmission System (Ozark), 1700 Pacific Avenue, LB–10, Dallas, Texas 75201 filed in Docket No. CP93–287–000 an application, as amended on April 6, 1993, pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of facilities to connect the Mueller Sigri Great Lakes No. 1–28 well (well) to its system, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Ozark states that it seeks this authorization to connect a new source of gas supply located in Township 9N, Range 26W in Franklin County, Arkansas. Ozark indicates that the facilities for which its seeks authorization consists of a tap and metering facilities to connect the well to the Ozark Carter lateral. According to Ozark, the connection of these facilities will not increase throughput in this lateral, but will serve to supplement and offset natural declines in sources of supply presently connected to the lateral. Ozark estimates that it will cost $20,000 to construct the proposed facilities. Further, Ozark states that it plans to use equity funds on hand to finance the proposed construction.

Comment date: May 6, 1993, in accordance with Standard Paragraph F at the end of this notice.

3. Arkla Energy Resources Company

[Docket No. CP93–284–000]

Take notice that on April 1, 1993, Arkla Energy Resources Company (AER), 525 Milam Street, Shreveport, Louisiana 71101, filed in Docket No. CP93–284–000, an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon a field sale to Mississippi River Transmission Corporation (MRT) provided pursuant to AER's Rate Schedule XFS–1, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that by order issued October 18, 1956, in Docket No. G–4438, AER, successor-in-interest to Arkansas Louisiana Gas Company and Arkla Energy Resources, a division of Arkla, Inc., was authorized to provide a field sale of natural gas to MRT, successor-in-interest to Mississippi River Fuel Corporation, at the outlet of a gasoline plant in Lincoln Parish, Louisiana. AER says that there is no longer a need for this certificated arrangement since it has been terminated by the written consent of both parties.

No facilities are proposed to be abandoned herein.

Comment date: May 6, 1993, in accordance with Standard Paragraph F at the end of this notice.

4. El Paso Natural Gas Company

[Docket No. CP93-290-000]

Take notice that on April 8, 1993, El Paso Natural Gas Company (El Paso), Post Office Box 1492, El Paso, Texas 79978, filed in Docket No. CP93-290-000 an application pursuant to sections 7(b) and 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the continued operation of certain facilities currently providing emergency service pending restoration of the permanent facilities, with pregranted abandonment, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

El Paso states that as a result of the flooding during the first half of January of 1993 of the Gila River and its tributaries in the State of Arizona, El Paso has recently incurred certain service interruptions on its interstate transmission system which required the construction and operation by El Paso of temporary facilities. El Paso indicates that it determined that an emergency situation existed and that it was necessary to construct and operate certain pipeline facilities in order to restore service to the Town of Mammoth, Arizona, the City of Florence, Arizona, and to Southern California Gas Company at the Ehrenberg Delivery Point in Maricopa County, Arizona due to damage occurring near the Gillespie Dam area in Maricopa County Arizona. It is stated that the temporary facilities serve to provide substantially equivalent service to the affected customers. El Paso also indicates that, except for the actual interruption of service, El Paso has not increased or decreased the quantities and service, but has attempted to meet all of the requirements of the affected customers.

El Paso further states that it also seeks a temporary certificate to continue the operation of the temporary facilities pending completion of the permanent facilities. El Paso requests that the temporary certificate, when issued, be effective for the respective time periods that the temporary facilities are necessary to provide service while permanent facilities are being restored to service, thus permitting El Paso to continue natural gas service to those identified customers. Finally, El Paso seeks pregranted abandonment authorization effective at the end of such periods to permit the removal of the temporary facilities from jurisdictional service.

El Paso states that on February 8, 1993, it filed its report of emergency construction of facilities in accordance with subpart I, § 284.270 of the Commission's Regulations. It is indicated that the Gila River has continued to flood and El Paso states that it was unable to re-install its pipeline facilities in their original pre-flood location within the initial 60-day period permitted by subpart I of the Regulations. El Paso states that, in accordance with § 284.264(b)(1) of the Commission's Regulations, it petitioned the Commission to waive the initial 60-day limitation for operation of emergency pipeline facilities until such time as permanent repairs could be completed. It is indicated that a 60-day extension was granted.

El Paso states that the subsequent rains in the area have continued to maintain the water depth and flow rate of the Gila River at levels that have prevented El Paso from completing permanent repairs. It is indicated that the necessary repairs will not be completed by the expiration of the extended 60-day periods.

Comment date: May 6, 1993, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., 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 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to agree or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 93-9460 Filed 4-22-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. JD93-07012T; Texas-134]

State of Texas; NGPA Notice of Determination By Jurisdictional Agency Designating Tight Formation

April 19, 1993

Take notice that on April 12, 1993, the Railroad Commission of Texas (Texas) submitted the above-referenced notice of determination pursuant to § 271.703(c)(3) of the Commission's regulations, that a portion of the Wilcox Upper Hinnant Sand Formation, underlying Webb, Jim Hogg and Zapata Counties, Texas, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978. The designated area comprises approximately 6,729 acres in Railroad Commission District No. 4 and is described on the attached appendix.

The notice of determination also contains Texas' findings that the referenced portions of the Wilcox Upper Hinnant Sand Formation meet the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,

Secretary.

The recommended area includes all or portions of the following surveys:

Albercas de Arriba Grant, A-1966, Blocks 69, 70 and 71
Las Animas Grant, A-2996
J.J.T. Wright Survey 309, A-1908,
J.J.T. Wright Survey 309, A-204
Blas M. Pena Survey 258, A-248
Blas M. Pena Survey 258, A-491
Blas M. Pena Survey 258, A-2656
Las Animas Grant, A-244, All of Share 1 except Blocks 7, 18 and 19

T.T.R.R. Co. Survey 257, A–323
T.T.R.R. Co. Survey 257, A–188
J.H. Hinnant Survey 116, A–472, East half
John H. Gibson Survey 115, A–43
John H. Gibson Survey 115, A–125
T.C.R.R. Co. Survey 255, A–315, Blocks 1, 2 and 3

[FR Doc. 93–9465 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–157–004]

Pacific Offshore Pipeline Co.; Compliance Filing

April 19, 1993

Take notice that on April 15, 1993, Pacific Offshore Pipeline Company ("POPCO") tendered for filing the following tariff sheets to its FERC Gas Tariff to become effective April 1, 1993 in compliance with ordering paragraph (B) of the Commission's order dated March 16, 1993:

FERC Gas Tariff—First Revised Volume No. 1, First Revised Sheet No. 5

POPCO states that copies of its filing are being served on all intervenors and interested parties in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211. All such protests should be filed on or before April 26, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9462 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–6–007]

Paiute Pipeline Co.; Compliance Filing

April 19, 1993

Take notice that on April 12, 1993, Paiute Pipeline Company (Paiute) tendered for filing and acceptance the following tariff sheets to be a part of its FERC Gas Tariff, First Revised Volume No 1–A

3rd Sub Third Revised Sheet No. 10
Substitute Original Sheet No 131

Paiute indicates that the purpose of its filing is to comply with the Commission's order issued March 26, 1993 in Docket Nos RP93–6–002 and RS92–75–001, wherein the Commission directed Paiute to file revised rates to further minimize the cost shifts upon certain firm transportation customers resulting from Paiute's proposed change to an SFV rate design methodology. In compliance with the Commission's order, Paiute has submitted revised rates and billing determinants which limit the impact of the rate design change upon each firm transportation customer to no more than 10%, along with supporting documents and an explanation of the further mitigation techniques. Paiute has requested an effective date of April 1, 1993 for the tendered sheets.

Paiute states that copies of its filing have been mailed to all jurisdictional customers and affected state regulatory commissions, as well as to all parties in Dockets Nos. RP93–6 and RS92–75.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before April 26, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9463 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–162–007]

Superior Offshore Pipeline Co.; Refund Report

April 19, 1993

Take notice that on March 29, 1993, Superior Offshore Pipeline Company (SOPCO) filed a letter stating that the Commission's order issued February 24, 1993, approving the Stipulation and Agreement in Docket No. RP92–162–000, et al., directed it to refund any amounts collected on or subsequent to December 1, 1992, in excess of the rates approved under the settlement and to file a refund report within 30 days after making refunds.

SOPCO states that it collected no amounts on or subsequent to December 1, 1992, in excess of the rates approved under the settlement and, therefore, no refunds are required.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211. All such protests should be filed on or before April. 26, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9464 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. GT93–29–000]

Transcontinental Gas Pipe Line Corp.; Report of Refunds

April 19, 1993.

Take notice that on March 15, 1993, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing with the Federal Energy Regulatory Commission (Commission) its report of refunds, made in compliance with section 26 of Transco's General Terms and Conditions of Volume No. 1 of its FERG Gas Tariff.

Transco states that on March 10, 1993, it distributed refunds in the amount of $305,345.94, inclusive of interest, the amount due S–2 customers for the flow-through of refunds from Texas Eastern Transmission Corporation for the period December 1, 1990 through November 30, 1992, concerning Docket Nos. RP88–67–050, RP88–81–000, RP88–221–000, RP90–119–000 and RP91–004–000.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 26, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9461 Filed 4–22–93; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4616-5]

Oxygenated Gasoline; Waiver Application Submitted by the State of California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public hearing.

SUMMARY: The State of California Air Resources Board (CARB) has submitted an application for a waiver of the oxygenated gasoline provisions set forth in section 211(m)(3)(A) of the Clean Air Act (the Act). This application seeks a waiver from the requirements of section 211(m)(2) to enable California to implement a program which requires between 1.8% and 2.2% oxygen by weight.

DATES: EPA will conduct a one-day public hearing on this application beginning at 10:00 a.m. on Tuesday, May 11, 1993 at the Holiday Inn Washington Dulles at 1000 Sully Road in Sterling, Virginia. Comments on this application will be accepted until June 11, 1993. Parties wishing to testify at the hearing should contact Meredith G. Miller at (202) 233-9031 by May 7, 1993. Speakers may also sign up to testify on the day of the hearing. EPA also requests that six copies of prepared hearing testimony be available at the time of the hearing for distribution to the hearing panel. Hearing testimony should also be submitted to the docket. Additional information on the submission of comments to the docket may be found below in the "Address" section of this notice.

ADDRESSES: Copies of the information relative to this application are available for inspection in public docket A-93-13 at the Air Docket (LE-131) of the EPA, room M-1500, 401 M Street, SW., Washington, DC 20460, (202) 260-7548, between the hours of 8:30 a.m. to noon and 1:30 p.m. to 3:30 p.m. weekdays. Any comments from interested parties should be addressed to this docket with a copy forwarded to Meredith G. Miller, Field Operations and Support Division (6406J), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. As provided in 40 CFR part 2, a reasonable fee may be charged for copying services.

FOR FURTHER INFORMATION CONTACT: Meredith G. Miller, Environmental Protection Specialist, Field Operations and Support Division (6406J), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 233-9031.

SUPPLEMENTARY INFORMATION: Section 211(m) of the Clean Air Act as amended by the Clean Air Act Amendments of 1990 ("the Act") requires that various states submit revisions to their State Implementation Plans (SIPs) and implement oxygenated gasoline programs. This requirement applies to all states with carbon monoxide (CO) nonattainment areas with design values of 9.5 parts per million or more, generally based on data for 1988 and 1989. Under section 211(m)(2), the oxygenated gasoline program must require gasoline in specified control areas to contain no less than 2.7% oxygen by weight during that portion of the year in which the areas are prone to high ambient concentrations of carbon monoxide. (States are strongly encouraged to adopt averaging programs consistent with section 211(m)(5), employing marketable oxygen credit to allow use of gasoline with higher oxygen content than required to offset use of gasoline with lower oxygen content than required.)

California currently has eight cities in carbon monoxide nonattainment which are required to implement an oxygenated gasoline program: San Diego, Fresno, Chico, Modesto, Sacramento, San Francisco, Stockton and Los Angeles. EPA has, in guidance, specified a control period from November 1 through February 29 for San Diego; from September 1 through February 29 for Los Angeles; and from October 1 through January 31 for the other six areas.[1]

Prior to the start date of November 1, 1992 specified in section 211(m) of the Act, the California Air Resources Board (CARB) formally adopted by Executive Order its own regulations pertaining to the use of oxygenated gasolines in California. These regulations went into effect on October 14, 1992, and can be found in sections 2258 and 2298 of title 13, California Code of Regulations, and in amendments to sections 2251.5 and 2296.

The CARB Executive Order requires the use of gasoline containing 1.8 to 2.2% oxygen by weight during the months of November through January or February as specified above. This requirement has the effect of implementing an oxygenate "cap" at 2.2% oxygen by weight throughout the state. Also, during October for all areas except San Diego and during September and October for Los Angeles, the state has no minimum oxygen content requirement. The California oxygenated gasoline program differs from the Clean Air Act mandate in both geographic scope and oxygen content. The oxygen content limitation and the lack of a minimum oxygen content during some months conflict with the general minimum oxygen content requirement specified in section 211(m)(2) of the Act.

California is requesting that EPA waive applicability of the minimum 2.7% oxygen content requirement in the areas reference above under section 211(m)(3)(A) of the Act. That provision states that the Administrator may waive, in whole or in part, the requirements pertaining to oxygenated gasoline upon a demonstration by the State, to the satisfaction of the Administrator, that the use of oxygenated gasoline would prevent or interfere with attainment by the area of either state or federal air quality standards for any pollutant other than CO.

California contends in its waiver application that the use of gasoline containing 2.7% oxygen by weight would increase emissions of nitrogen oxides, and thereby interfere with attainment of air quality standards for nitrogen dioxide, PM_{10} (particulate matter) and ozone.

EPA invites comments concerning whether it should grant or deny this waiver petition.

Dated: April 1, 1993.

Michael H. Shapiro,

Acting Administrator for Air and Radiation.

[FR Doc. 93-9550 Filed 4-22-93; 8:45 am]

BILLING CODE 6560-50-P

[1] See the Notice of Availability, "Guidelines for Oxygenated Gasoline Credit Programs and Guidelines for Esteblishment of Control Periods Under Section 211(m) of the Clean Air Act as Amended," 57 FR 47849 (October 20, 1992).

[FRL-4616-6]

Public Water Supervision Program: Program Revision for the State of New Hampshire

SUMMARY: Notice is hereby given that the State of New Hampshire is revising its approved State Public Water Supervision Primacy Program. New Hampshire has adopted: (1) Drinking water regulations for total coliforms (including fecal coliforms and E. Coli) that correspond to the National Primary Drinking Water Regulations for total coliforms (including fecal coliforms and E. Coli) promulgated by EPA on June 29, 1989 (54 FR 27544) and (2) filtration, disinfection, turbidity, Giardia lamblia, viruses, Legionella, and heterotrophic bacteria that correspond to the National Primacy Drinking Water Regulations for filtration, disinfection, turbidity, Giardia lamblia, viruses, Legionella, and heterotrophic bacteria requirements promulgated on June 29, 1989 (54 FR

27486). EPA has determined that the State program revisions are no less stringent than the corresponding Federal regulations. Therefore, EPA has tentatively decided to approve these State program revisions. All interested parties are invited to request a public hearing. A request for a public hearing must be submitted by (date) to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by (date), a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become effective (date).

Any request for a public hearing shall include the following: (1) The name, address, and telephone number of the individual, organization or other entity requesting a hearing. (2) A brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intended to submit at such hearing. (3) The signature of the individual making the request: or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m. Monday through Friday, at the following offices:

New Hampshire Department of Environmental Services, Water Supply Engineering Bureau, P.O. Box 95, Hazen Drive, Concord, NH 03301

and

Regional Administrator, U.S. Environmental Protection Agency—Region I, JFK Federal Building, Boston, MA 02203.

FOR FURTHER INFORMATION CONTACT: Martha Johnson, U.S. Environmental Protection Agency—Region I, Ground Water Management and Water Supply Branch, JFK Federal Building, Boston, MA 02203, Telephone: (617) 565–3613.

Section 1413 of the Safe Drinking Water Act, as amended (1986); and 40 CFR 142.10 of the National Primary Drinking Water Regulations.

Dated: March 26, 1993.

Paul Keough,

Acting Regional Administrator.

[FR Doc. 93–9540 Filed 4–22–93; 8:45 am]

BILLING CODE 6560–50–P

[ER–FRL–4598–8]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared April 5, 1993. Through April 9, 1993 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 9, 1993 (58 FR 18392).

Draft EISs

ERP No. D–UAF–G11024–TX Rating EC2, Carswell Air Force Base (AFB) Disposal and Reuse, Implementation, Tarrant County, TX.

Summary: EPA expressed environmental concerns with IRP progress, scheduling, and air enforcement issues. EPA also requested additional information on mitigation measures by the installation recipients, and air quality compliance data.

ERP No. D–USN–K11100–CA Rating EC2, San Diego Bay Programmatic Project, Disposal of Dredged Material, Implementation, San Diego County, CA.

Summary: EPA expressed concern regarding the insufficient information on disposal options for contaminated material or material unsuitable for aquatic disposal and on dredging operations and alternatives. EPA encouraged the Navy to consider beneficial reuse as the preferred option, followed by ocean and in-bay disposal.

ERP No. D–VAD–G99005–OK Rating LO, Oklahoma City Area National Cemetery Construction and Operation, Site Selection, Lake Arcadia, City of Guthrie or Fort Reno, Logan, Canadian or Oklahoma County, OK.

Summary: EPA had no objections to the project.

Final EISs

ERP No. F–NPS–K61122–AZ

Petrified Forest National Park General Management and Develop Concept Plans, Implementation, Navajo and Apache Counties, AZ.

Summary: Review of the Final EIS was not deemed necessary. No formal letter was sent to the preparing agency.

ERP No. F–UAF–E11021–NC

Pope Air Force Base (AFB) Beddown of a Composite Wing under the Air Combat Command (ACC), Implementation, NC.

Summary: EPA continued to have environmental concerns regarding the potential consequences/impacts of off-base and cumulative noise effects. EPA recommended that discussion with the local government and public be continued regarding noise impacts.

ERP No. FS–COE–D39022–WV

Kanawha River Navigation Study, Winfield Locks and Dam, Lock Replacement, Implementation, Putnam County, WV.

Summary: EPA requested that the Planting Plan include management and monitoring information, and recommended that wetland mitigation efforts begin as soon as possible to offset the existing wetland losses. Additionally, EPA would like to review a draft version of the Record of Decision to ensure that a satisfactory mitigation plan is developed.

ERP No. FS–USN–K35030–CA

P–202 Naval Air Station Alameda and P–882 Naval Supply Center Oakland Dredging Projects, Additional Information, Site Designation, Implementation and Section 404 Permit, Alameda and Oakland Cities, San Francisco Bay, CA.

Summary: EPA believed that the Navy presented sufficient information to demonstrate that ocean disposal of suitable dredged material was an acceptable alternative pursuant to the Marine Protection, Research and Sanctuaries Act. However, EPA did not believe that the FSEIS adequately evaluated options for unsuitable material or any additional dredged material the Navy may need to manage; a more thorough analysis of disposal options would have been preferable. EPA recommended preparation of a second SEIS which would provide a thorough evaluation of dredging and non-ocean disposal material placement alternatives for any unsuitable material or future dredged material.

ERP No. F1–AFS–G61009–AR

Mount Magazine State Park Recreational Development and Maintenance Plan, Special Use Permit, Ozark National Forest, Logan County, AR.

Summary: EPA had no objections to the proposed project.

Dated: April 20, 1993.

Marshall Cain,

Senior Legal Advisor.

[FR Doc. 93–9559 Filed 4–22–93; 8:45 am]

BILLING CODE 6560–50–M

[ER-FRL-4598-7]

Environmental Impact Statements; Availability

Responsible Agency: Office of Federal Activities, General Information (202) 260-5076 or (202) 260-5075.

Weekly Receipts of Environmental Impact Statements Filed April 12, 1993, Through April 16, 1993 Pursuant to 40 CFR 1506.9.

EIS No. 930124, Draft Supplement, BLM, CA, South Fork Eel Wild and Scenic River Management, New Information, Implementation, Arcata Resources Area, Ukiah District, Mendocino County, CA, Due: June 22, 1993, Contact: Linda Hansen (707) 462-3843.

EIS No. 930125, Final EIS, AFS, AK, North and East Kuiu Timber Harvest, Availability of Timber to the Alaska Pulp Long-Term Timber Sale Contract, Timber Sale and Road Construction, Implementation, Tongass National Forest, Kuiu Island, AK, Due: May 24, 1993, Contact: Bob Gerdes (907) 772-3841.

EIS No. 930126, Draft EIS, AFS, OR, Spirit Fire Recovery Project, Harvest Timber and Road Construction, High Spirit Fire Area, Willamette National Forest, Oakridge Ranger District, Lane County, OR, Due: June 07, 1993, Contact: Robert L. Barstad (503) 782-2291.

EIS No. 930127, Draft EIS, USA, Theater Missile Defense (TMD) Comprehensive System, Research and Development, Active Defense Counterforce and Passive Defense, Implementation, United States, Due: June 07, 1993, Contact: Michael A. Aimone (703) 693-1743.

EIS No. 930128, Draft EIS, AFS, MT, Upper Sunday Timber Sales, Harvest Timber, Implementation, Kootenal National Forest, Fortine Ranger District, Flathead County, MT, Due: June 07, 1993, Contact: Mike Liu (406) 882-4451.

EIS No. 930129, Legislative Final EIS, NOA, Regime to Govern the Incidental Taking of Marine Mammals during Commercial Fishing Operations after October 1, 1993 Development and Management, Permit Approval, Due: May 24, 1993, Contact: Herbert Kaufman (301) 713-2231.

EIS No. 930130, Draft EIS, FTA, OR, WA, Hillsboro Corridor Transit Improvements, Implementation, Between S.W. 185th Avenue and downtown Hillsboro, Funding, Washington, Clackamas and Multnomah Counties, OR and Clark County, WA, Due: June 07, 1993, Contact: Donald J. Emerson (202) 366-0096.

EIS No. 930131, Final EIS, AFS, ID, Steen Creek Salvage Timber Sale, Salvage Harvest Timber and Possible Road Construction, Payette National Forest, Adams County, ID, Due: May 24, 1993, Contact: Pete Johnston (208) 253-4215.

EIS No. 930132, Draft EIS, MMS, AL, LA, MS, TX, 1994 Central and Western Gulf of Mexico Outer Continental Shelf (OCS) Oil and Gas Sales 147 (March 1994) and 150 (August 1994), Lease Offering, AL, MS, LA and TX, Due: July 20, 1993, Contact: Richard H. Miller (703) 787-1665.

EIS No. 930133, Final EIS, BPA, WA, ID, OR, Adoption—1992 Columbia/Snake Rivers Salmon Flow Measures, Acquiring Replacement Power for that lost from Additional Water Releases, Implementation, WA, OR and ID. Contact: Carol Borgstrom (503) 230-4261.

The US Department of Energy, Bonneville Power Administration (BPA) has adopted the US Army Corps of Engineers' (COE) final EIS filed with the US Environmental Protection Agency on 1-16-92. The BPA was a Cooperating Agency on the COE's EIS.

Dated: April 20, 1993.

Marshall Cain,

Senior Legal Advisor.

[FR Doc. 93-9560 Filed 4-22-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4517-7]

Gulf of Mexico Program Citizens Advisory Committee Meeting

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of meeting of the Citizens Advisory Committee of the Gulf of Mexico Program.

SUMMARY: The Gulf of Mexico Program's Citizens Advisory Committee will hold a meeting on May 7-8, 1993, at the Holiday Inn Airport in New Orleans, Louisiana.

FOR FURTHER INFORMATION CONTACT: Dr. Douglas Lipka, Acting Director, Gulf of Mexico Program Office, Building 1103, John C. Stennis Space Center, Stennis Space Center, MS 39529-6000, at (601) 688-3726.

SUPPLEMENTARY INFORMATION: A meeting of the Citizens Advisory Committee of the Gulf of Mexico Program will be held on May 7-8, 1993, at the Holiday Inn Airport in New Orleans, Louisiana, from 8:30 a.m. to 4:30 p.m. on May 7 and from 8:30 a.m. to 2:30 a.m. on May 8. Proposed agenda items are: Program update; Gulf Program calendar and budget planning process overview; review of "Success in '93" projects; action agenda overview; future financing/interagency budgeting; proposed Business Council resolution; Citizens Monitoring, "The Role of the Gulf of Mexico Program; future local government initiative and CAC activity planning; FY93/94 CAC budget and future directions; legislative update; advance planning for 1995 Gulf Symposium; Year of the Gulf update; state activity reports. The meeting is open to the public.

Tudor Davies,

Acting Assistant Administrator, Office of Water.

[FR Doc. 93-9680 Filed 4-22-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4617-6]

Gulf of Mexico Program Management Committee Meeting

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of meeting of the Management Committee of the Gulf of Mexico Program.

SUMMARY: The Gulf of Mexico Program's Management Committee will hold a meeting on April 27-28, 1993, at the Pontchartrain Hotel in New Orleans, Louisiana.

FOR FURTHER INFORMATION CONTACT: Dr. Douglas Lipka, Acting Director, Gulf of Mexico Program Office, Building 1103, John C. Stennis Space Center, Stennis Space Center, MS 39529-6000, at (601) 688-3726.

SUPPLEMENTAL INFORMATION: A meeting of the Management Committee of the Gulf of Mexico Program will be held on April 27-28, 1993, at the Pontchartrain Hotel in New Orleans, Louisiana, from 8:30 a.m. to 5 p.m. on April 27, and from 8:30 a.m. to 12 noon on April 28. Agenda items will include: Issue committee co-chair and membership appointments; Success in '93 proposed project awards; site selection for 1994-95 Symposium; Gulf of Mexico Business Council; Gulf of Mexico Program Office proposed Interagency Associate Director roles; FY94 planning; Public Health Action Agenda outreach; and Five Year Strategy. The meeting is open to the public.

Tudor Davies,

Acting Assistant Administrator, Office of Water.

[FR Doc. 93-9682 Filed 4-22-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4617-8]

Gulf of Mexico Program Policy Review Board Meeting

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of meeting of the Policy Review Board of the Gulf of Mexico Program.

SUMMARY: The Gulf of Mexico Program's Policy Review Board will hold a meeting on May 11, 1993, at the Pontchartrain Hotel in New Orleans, Louisiana.

FOR FURTHER INFORMATION CONTACT: Dr. Douglas Lipka, Acting Director, Gulf of Mexico Program Office, Building 1103, John C. Stennis Space Center, Stennis Space Center, MS 39529-6000, at (601) 688-3726.

SUPPLEMENTARY INFORMATION: A meeting of the Policy Review Board of the Gulf of Mexico Program will be held on May 11, 1993, at the Pontchartrain Hotel in New Orleans, Louisiana, from 8:30 a.m. to 4:30 p.m. Proposed agenda items are: Discussion on Restructuring the Gulf of Mexico Program; Five Year Strategy; Action Agendas; Proposed FY93 Projects; FY93/94 Budget Process; Management Committee and Issue Committee Bylaws; Appointment of Issue Committee Co-chairs; 1994/95 Symposium Criteria; Proposed Business Council Resolution; and Science and Policy Interactions on the Coastal Ocean—Key Issues for National Academy of Science Workshop. The meeting is open to the public.

Tudor Davies,

Acting Assistant Administrator, Office of Water.

[FR Doc. 93-9681 Filed 4-22-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4614-7]

Notice of Release of Possible Confidential Business Information Pursuant to a Protective Order in U.S. v. American Cyanamid Company, et al., Civil Action No. 2:91-1185 (S.D.W.Va.)

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: Notice is hereby given pursuant to 40 CFR 2.209(d) of the release of possible confidential business information pursuant to a protective order to be proposed for entry by the United States District Court for the Southern District of West Virginia no sooner than fifteen (15) business days after the date of this notice. EPA is planning to make available to thirteen companies which are the signatories to the protective order various documents and other discovery obtained from the Fike Chemicals, Inc. (a.k.a. Artel Chemical Corporation) located in Nitro, W.Va. Certain of these documents may contain confidential business information (CBI) that meet the criteria set forth in 40 CFR 2.208. Access to any such potential CBI information is strictly controlled by the terms of the protective order. Due to the voluminous nature of the documents in question (over one million documents spanning almost 30 years) and the need for EPA to provide the companies in question with access to such documents to evaluate their potential liability for various site remediation activities at the Fike/Artel Superfund site, EPA and these companies have determined that the most appropriate way of providing such access while protecting any potential CBI information is to request the Court to enter the proposed protective order. The parties believe the Court's jurisdiction in this matter to be limited to the exchange of the documentation referenced by this order and not to extend to site remediation and/or cost recovery issues associated with this site other than the oversight of the implementation of the consent decree styled *U.S.* v. *American Cyanamid Company, et al.*, Civil Action No. 2:91-1185, and entered by this Court on February 20, 1992.

EPA has sent written notifications of the protective order to the approximately 200 companies known to have a potentially significant involvement with the Fike/Artel Superfund site. This Federal Register notice is also being published to further ensure that all potentially affected companies have been contacted concerning entry of the proposed protective order.

The protective order will not be entered by the Court for at least fifteen (15) days after the publication of this notice. A copy of the protective order may be obtained from EPA at the below address.

Comments on the terms and conditions of the proposed protective order (including entry of the order itself) may also be submitted to EPA at the below address. EPA will forward these comments and its response to these comments to the Court for its consideration in determining whether, and under what conditions, to enter the protective order.

DATES: Please submit any comments on this proposed order to EPA at the below listed address within ten (10) business days of this notice.

ADDRESSES: To request a copy of the protective order or to submit comments on the entry or terms of this order, please send such requests to Jim Heenehan, Sr. Asst. Reg. Counsel, Office of Regional Counsel, U.S. EPA Region III, 841 Chestnut Building, Philadelphia, PA 19107. Mr. Heenehan may be reached by phone at (215) 597-8916. Requests for a copy of the protective order should refer to: "Fike/Artel Superfund Site Protective Order".

FOR FURTHER INFORMATION CONTACT: Eugene Wingert, Remedial Project Manager, Hazardous Waste Management Division, U.S. EPA, Region III, 841 Chestnut Building, Philadelphia, PA 19107, (215) 597-1727.

SUPPLEMENTARY INFORMATION: On February 20, 1992, the United States District Court for the Southern District of West Virginia entered a consent decree between the United States and thirteen settling defendants requiring these defendants to implement EPA's preferred remedial alternative for Operable Unit 2 at the Fike/Artel Superfund site (*United States* v. *American Cyanamid, et al.* Civil Action No. 91-1185). The consent decree resolves various claims the United States has against these parties pursuant to Sections 106, 107 and 113 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S.C. Sections 9606, 9607 and 9613. The thirteen settling defendants to the consent decree are American Cyanamid Company, E.I. du Pont de Nemours & Co., Inc., Ethyl Petroleum Additives, Inc., Halliburton Services, Hollingsworth & Vose Co., Miles, Inc. (formerly Mobay Corporation), Monsanto Company, Morton International, Inc., PB & S Chemical Company, Polaroid Corporation, PPG Industries, Inc., Specialty Polymers, Inc., and Union Carbide Corporation.

Because of the ongoing nature of the remediation work at the Fike/Artel Superfund site, the thirteen parties listed above need access to the Fike/Artel documents to properly assess their potential liability for site remediation work at this site. In order to provide the settling parties with the documentary information provided to the U.S. EPA by the Fike/Artel Corporation that is relevant to the issues of the settling companies' potential CERCLA liability, EPA has agreed to enter into the proposed protective order with these parties. This will allow the settling parties the opportunity to review the one million plus documents in a timely and efficient manner while maintaining necessary safeguards against the

possible misuse of potential CBI documents. However, because a limited disclosure will occur pursuant to a court order, this notice is being provided to potentially affected businesses as required by 40 CFR 2.209(d).

Amongst the safeguards for ensuring that possible CBI information relating or concerning companies not a party to the proposed protective order are the following:

a. All documents referring or relating to such non-party companies shall be treated as confidential and each page of such documents shall be so marked;

b. The Court will provide notice to any affected party before it determines that any party's documents or information are not confidential because they are in the public domain and/or do not contain information within the scope of Fed. R. Civ. P. 26(c)(7), 40 CFR Part 2 (1990), 18 U.S.C. Section 1905, or other statute or regulation restricting disclosure;

c. Confidential information may only be disclosed to counsel of record for any party to the order only if the counsel of record agrees in writing to be bound by the terms of the order by executing a confidentiality agreement prohibiting the disclosure of any such information to anyone other than those authorized to review such information by the order itself upon threat of penalty of contempt by the Court;

d. Confidential information may be disclosed to a limited number of other individuals associated with the anticipated litigation under the same conditions as set forth for counsel of record;

e. Persons who obtain confidential information may only use or disclose such information in connection with, or in preparation for, cost allocation and other settlement negotiations, discovery, trial, and other proceedings in connection with litigation concerning the Fike/Artel site; and

f. Papers containing confidential information that are filed with the Court shall be filed in a sealed envelope.

By this notice, EPA has complied with its obligations under 40 CFR 2.209(d).

Dated: April 7, 1993.

Stanley L. Laskowski,

Acting Regional Administrator, United States Environmental Protection Agency, Region III.

[FR Doc. 93-9549 Filed 4-22-93; 8:45 am]

BILLING CODE 6560-50-M

[OPPTS-59963; FRL-4582-8]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of November 11, 1984, (49 FR 46066) (40 CFR 723.250), EPA published a rule which granted a limited exemption from certain PMN requirements for certain types of polymers. Notices for such polymers are reviewed by EPA within 21 days of receipt. This notice announces receipt of 11 such PMN(s) and provides a summary of each.

DATES: Close of review periods:

Y 93-69, 93-70, 93-71, 93-72, 93-73, 93-74, 93-75, April 5, 1993.

Y 93-76, 93-77, 93-78, April 7, 1993.

Y 93-79, April 8, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-545, 401 M St., SW., Washington, DC, 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the TSCA Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office, ET G-102 at the above address between 8 a.m. and noon and 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays

Y 93-69

Manufacturer. Confidential.

Chemical. (G) Styrene acrylic copolymer.

Use/Production. (S) Powder coating for metal substrates; resin for coatings, inks, and adhesives. Prod. range: Confidential.

Y 93-70

Manufacturer. Confidential

Chemical. (G) Styrenated acrylic graft copolymer wth fumaric resin, amine salt.

Use/Production. (G) Printing ink resin. Prod. range: Confidential.

Y 93-71

Manufacturer. Confidential.

Chemical. (G) Styrenated acrylic graft copolymer with fumaric resin, amine salt.

Use/Production. (G) Printing ink resin. Prod. range: Confidential.

Y 93-72

Manufacturer. Essex Specialty Products.

Chemical. (G) Hydroxyl functional polycarbomoyl (polyalkylene oxide) oligomer.

Use/Production. (S) Polymer used in sealant manufacture. Prod. range: Confidential.

Y 93-73

Manufacturer. Eastman Chemical Company.

Chemical. (S) Trans-1,4-cyclohexanedicarboxylic acid, dimethyl ester; 1,4-butanediol.

Use/Production. (S) Powdered coatings. Prod. range: Confidential.

Toxicity Data. Acute oral: LD50 > 2,000 mg/kg (rat). Acute dermal: > 2,000 mg/kg (rat). Eye irritation: None (rabbit). Skin irritation: None (rabbit). Skin sensitization: Negative (guinea pig).

Y 93-74

Manufacturer. Eastman Chemical Company.

Chemical. (S) Trans-1,4-cyclohexanedicarboxylic acid, dimethyl ester: 1,4-butanediol.

Use/Production. (S) Powder coatings. Prod. range: Confidential.

Toxicity Data. Acute oral: LD50 > 2,000 mg/kg (rat). Acute dermal: > 2,000 mg/kg (rat). Eye irritation: None (rabbit) Skin irritation: None (rabbit). Skin sensitization: Negative (guinea pig)

Y 93-75

Manufacturer. Graver Chemical Company.

Chemical. (G) Morpholine form ion exchange resin.

Use/Production. (G) Morpholine form ion exchange resin Prod. range Confidential

Y 93-76

Manufacturer Confidential.

Chemical. (G) Water-reducible alkyd resin

Use/Production (S) Water-reducible air-dry interior paints. Prod. range Confidential

Y 93-77

Manufacturer Confidential

Chemical. (G) Polyester resin solution.

Use/Production. (S) Industrial coatings, especially furniture finishes. Prod. range: Confidential.

Y 93-78

Manufacturer. Confidential.

Chemical. (G) Unsaturated polyester resin.

Use/Production. (S) Manufacture of fiberglass boats, room dividers, and similar structural items. Prod. range: Confidential.

Y 93-79

Importer. Confidential.

Chemical. (S) Polyester resin.

Use/Import. (S) Component polymer for industrial powder coatings. Import range: Confidential.

April 16, 1993.

Frank V. Caesar,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxic Substances.

[FR Doc. 93-9551 Filed 4-23-93; 8:45 am]

BILLING CODE 6560-50-F

[FRL-4613-4]

CWA 304(l): Availability of List Submissions and Proposed Approval Decisions for the State's of Arkansas, Louisiana, New Mexico, Oklahoma and Texas

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of lists submitted to EPA pursuant to CWA section 304(l)(1)(C) as well as EPA's proposed approval decisions, and requests public comment.

DATES: Comments must be submitted to EPA on or before May 24, 1993.

FOR FURTHER INFORMATION CONTACT: Copies of these items can be obtained by writing or calling Brad Lamb, U.S. EPA Region 6 (6W-QS), 1445 Ross Avenue, Dallas, Texas 75202-2733, 214-655-6683.

SUPPLEMENTARY INFORMATION: Section 304(l)(1) of the Clean Water Act (CWA) required each state, within two years after February 4, 1987, to submit to the U.S. Environmental Protection Agency (EPA) three lists of waters, including a list (the "B List" or "Short List") of those waters that the state does not expect to achieve applicable water quality standards, after application of technology-based controls, due to discharges of toxic pollutants from point sources. Section 304(l)(1)(B), 33 U.S.C. 1314(l)(1)(B). The second or "Mini", list consists of waters that are not meeting the new water quality standards developed under section 303(c)(2)(B) for toxic pollutants because of pollution from point and nonpoint sources. Section 304(l)(1)(A)(i), 33 U.S.C. 1314(l)(1)(A)(i). The third or "Long", list includes all waters on the other two lists, plus any waters which after the implementation of technology-based controls, are not expected to meet the water quality goals of the Act. Section 304(l)(1)(A)(ii), 33 U.S.C. 1314(l)(1)(A)(ii). For each water segment identified in these lists, the state was required, by February 4, 1989, to submit a "C List" specifying point sources discharging toxic pollutants believed to be preventing or impairing such water quality. Section 304(l)(1)(C), 33 U.S.C. 1314(l)(1)(C); *see Natural Resources Defense Council* v. *EPA*, 915 F.2d 1313, 1323-24 (9th Cir. 1990); 57 FR 33040-33050, (July 24, 1992) (amending EPA's section 304(l) regulations to require point sources to be identified for each listed water segment). For each point source identified on the state's C List as discharging toxic pollutants into a water segment on the state's B List, the state was further required to submit to EPA an individual control strategy (ICS) that the state determined would serve to reduce point source discharges of toxic pollutants to the receiving water to a degree sufficient to attain water quality standards in that water within three years after the date of the establishment of the ICS. 33 U.S.C. 1314(l)(1)(D).

EPA initially interpreted the statute to require states to identify on the "C List" only those facilities that discharge toxic pollutants believed to be impairing waters listed on the "B List". In *Natural Resources Defense Council* v. *EPA*, the Ninth Circuit Court of Appeals remanded that portion of the regulation and directed EPA to amend the regulation to require the states to identify all point sources discharging any toxic pollutant that is believed to be preventing or impairing water quality of any stream segment listed on any of the three lists of waters, and to indicate the amount of the toxic pollutant discharged by each source. EPA amended 40 CFR 130.10(d)(3) accordingly. See 57 FR 33040 (July 24, 1992).

Consistent with EPA's amended regulation, Arkansas, Louisiana, New Mexico, Oklahoma and Texas have submitted to EPA for approval their listing decisions under section 304(l)(1)(C). EPA today proposes to approve these lists hereby and solicits public comment on both the approval decisions and on the state lists.

Dated: March 23, 1993.

Richard Hoppers,

Acting Director, Water Management Division.

[FR Doc. 93-9538 Filed 4-22-93; 8:35 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

April 16, 1993.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission 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 this submission contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: None.

Title: Section 76.701, Commercial Leased Access Channels.

Action: New collection.

Respondents: Individual or households, state or local governments, and businesses or other for-profit (including small businesses).

Frequency of Response: Recordkeeping requirement.

Estimated Annual Burden: 497 recordkeepers; 2 hours average burden per recordkeeper; 7,455 hours total annual burden.

Needs and Uses: On 2/1/93, the Commission adopted a First Report and Order in MM Docket No. 92-258, Implementation of Section 10 of the Cable Consumer Protection and Competition Act of 1992 (P.L. No. 102-385). This First R&O adopts regulations that are intended to govern indecent programming on commercial leased access channels that cable operators have not voluntarily prohibited under section 10(a) of the new Act. Section 76.701(a) permits cable operators to adopt and enforce voluntarily a written and published policy of prohibiting indecent programming on commercial leased access channels. We believe that a substantial number of cable operators with leased access

channels will have a written and published policy in place. Section 76.701(c) requires cable operators to make indecent programming available to subscribers within 30 days of receipt of a written request by subscribers for access to that programming and to terminate a subscriber's access to such programming upon written request. The cable system must retain this request for one year. Section 76.701(d) requires program providers requesting access on a leased access channel to identify in writing any programming that is indecent. Section 76.701(h) requires cable operators to retain records sufficient to verify their compliance with these requirements. The identification of indecent programming by program suppliers enables the cable operator to place the programs on a blocked access channel. Written requests for access to the leased channel enables the cable operator to identify those subscribers who wish to receive indecent programming. The record retention ensures that cable operators are in compliance with the Commission's rules.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93-9499 Filed 4-22-93; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

April 19, 1993.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of the submission 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 this submission contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0441.

Title: Section 90.621(b)(4), Selection and Assignment Frequencies.

Action: Revision of a currently approved collection.

Respondents: Businesses or other for-profit (including small businesses).

Frequency of Response: On occasion reporting.

Estimated Annual Burden: 33 responses; 1.5 hours average burden per response; 50 hours total annual burden.

Needs and Uses: This rule requires applicants in the Specialized Mobile Radio (SMR) category to submit letters of concurrence if they intend to construct less than 70 miles from an existing system operating on the same channel. The Commission will use the information to determine whether to grant licenses to applicants whose systems do not satisfy mileage separation requirements. Without this information the Commission would deny the applications or require the applicant to request a waiver of the Rules.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93-9500 Filed 4-22-93; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

April 20, 1993.

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, Suite 140, Washington, DC 20037, (202) 857-3800. For further information on these submissions contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on these information collections should contact Jonas Neihardt, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0307.

Title: Section 90.629(a), Extended implementation period.

Action: Revision of a currently approved collection.

Respondents: Non-profit institutions and businesses or other for-profit (including small businesses).

Frequency of Response: On occasion reporting.

Estimated Annual Burden: 100 responses; 1 hour average burden per response; 100 hours total annual burden.

Needs and Uses: Applicants requesting frequencies in the Public Safety, Industrial/Land Transportation, Business and General Category pools for either trunked or conventional operations may be authorized a period of up to five (5) years for placing a station in operation in accordance with certain conditions. The applicant must submit a justification for an extended implementation period. The justification must include an implementation schedule, including a description of the applicant's proposed system, benchmarks for construction of proposed base stations (including identification of channels to be "constructed" at each station at each of the indicated benchmarks), etc. This provides flexibility to those entities needing longer implementation periods due to multi-year funding cycles, system size or complexity. Commission licensing personnel use the information to determine if the grant of an extended implementation schedule is warranted.

OMB Number: 3060-0517.

Title: Section 90.607, Supplemental information to be furnished by applicants for facilities under this subpart.

Action: Revision of a currently approved collection.

Respondents: Individuals or households, businesses or other for-profit (including small businesses).

Frequency of Response: Other: one-time requirement.

Estimated Annual Burden: 144 responses; 2.5 hours average burden per response; 360 hours total annual burden.

Needs and Uses: FCC rules require applicants for new nationwide systems in the 900 MHz band to append additional information to FCC Form 574 to demonstrate that they meet the entry criteria specified in 47 CFR 607(d). Licensing Division personnel will use the data to determine the eligibility of the applicant to hold a radio station authorization. Land Mobile and Microwave Division personnel will use the data for rulemaking proceedings. Compliance personnel in conjunction with field engineers will use the data for enforcement purposes.

OMB Number: 3060-0518.

Title: Section 90.631, Trunked system loading, construction and authorization requirements.

Action: Revision of a currently approved collection.

Respondents: Businesses or other for-profit (including small businesses).

Frequency of Response: Other: 4,6, and 10 years after initial license, every 10 years after license grant.

Estimated Annual Burden: 45 responses; 1.5 hours average burden per response; 68 hours total annual burden.

Needs and Uses: This rule section requires licensees of nationwide systems in the 900 MHz band to file a system progress report to demonstrate that they have met the construction benchmarks specified in 47 CFR 90.631. Nationwide licensees not meeting the four, six, or ten-year benchmarks shall lose their entire nationwide authorization including authorization to operate any stations already constructed. Regional licensees not meeting the two or five-year benchmarks shall lose their entire regional authorization including authorization to operate any stations already constructed. Licensing Division personnel will use the data to determine whether nationwide licensees have fulfilled the mandatory construction requirements as set forth in this rule section in order to determine whether or not the licensee will maintain rights to the licensed spectrum. Land Mobile and Microwave personnel will use the data for rule making proceedings. Compliance personnel in conjunction with field engineers will use the data for enforcement purposes.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93-9501 Filed 4-22-93; 8:45 am]

BILLING CODE 6712-01-M

Tutorial on Allotment and Assignment Modeling for an Advanced Television Service

The Planning Subcommittee (Working Party 3) of the Advisory Committee on Advanced Television Service and the staff of the Federal Communications Commission will present a tutorial on computer modeling techniques and considerations now being used to prepare for the adoption and implementation of an advanced television service. the tutorial will be held: May 7, 1993, 9:30 a.m.-12:30 p.m., Commission Meeting Room, room 856, 1919 M Street, N.W., Washington, DC.

The speakers will describe the development and use of the various software programs which are being used by the Commission to prepare an allotment/assignment plan for advanced television stations, and by the Advisory Committee to evaluate the proposed advanced television systems with respect to spectrum usage. The subjects to the covered include:

- Basis for software
- Methodology
- A Planning factor assumptions
- Spectrum planning exercises
- Representative plans

For further information please contact Donald Jansky, Planning Subcommittee (Working Party 3), at (202) 467-6400.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93-9451 Filed 4-22-93; 8:45 am]

BILLING CODE 6712-01-M

[MM Docket No. 93-56, FCC 93-135]

Licenses Renewal Hearing Designation Order

AGENCY: Federal Communications Commission.

ACTION: Hearing Designation Order (HDO).

SUMMARY: The FCC is designating the license renewal applications of Stations KBER-FM, Ogden, Utah, and KQOL-FM, Spanish Fork, Utah, for a consolidated hearing before an administrative law judge. This hearing is necessary to determine if the parties operating the stations in question violated the Commission's multiple ownership rules, engaged in an unauthorized assignment of the license of Station KQOL-FM, and misrepresented information to the Commission. This hearing is intended to determine if the parties violated the Commission's Rules and whether they possess the requisite qualifications to warrant the grant of the license renewal applications for the stations.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Paulette Laden, (202) 632-6402 or Robert B. Somers (202) 632-3922.

SUPPLEMENTARY INFORMATION: The Commission has before it for consideration: (a) The license renewal applications of licensees, C. Devine Media, Inc. (Devine), for Radio Station KBER-FM, Ogden, Utah, and Street Stryder (Stryder), for Radio Station KQOL-FM, Spanish Fork, Utah; and (b) the results of its investigation of stations KBER-FM and KQOL-FM. Information supplied by the licensees on applications submitted to the Commission and in response to Commission letters of inquiry, a Petition for Reconsideration of a grant of an application for the assignment of the license of Station KQOL-FM from Devine to Stryder, and an independent investigation by Commission staff, indicate that Devine may have engaged in a sham assignment of the license of KQOL-FM to Stryder to circumvent the Commission's multiple ownership rules set forth in § 73.3555(a)(2) of the Commission's Rules. It also appears that Stryder may have engaged in an unauthorized assignment of KQOL's license in violation of § 73.3540 of the Commission's Rules and section 310 of the Communications Act. Furthermore, the responses of both licensees to Commission inquiries concerning this assignment appear to have been false or deceptive, in violation of §§ 73.1015 and 1.17 of the Commission's Rules and raise substantial and material questions as to whether Devine and Stryder possess the requisite qualifications to warrant granting the applications for renewal of the licensees of KBER-FM and KQOL-FM.

The Hearing Designation Order (HDO) was adopted on March 9, 1993, and released on April 8, 1993. A copy of the Hearing Designation Order and related documents in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC 20554. These documents may also be purchased from the Commission's contractor, International Transcript Services, Inc., 2100 M Street NW., Washington, DC 20037 (Telephone [202] 857-3800).

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93-9450 Filed 4-22-93; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed; United States Atlantic and Gulf Ports et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The

requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202–009548–046.

Title: United States Atlantic and Gulf Ports/Eastern Mediterranean and North African Freight Conference.

Parties:

Farrell Lines, Inc.
Lykes Bros. Steamship Co., Inc.
Waterman Steamship Corporation
Levant Line, S.A.

Synopsis: The proposed amendment deletes Levant Line, S.A. as a party to the Agreement and clarifies the member line's space chartering arrangement with non-agreement members. It also adds a new provision to the Agreement clarifying the rules governing agreement members' participation in non-exclusive transshipment agreement with a non-member carriers.

Agreement No.: 202–010984–016.

Title: Mediterranean/Puerto Rican Conference.

Parties:

Nordana Line AS
Sea-Land Service, Inc.
P&O Containers Limited
Zim Israel Navigation Company, Ltd.

Synopsis: The proposed amendment revises the rules governing independent action by clarifying the applicability of the 10-day notice period.

By Order of the Federal Maritime Commission.

Dated: April 19, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 93–9474 Filed 4–22–93; 8:45 am]

BILLING CODE 6730–01–M

GOVERNMENT PRINTING OFFICE

Depository Library Council to the Public Printer; Meeting

The Depository Library Council to the Public Printer (DLC) will hold its Spring 1993 meeting on May 17–18, 1993, at the U.S. Government Printing Office (GPO). It will be held in the Carl Hayden Room, GPO, 732 North Capitol Street NW., Washington, DC 20401. The purpose of this meeting is to discuss the Federal Depository Library Program. The meeting is open to the public.

The Council Meeting will take place from 1 p.m. to 4 p.m. on Monday, May 17, and from 8:30 a.m. to 11:30 a.m. on Tuesday, May 18. The Council members will have an informal session Monday morning to prepare for the Council Meeting, and an informal Post-Council discussion on Tuesday afternoon.

Anyone who wishes to attend the meeting must notify Josephine Williams, U.S. Government Printing Office (SL), Washington, DC 20401. Telephone: (202) 512–1114. A limited number of hotel rooms have been reserved at the Bellevue Hotel, 15 E Street NW., Washington, DC 20402, for anyone needing hotel accommodations. Telephone: (202) 638–0900. Room cost per night is $88.50 single and $101 double.

Michael F. DiMario,

Acting Public Printer.

[FR Doc. 93–9567 Filed 4–22–93; 8:45 am]

BILLING CODE 1505–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

On Fridays, the Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The following are those information collections recently submitted to OMB.

1. Analysis and Comparison of State Board and Care Regulations and their Effect on the Quality of Care in Board and Care Homes—New—This study will examine the effects of different state regulatory systems on the performance of board and care homes in the ten study states. The study will also examine the effect of licensure on the quality of care in the homes and provide descriptive data about the homes, owners/operators, staff and residents. Respondents: State or local governments, business or other for-profit, small businesses; Burden Information on the Operator Interview and Supplement—Number of Respondents: 612; Frequency of Response: once; Average Burden per Response: 40 minutes; Estimated Burden: 408 hours—Burden Information on the Staff Interview—Number of Respondents: 912; Frequency of Response: once; Average Burden per Response: 20 minutes; Estimated Burden: 304 hours—Burden Information on the Resident Interview—Number of Respondents: 3,460; Frequency of Response: once; Average Burden per Response: 20 minutes; Estimated Burden: 1,153 hours—Burden Information on Resident Medication Supplement—Number of Respondents: 3,460; Frequency of Response: once; Average Burden per Response: 5 minutes; Estimated Burden: 214 hours—Total Burden for all Information Collections: 2,079 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 619–0511. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, room 3208, Washington, DC 20503.

Dated: April 15, 1993

Dennis P. Williams,

Deputy Assistant Secretary, Budget

[FR Doc. 93–9456 Filed 4–22–93; 8:45 am]

BILLING CODE 4150–04–M

Centers for Disease Control and Prevention

Preapplication Videoconference Workshop—Cooperative Agreements for Minority Community-Based Organization(s) Human Immunodeficiency Virus (HIV) Prevention Project—Program Announcement Number 303: Notice of Correction

In notice document 93–7067 on page 16535, in the issue of Monday, March 29, 1993, in the first column under "Eligibility" in line 7, "nonprofit" should read "tax-exempt (under Internal Revenue Service Code, Section 501(c)(3))." In the first column under "Eligibility" in lines 8, 9, and 23, "nonprofit" should read "tax-exempt." In the last paragraph of the first column under "Eligibility," lines 37 through 46, "High prevalence MSAs are defined by (1) cumulative reports of 1,000 or more acquired immunodeficiency syndrome (AIDS) cases through June 30, 1992; (2) cumulative reports of 300 or more AIDS cases occurring in racial/ethnic minorities (African-Americans, Alaskan Natives, American Indians, Asian Americans, Latinos/Hispanics, and Pacific Islanders) through June 30, 1992; or (3)" should be combined to read "High prevalence MSAs are defined by (1) cumulative reports of 160 or more acquired immunodeficiency syndrome (AIDS) cases in racial or ethnic minorities in the 3-year period October 1, 1989, to September 30, 1992, (African-Americans, Alaskan Natives, American Indians, Asian Americans,

Latinos/Hispanics, and Pacific Islanders) and (2)." In the second column under "Matters to be Discussed," in line 8, "Street Outreach Programs" should read "Street and Community Outreach Programs."

Dated: April 19, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93-9502 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

Request for Nominations for Representatives of Consumer and Industry Interests on Public Advisory Committees or Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for consumer and industry representatives to serve on certain device panels of the Medical Devices Advisory Committee and other committees in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and for those that will or may occur during the next 12 months or more.

FDA has a special interest in ensuring that women, minority groups, the physically handicapped, and small businesses are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and physically handicapped candidates, and nominations from small businesses that manufacture medical devices subject to the regulations.

DATES: Nominations should be received by June 22, 1993, for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae for consumer representatives for the panels and the Device Good Manufacturing Practice Advisory Committee shall be submitted in writing to Phyllis Weller (address below).

All nominations and curricula vitae (which includes nominee's office address and telephone number) for industry representatives shall be submitted in writing to Kay Levin (address below).

FOR FURTHER INFORMATION CONTACT: Regarding consumer interests for the panels and the Device Good Manufacturing Practice Advisory Committee: Phyllis Weller, Office of Consumer Affairs (HFE-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

Regarding industry interests for the panels, consumer or industry interests for the Technical Electronic Product Radiation Safety Standards Committee, and industry interests for the Device Good Manufacturing Practice Advisory Committee: Kay Levin, Center for Devices and Radiological Health (HFZ-20), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301-443-4016.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members representing consumer and industry interests for the following vacancies listed below:

Committee or panel	Approximate date representative is needed	
	Consumer	Industry
Anesthesiology and Respiratory Therapy Devices Panel	Dec. 1, 1993	Dec. 1, 1993
Circulatory System Devices Panel	NV [1]	July 1, 1993
Clinical Chemistry and Clinical Toxicology Devices Panel	Mar. 1, 1994	IMMED [2]
Dental Products Panel	NV	Nov. 1, 1993 (Devices)
Device Good Manufacturing Practice Advisory Committee	NV	June 1, 1994
Ear, Nose, and Throat Devices Panel	NV	Nov. 1, 1993
General and Plastic Surgery Devices Panel	Sept. 1, 1993	Sept. 1, 1993
General Hospital and Personal Use Devices Panel	NV	Jan. 1, 1994
Hematology and Pathology Devices Panel	NV	IMMED
Microbiology Devices Panel	Mar. 1, 1994	IMMED
Neurological Devices Panel	NV	IMMED
Ophthalmic Devices Panel	Nov. 1, 1993	Nov. 1, 1993
Orthopedic and Rehabilitation Devices Panel	NV	Sept. 1, 1993
Radiological Devices Panel	NV	Feb. 1, 1994
Technical Electronic Product Radiation Safety Standards Committee	IMMED (1)	IMMED (3)
	Jan. 1, 1994 (2)	Jan. 1, 1994 (1)

[1] NV = No vacancy
[2] IMMED = Immediate vacancy

Functions

Medical Devices and Dental Products Panels

The functions of the medical devices and dental products panels are to: (1) Review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices; (2) advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; (3) recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; (4) advise on any possible risks to health associated with the use of devices; (5) advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; (6) review classification of devices to recommend changes in classification as appropriate; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; and (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Dental Products Panel will also function at times as a nonprescription drug advisory panel. As such, the panel reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use, the adequacy of their labeling, and advises the Commissioner of Food and Drugs on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded. The panel also evaluates

and recommends whether various prescription drug products should be changed to over-the-counter status and makes recommendations concerning the approval of new drug products for human use.

Device Good Manufacturing Practice Advisory Committee

The function of the Device Good Manufacturing Practice Advisory Committee is to review regulations for promulgation regarding current good manufacturing practices (CGMP's) governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines (e.g., "Guideline on General Principles of Process Validation") developed to assist the medical device industry in meeting the CGMP requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from CGMP regulations.

Technical Electronic Product Radiation Safety Standards Committee

The function of the Technical Electronic Product Radiation Safety Standards Committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Consumer and Industry Representation

Medical Devices and Dental Products Panels

Section 513 of the act, as amended by the Medical Device Amendments of 1976 (21 U.S.C. 360c), provides that each medical devices panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the device manufacturing industry.

The charter for the Medical Devices Advisory Committee that was approved October 27, 1990, by the Acting Commissioner of Food and Drugs provides for three nonvoting industry representatives on the Dental Products Panel (one each to represent the medical device industry, the nonprescription drug industry, and the cosmetics industry). No more than one representative of industry interests shall participate in the panel review of a particular matter or application.

Device Good Manufacturing Practice Advisory Committee

Section 520 of the act, as amended by the Medical Device Amendments of 1976 (21 U.S.C. 360j), provides that the Device Good Manufacturing Practice Advisory Committee include as members two voting representatives of the general public and two voting representatives of interests of the device manufacturing industry.

Technical Electronic Product Radiation Safety Standards Committee

Section 534(f) of the act, as amended by the Safe Medical Devices Act of 1990 (21 U.S.C. 360kk), provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from the affected industries and five members from the general public, of which at least one shall be a representative of organized labor.

Nomination Procedures

Consumer Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Nominations shall include a complete curriculum vitae of each nominee and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

Industry Representatives for Medical Devices and Dental Products Panels

Any organization in the medical device or dental products manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industrial representatives for the panels will not participate in the selection process. It is, therefore, recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, trade associations, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vitae of each nominee. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

Device Good Manufacturing Practice Advisory Committee and Technical Electronic Product Radiation Safety Standards Committee

Any interested person may nominate one or more qualified persons to represent industry interests on these committees as identified in this notice. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee. The term of office is up to 4 years, depending on the appointment date.

Selection Procedures

Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Industry Representatives for Medical Devices and Dental Products Panels

Regarding nominations for members representing the interests of industry on the medical devices or dental products panels, a letter will be sent to each person who has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to

consult with the others in selecting a single member representing industry interests for that particular panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

Device Good Manufacturing Practice Advisory Committee and Technical Electronic Product Radiation Safety Standards Committee

Regarding nominations for persons to represent industry interests on these committees, they shall be forwarded to the Office of the Commissioner of Food and Drugs for final selection.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App. 2) and 21 CFR part 14 relating to advisory committees.

Dated: April 6, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93-9523 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-01-F

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on certain device panels of the Medical Devices Advisory Committee and other committees in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and for those that will or may occur during the next 12 months or more.

FDA has a special interest in ensuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and physically handicapped candidates.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations and curricula vitae for the panels shall be sent to Nancy Pluhowski, Center for Devices and Radiological Health (HFZ-400), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850.

All nominations and curricula vitae for the Device Good Manufacturing Practice Advisory Committee shall be sent to Sharon Kalokerinos, Center for Devices and Radiological Health (HFZ-332), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850.

All nominations and curricula vitae for the Technical Electronic Product Radiation Safety Standards Committee shall be sent to Howard A. Goldstein, Center for Devices and Radiological Health (HFZ-83), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kay Levin, Center for Devices and Radiological Health (HFZ-20), Food and Drug Administration, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301-443-4016.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members for vacancies listed below. If specific expertise is not indicated, individuals should have expertise relevant to the field of activity of the panel or committee.

1. *Anesthesiology and Respiratory Therapy Devices Panel*: Four vacancies occurring December 1, 1993; general anesthesiologists, anesthesiologists with specialty in regional anesthesia, or physicians having expertise in ventilatory support.

2. *Clinical Chemistry and Clinical Toxicology Devices Panel*: One vacancy immediately; two vacancies occurring March 1, 1994; doctors of medicine or philosophy experienced with clinical chemistry, clinical toxicology, or oncology.

3. *Device Good Manufacturing Practice Advisory Committee*: One vacancy occurring June 1, 1994; one representative from Federal, State, or local government. Areas of committee need include persons with knowledge of quality assurance concepts applied to medical device manufacturing and representatives with experience in international standards and ISO 9001.

4. *Ear, Nose, and Throat Devices Panel*: Four vacancies occurring November 1, 1993; audiologists or persons with knowledge of otoacoustic emission devices or cochlear and phonosurgical implants, and other biocompatible devices used in ear, nose, and throat surgery.

5. *Gastroenterology and Urology Devices Panel*: Two vacancies occurring January 1, 1994; gastroenterologists, nephrologists, or urologists with expertise in pediatrics or lithotripsy, or experience in diagnosis and treatment of impotence, incontinence, and prostatism.

6. *General and Plastic Surgery Devices Panel*: Two vacancies occurring September 1, 1993; cosmetic surgeons, burn surgeons, immunologists, or dermatologic specialists with laser background.

7. *General Hospital and Personal Use Devices Panel*: Two vacancies occurring January 1, 1994; biomedical engineers with expertise in infusion pumps; individuals with a specialty in geriatric nursing or gerontology and experience with pumps or implanted port catheters; intravascular nurse or those in medical nursing with experience with intravenous devices.

8. *Hematology and Pathology Devices Panel*: Two vacancies immediately, one vacancy occurring March 1, 1994; individuals involved in the practice of medicine or clinical laboratory science familiar with clinical hematology and biotechnology.

9. *Immunology Devices Panel*: Four vacancies immediately, one vacancy occurring March 1, 1994; immunologists with experience in allergies or medical oncologists with experience in tumor markers, tumor diagnosis, and treatment.

10. *Microbiology Devices Panel*: Three vacancies occurring March 1, 1994; disease clinicians or individuals with expertise in antimicrobial susceptibility testing devices, and/or virology testing devices, and/or biotechnology; clinical oncologists with experience with tumor markers.

11. *Neurological Devices Panel*: Three vacancies immediately; neurologists, biomedical engineers, interventional neuroradiologists, neurosurgeons with interest in medical devices, or persons experienced with neurological devices with a strong background in biostatistics.

12. *Obstetrics and Gynecology Devices Panel*: Two vacancies immediately; individuals with expertise in endoscopy, electrosurgery, laser surgery, and assisted reproductive technologies, contraception, and/or instrumentation used during these procedures.

13. *Ophthalmic Devices Panel*: Three vacancies immediately, two occurring November 1, 1993; ophthalmologists or optometrists.

14. *Orthopedic and Rehabilitation Devices Panel*: Three vacancies immediately, two vacancies occurring September 1, 1993; orthopedic surgeons with expertise in joint structure and function, prosthetic ligament devices, joint biomechanics and implants, or spinal instrumentation; physical therapists with expertise in spinal cord

injuries, neurophysiology, electrotherapy, and joint biomechanics.

15. *Radiological Devices Panel*: Two vacancies immediately; radiologists, radiation oncologists, physicians, and postdoctoral researchers with expertise in radiological devices.

16. *Technical Electronic Product Radiation Safety Standards Committee*: One vacancy immediately and two vacancies occurring January 1, 1994; employees of a governmental agency, including State or Federal governments.

Functions

Medical Devices Panels

The functions of the panels are to: (1) Review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices; (2) advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; (3) recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; (4) advise on any possible risks to health associated with the use of devices; (5) advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; (6) review classification of devices to recommend changes in classification as appropriate; (7) recommend exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (8) advise on the necessity to ban a device; and (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Device Good Manufacturing Practice Advisory Committee

The function of the Device Good Manufacturing Practice Advisory Committee is to review regulations for promulgation regarding current good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines (e.g., "Guideline on General Principles of Process Validation"), developed to assist the medical device industry in meeting the current good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from current good manufacturing practice regulations.

Technical Electronic Product Radiation Safety Standards Committee

The function of the Technical Electronic Product Radiation Safety Standards Committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Qualifications

Medical Devices Panels

Persons nominated for membership on the panels shall have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are shown above. The term of office is up to 4 years, depending on the appointment date.

Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership on the Device Good Manufacturing Practice Advisory Committee should have expertise in any one or more of the following areas: Quality assurance concerning manufacturing of medical devices and/or sterilization of medical devices during the manufacturing process. In addition, nominees should have experience with the use and application of medical devices. The particular needs for this committee are shown above. The term of office is up to 4 years, depending on the appointment date.

Technical Electronic Product Radiation Safety Standards Committee

Persons nominated for the Technical Electronic Product Radiation Safety Standards Committee must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs for this committee are identified above. The term of office is up to 4 years, depending on the appointment date.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees or panels. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: April 16, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93-9524 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-01-F

Food and Drug Administration

[Docket No. 92D-0195]

Tracers in Animal Feed; Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised Compliance Policy Guide (CPG) 7126.01 entitled "Tracers in Animal Feed." A tracer is a harmless substance such as reduced iron grit coated with an FDA certified color. Under certain conditions, a tracer may be added to a Type A medicated article to help assure the presence and thorough mixing of a drug component. A tracer may be used in this manner only if such use is approved before implementation in a new animal drug application (NADA) or supplement. However, it has been brought to the agency's attention that some confusion exists with regard to this requirement (i.e., some manufacturers have incorporated tracers into Type A medicated articles before receiving FDA approval to do so). The revised CPG makes it clear that preclearance is required.

ADDRESSES: Submit written requests for single copies of CPG 7126.01 to the Industry Information Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. CPG 7126.01 is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Edward J. Ballitch, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8726.

SUPPLEMENTARY INFORMATION: CPG 7126.01 states that the use of a tracer in a new animal drug Type A medicated article must be covered by an NADA or supplemental NADA. The CPG is revised because there is some confusion as to whether or not that kind of manufacturing change (i.e., component) in a product may be implemented before FDA approval of an NADA or supplement. The revised CPG explicitly states that inclusion of a tracer in a Type A medicated article is the kind of change that FDA must approve before implementation.

The statements made herein are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended merely for internal FDA guidance.

Dated: April 5, 1993.

Susan M. Setterberg,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 93–9522 Filed 4–22–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Councils; Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory bodies scheduled to meet during the month of June 1993:

Name: National Advisory Committee on Rural Health.

Date and Time: June 13-16, 1993; 12 p.m.

Place: The Westin Hotel, 1900 Fifth Avenue, Seattle, Washington 98101, (206) 728-2007 (FAX). The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary with respect to the delivery, financing, research, development and administration of health care services in rural areas.

Agenda: The Committee will conduct a site visit to Cle Elum, Washington at noon on Sunday, June 13. The purpose of that site visit is to meet with rural primary care physicians in a town where the town closed the hospital 17 years ago. The Committee and a limited number of guests will be bused to Cle Elum from the Hotel and returned to the Hotel late evening.

During the plenary session on Monday, June 14, the Committee intends to address the legal and regulatory barriers to health care reform (Antitrust; Corporate Practice of Medicine; and Fraud and Abuse); and discuss the Oregon State Health Care Waiver Program and the Washington State Health Benefit Package. On Monday afternoon and all day Tuesday, the Committee's Health Care Financing and Education and Health Services Work Groups will be developing recommendations for the Sixth Report to the Secretary. The meeting will end on Wednesday, June 16, with reports from the two Work Groups.

The entire meeting is open to the public, however, no transportation to the sites will be provided for public attendees.

Anyone requiring information regarding the subject Council should contact Dena S. Puskin, Sc.D., Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9-05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-0835, FAX (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson, Director of Operations, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443-0835.

* * * * * * *

Name: Maternal and Child Health Research Grants Review Committee.

Date and Time: June 16-18, 1993, 9 a.m.

Place: Conference Room M, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Open on June 16, 1993, 9 a.m. - 10 a.m. Closed for remainder of meeting.

Purpose: To review research grant applications in the program area of maternal and child health administered by the Maternal and Child Health Bureau.

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Systems, Education and Science, Maternal and Child Health Bureau, who will report on program issues, congressional activities and other topics of interest to the field of maternal and child health. The meeting will be closed to the public on June 16 at 10 a.m. for the remainder of the meeting for the review of grant applications. The closing is in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., and the Determination by the Administrator, Health Resources and Services Administration, pursuant to Public Law 92-463.

Anyone requiring information regarding the subject Council should contact Gontran Lamberty, Dr.Ph.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, room 18A-55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2190.

Agenda Items are subject to change as priorities dictate.

Dated: April 19, 1993.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 93-9519 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-15-P

National Institutes of Health

Meeting of the National Advisory Council for Human Genome Research

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Center for Human Genome Research, May 16 and 17, 1993, in Chevy Chase I & II, Embassy Suites Hotel, Chevy Chase Pavilion, 4300 Military Road, NW., Wisconsin at Western Avenue, Washington, DC.

This meeting will be open to the public on May 17, 1993, from 8:30 a.m. to 10 a.m. to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on May 16 from 7 p.m. to recess and on May 17,

1993, from 10 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Center for Human Genome Research, National Institutes of Health, Building 38A, room 605, Bethesda, Maryland 20892, (301) 496–0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Jane Ades, (301) 402–2205, two weeks in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9513 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Meeting of the National Advisory Council on Aging

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council on Aging, National Institute on Aging, May 25, 1993, to be held at the National Institutes of Health, Building 31, Conference Room 6, Bethesda, Maryland. This meeting will be open to the public on Tuesday, May 25, from 8 a.m. to 3 p.m. for a status report by the Acting Director, NIA.; a report on Program Initiatives in Support of the New Administration's Health Care Objectives; a DRG report on Review of Aging Applications, and a report on the Working Group on Program. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Council will be closed to the public on May 25 from 3 p.m. until adjournment for the review, discussions and evaluation of grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June McCann, Committee Management Officer for the National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, suite 2C218, Bethesda, Maryland 20892 (301/496–9322), will provide a summary of the meeting and a roster of committee members upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. June McCann at (301) 496–9322, in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9514 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Notice of Meeting: Microbiology and Infectious Diseases Research Committee

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Microbiology and Infectious Diseases Research Committee, National Institute of Allergy and Infectious Diseases, on June 3–4, 1993, at the Holiday Inn Chevy Chase, Palladian West Room, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.

The meeting will be open to the public from 8 a.m. to 10 a.m. on June 3, to discuss administrative details relating to committee business and for program review. Attendance by the public will be limited to space available. In accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public for the review, discussion, and evaluation of individual grant applications and contract proposals from 10 a.m. until recess on June 3, and from 8 a.m. until adjournment on June 4. These applications, 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 proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Claudia Goad, Committee Management Officer, National Institute of Allergy and Infectious Diseases, Solar Building, room 4C02, National Institutes of Health, Bethesda, Maryland 20892, 301–496–7601, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Goad in advance of the meeting.

Dr. Peter R. Jackson, Scientific Review Administrator, Microbiology and Infectious Diseases Research Committee, NIAID, NIH, Solar Building, room 4C13, Rockville, Maryland 20892, telephone 301–496–8426, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program No. 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9510 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of Allergy and Infectious Diseases; Meeting: Board of Scientific Counselors

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases, on May 26–28, 1993 at the Rocky Mountain Laboratories, Building 6, Conference Room 349, Hamilton, Montana 59840.

The meeting will be open to the public on May 26 from 9 a.m. to 12:30 p.m. and from 1:30 p.m. to 2:30 p.m. On May 27 the meeting will be open from 8 a.m. until 9 a.m. During the open sessions, the permanent staff of the Laboratory of Persistent Viral Diseases, the Laboratory of Microbial Structure and Function, the Laboratory of Vectors and Pathogens, and the Laboratory of Intracellular Parasites will present and discuss their immediate past and present research activities.

In accordance with the provisions set forth in section 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on May 26 from 8:30 a.m. until 9 a.m., from 12:30 p.m. until 1:30 p.m., and from 2:30 p.m. until recess, on May 27 from 10:30 a.m. until recess, and on May 28 from 8:30 a.m. until adjournment for the review, discussion, and evaluation of individual intramural

programs and projects conducted by the Rocky Mountain Laboratories, including consideration of personal qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Claudia Goad, Committee Management Officer, National Institute of Allergy and Infectious Diseases, Solar Building, room 4C02, National Institutes of Health, Bethesda, Maryland 20892, 301–496–7601, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Goad in advance of the meeting.

Dr. John I. Gallin, Executive Secretary, Board of Scientific Counselors, NIAID, National Institutes of Health, Building 10, room 4A31, telephone 301–496–3006, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program No. 93–301, National Institutes of Health)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9516 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Meetings of the Board of Scientific Counselors, Division of Cancer Prevention and Control and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the Board of Scientific Counselors, Division of Cancer Prevention and Control (DCPC), National Cancer Institute, and its Subcommittees on May 6–7, 1993. The full Board will meet in Conference Room 6, 6th Floor, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. Meetings of the Subcommittees will also be held at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892 at the times listed below. Except as noted below, the meetings of the Board and its Subcommittees will be open to the public to discuss issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

A portion of the Board meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, for the critique and evaluation of individual DCPC intramural and extramural programs and projects. The discussions could reveal confidential trade secrets or commercial property, such as patentable material, as well as personnel qualifications and performance, the competence of individual investigators and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Office, National Cancer Institute, National Institutes of Health, Executive Plaza North, room 630, 9000 Rockville Pike, Bethesda, Maryland 20892 (301/496–5708) will provide a summary of the meetings and rosters of committee members, upon request.

Other information pertaining to these meetings can be obtained from the Executive Secretary, Linda M. Bremerman, National Cancer Institute, National Institutes of Health, Executive Plaza North, room 318, 9000 Rockville Pike, Bethesda, Maryland 20892 (301–496–8526), upon request.

Name of Committee: Board of Scientific Counselors, Division of Cancer Prevention and Control.

Contact Person: Mrs. Linda M. Bremerman, Building—EP/N, room 318, Bethesda, MD 20892; (301) 496–8526.

Dates of Meeting: May 6–7, 1993.

Place of Meeting: Building 31, Conference Room 6.

Open: May 6–8:30 a.m. to 2:45 p.m.

Agenda: Review progress of programs within the Division and review of concepts being considered for funding.

Open: May 7–8:30 a.m. to 12 noon.

Agenda: Review progress of programs within the Division and review of concepts being considered for funding.

Closed: May 7–12 noon to recess.

Agenda: For the critique and evaluation of individual intramural and extramural programs and projects.

Name of Committee: Surveillance Subcommittee.

Contact Person: Mrs. Linda M. Bremerman, Building—EP/N, room 318, Bethesda, MD 20892; (301) 496–8526.

Date of Meeting: May 6, 1993.

Place of Meeting: Building 31C, Conference Room 8.

Open: 3 p.m. to 5 p.m.

Agenda: Discuss current and future programs of Surveillance Subcommittee and review of concepts being considered for funding.

Name of Committee: Early Detection and Community Oncology Subcommittee.

Contact Person: Mrs. Linda M. Bremerman, Building—EP/N, room 318, Bethesda, MD 20892; (301) 496–8526.

Date of Meeting: May 6, 1993.

Place of Meeting: Building 31C, Conference Room 9.

Open: 3 p.m. to 5 p.m.

Agenda: Discuss current and future programs of Early Detection and Community Oncology Subcommittee and review of concepts being considered for funding.

Name of Committee: Cancer Control Science Subcommittee.

Contact Person: Mrs. Linda M. Bremerman, Building—EP/N, room 318, Bethesda, MD 20892; (301) 496–8526.

Date of Meeting: May 6, 1993.

Place of Meeting: Building 31C, Conference Room 7.

Open: 4 p.m. to 5 p.m.

Agenda: Discuss current and future programs of Cancer Control Science Subcommittee and review of concepts being considered for funding.

Name of Committee: Cancer Prevention Research Subcommittee.

Contact Person: Mrs. Linda M. Bremerman, Building—EP/N, room 318, Bethesda, MD 20892; (301) 496–8526.

Date of Meeting: May 6, 1993.

Place of Meeting: Building 31C, Conference Room 6.

Open: 3 p.m. to 5 p.m.

Agenda: Discuss current and future programs of Cancer Prevention Research Subcommittee and review of concepts being considered for funding.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Linda M. Bremerman, (301) 496–8526 in advance of the meeting.

(CATALOG OF FEDERAL DOMESTIC ASSISTANCE PROGRAM NUMBERS: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: April 16, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9508 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meetings of the National Deafness and Other Communication Disorders Advisory Council and its Research Subcommittee

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Deafness and Other Communication Disorders Advisory Council and its Research Subcommittee on May 19–21, 1993, at the National

Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The meeting of the full Council will be held in Conference Room 6, Building 31C and the meeting of the subcommittee will be in room 3C07, Building 31C.

The meeting of the Research Subcommittee will be open to the public on May 19 from 2 p.m. until 3 p.m. for the discussion of policy issues. The meeting of the full Council will be open to the public on May 20 from 8:30 a.m. until recess for a report from the Institute Director and discussion of extramural policies and procedures at the National Institutes of Health and the National Institute on Deafness and Other Communication Disorders and on May 21 from 8:30 a.m. to approximately 9 a.m. for a report on extramural programs of the Division of Communication Sciences and Disorders.

In accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Research Subcommittee on May 19 will be closed to the public from 3 p.m. to adjournment. The meeting of the full Council will be closed to the public on May 21 from approximately 9 a.m. until adjournment. The closed portions of the meetings will be for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council and Subcommittee meetings may be obtained from Dr. John C. Dalton, Executive Secretary, National Deafness and Other Communication Disorders Advisory Council, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Executive Plaza South, room 400B, Bethesda, Maryland 20892, 301–496–8693. A summary of the meetings and rosters of the members may also be obtained from his office. For individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations, please contact Dr. Dalton two weeks prior to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Other Communicative Disorders)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9512 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the following National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These 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.

Name of Panel: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Dates of Meeting: May 6–7, 1993.

Time of Meeting: May 6—3 pm to recess; May 7—8 am to adjournment.

Place of Meeting: Holiday Inn, Fort Lee, New Jersey.

Agenda: Review of Program Project Grant.

Contact Person: Dr. Craig Jordan, Scientific Review Administrator, NIDCD/SRB, Executive Plaza South, room 400B, Bethesda, Maryland 20892, (301) 496–8683.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Other Communicative Disorders)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9509 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Drug Abuse; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council on Drug Abuse, National Institute on Drug Abuse on May 11–12, 1993, at the National Institutes of Health, Building 31C, Conference Room 10, 9000 Rockville Pike, Bethesda, Maryland 20892.

The meeting will be open to the public on May 11 from 9 a.m. to 1 p.m. and on May 12, from 9 a.m. to 5 p.m. for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

In accordance with provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on May 11 from 1 p.m. to 5 p.m. for the review, discussion, and evaluation of grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

A summary of the meeting and a roster of committee members may be obtained from Ms. Camilla L. Holland, NIDA Committee Management Officer, National Institutes of Health, Parklawn Building, room 10–42, 5600 Fishers Lane, Rockville, Maryland 20857 (301/443–2755).

Substantive program information may be obtained from Dr. Michael S. Backenheimer, room 10–42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301/443–2755).

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the contact person named above in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Research Scientist Development and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs)

Dated: April 16, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9507 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meetings of the National Heart, Lung, and Blood Advisory Council and its Research Subcommittee and Training Subcommittee

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Heart, Lung, and Blood Advisory Council, National Heart, Lung, and Blood Institute, May 27–28, 1993,

National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, Maryland 20892. In addition, the Research Subcommittee and the Training Subcommittee of the above Council will meet together on May 26, at the Marriott Hotel, Bethesda, Maryland.

The Council meeting will be open to the public on May 27 from 9 a.m. to approximately 3:30 p.m. for discussion of program policies and issues. Attendance by the public is limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C., section 10(d) of Public Law 92–463, the Council meeting will be closed to the public from approximately 3:30 p.m. to recess on May 27 and from 8:30 a.m. to adjournment on May 28 for the review, discussion and evaluation of individual grant applications. The meetings of the Research Subcommittee and the Training Subcommittee of the above Council on May 26, will be closed from 7 p.m. to adjournment for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Terry Long, Chief, Communications and Public Information Branch, National Heart, Lung, and Blood Institute, Building 31, room 4A21, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–4236, will provide a summary of the meetings and a roster of the Council members.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dr. Ronald G. Geller, Executive Secretary, National Heart, Lung, and Blood Advisory Council, Westwood Building, room 7A–17, National Institutes of Health, Bethesda, Maryland 20892, (301) 594–7454, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.837. Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9511 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meeting of Board of Scientific Counselors

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Heart, Lung, and Blood Institute on June 3 and 4, 1993, National Institutes of Health, 9000 Rockville Pike, Building 10, room 7N238, Bethesda, Maryland 20892.

This meeting will be open to the public from 9 a.m. to 5 p.m. on June 3 and from 9 a.m. to 1 p.m. on June 4 for discussion of the general trends in research relating to cardiovascular, pulmonary and certain hematologic diseases. Attendance by the public will be limited to space available.

In accordance with the provision set forth in section 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public from 1 p.m. to adjournment on June 4, 1993 for the review, discussion, and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Terry Long, Chief, Communications and Public Information Branch, National Heart, Lung, and Blood Institute, Building 31, room 4A21, National Institutes of Health, Bethesda, Maryland 20892, phone (301) 496–4236, will provide a summary of the meeting and a roster of the Board members.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Substantive program information may be obtained from Dr. Edward D. Korn, Executive Secretary and Director, Division of Intramural Research, NHLBI, NIH, Building 10, room 7N214, phone (301) 496–2116.

Dated: April 19, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9515 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Advisory Mental Health Council and the review committees of the National Institute of Mental Health (NIMH) for May 1993.

These meetings will be open to the public as indicated below for the discussion of NIMH policy issues and will include current administrative, legislative, and program developments.

All meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Area Code 301, 443–4333, will provide summaries of the meetings and rosters of committee members, upon request.

Other information pertaining to the meetings may be obtained from the contact persons indicated.

Committee Name: National Advisory Mental Health Council.

Contact: Carolyn Strete, Ph.D., Parklawn Building, room 9–105, Telephone: 301, 443–3367.

Meeting Date: May 13–14, 1993.

Place: May 13—Conference Rooms D and E, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. May 14—Building 31, Conference Room 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: May 14, 8:30 a.m. to adjournment.

Closed: May 13, 8:30 a.m. to 5 p.m.

Committee Name: Neuropharmacology and Neurochemistry Review Committee.

Contact: William H. Radcliff, Parklawn Building, room 9C–18, Telephone: 301, 443–3857.

Meeting Date: May 20–21, 1993.
Place: The Hampshire Hotel, 1310 New Hampshire Avenue, NW., Washington, DC 20036.
Open: May 20, 1993, 8:30 a.m.–9:30 a.m.
Closed: May 20, 1993, 9:30 a.m.–5 p.m.; May 21, 1993, 8:30 a.m.–adjournment.
Committee Name: Emotion and Personality Review Committee.
Contact: Sheri L. Schwartzback, Parklawn Building, room 9C–05, Telephone: 301, 443–4843.
Meeting Date: May 27–28, 1993.
Place: Embassy Suites Hotel, 4300 Military Road, NW., Washington, DC 20015.
Open: May 27, 1993, 9 a.m.–9:30 a.m.
Closed: May 27, 1993, 9:30 a.m.–5 p.m.; May 28, 1993, 8:30 a.m.–adjournment.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the contact person named above in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Numbers 93.126, Small Business Innovation Research; 93.176, ADAMHA Small Instrumentation Program Grants; 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training; and 93.921, ADAMHA Science Education Partnership Award.)

Dated: April 16, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9506 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Advisory Panel on Alzheimer's Disease for May 1993.

This meeting will be open for the discussion of draft material for the Panel's fifth annual report and other business before the advisory panel. Attendance by the public will be limited to space available.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, room 9–105, 5600 Fishers Lane, Rockville, MD 20857, area code 301, 443–4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meetings may be obtained from the contact person indicated.

Committee Name: Advisory Panel on Alzheimer's Disease.
Contact: Theodore Fine, room 3C307, Gateway Building. Telephone: 301, 496–9350.
Meeting Date: May 17–18, 1993.
Place: Madison Hotel, 1177 15th Street, NW., Washington, DC 20005.
Open: May 17, 9 a.m. to 5 p.m. May 18, 9 a.m. to adjournment.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the contact person named above in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Numbers 93.126, Small Business Innovation Research; 93.176, ADAMHA Small Instrumentation Program Grants; 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training; and 93.921, ADAMHA Science Education Partnership Award.)

Dated: April 15, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–9517 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

Recombinant DNA Research: Actions under the Guidelines

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth eight actions to be taken by the Director, National Institutes of Health (NIH), under the May 7, 1986, NIH Guidelines for Research Involving Recombinant DNA Molecules (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 eight actions are being promulgated under the *NIH Guidelines for Research Involving Recombinant DNA Molecules.* These eight proposed actions were published for comment in the **Federal Register** of November 2, 1992 (57 FR 49584), and February 12, 1993 (58 FR 8500), and reviewed and recommended for approval by the NIH Recombinant DNA Advisory Committee (RAC) at its meetings on December 3–4, 1992, and March 1–2, 1993.

I. Background Information and Decisions on Actions Under the NIH Guidelines

A. Addition of Appendix D–XXXX to the NIH Guidelines

In a letter dated October 5, 1992, Dr. Michael J. Welsh, Howard Hughes Medical Institution Research Laboratories, Iowa City, Iowa, submitted a human gene transfer protocol to the RAC for formal review and approval. The title of this protocol is: *Cystic Fibrosis Gene Therapy Using an Adenovirus Vector: In Vivo Safety and Efficacy in Nasal Epithelium.* This request was published for comment in the **Federal Register** on November 2, 1992 (57 FR 49584).

The protocol was reviewed during the RAC meeting on December 3–4, 1992. By a vote of 16 in favor, 0 opposed, and no abstentions, the RAC recommended approval of the protocol with the following stipulations: (1) Deletion of the requirement for the E1a and the rat-1 transformation assays from the protocol, (2) submission of the complete adenovirus vector sequence, and (3) incorporation of minor changes in the Informed Consent document.

On December 14, 1992, and February 15, 1993, Dr. Welsh submitted modifications and additional information to ORDA as requested by the RAC. The information was reviewed by the primary reviewers, and it was determined that the additional documentation satisfied the RAC's stipulations for approval of the protocol. The following section may be added to Appendix D:

"Appendix D–XXXX

"Dr. Michael J. Welsh, Howard Hughes Medical Institute Research Laboratories, University of Iowa College of Medicine, Iowa City, Iowa, may conduct experiments on 3 cystic fibrosis (CF) patients ≥ 18 years of age with mild to moderate disease. This Phase I study will determine the: (1) *In vivo* safety and efficacy of the administration of the replication-deficient type 2 adenovirus vector, Ad2/CFTR–1, to the nasal epithelium; (2) efficacy in correcting the CF chloride transport defect *in vivo*; and (3) effect of adenovirus vector dosage on safety and efficacy."

I accept this recommendation, and Appendix D–XXXX of the *NIH Guidelines* will be added accordingly.

B. Addition of Appendix D–XXXXI to the NIH Guidelines

In a letter dated October 7, 1992, Dr. Ronald G. Crystal, National Institutes of

Health, Bethesda, Maryland, submitted a human gene therapy protocol to the RAC for formal review and approval. The original title of this protocol was: *Gene Therapy of the Respiratory Manifestations of Cystic Fibrosis using a Replication Deficient, Recombinant Adenovirus to Transfer the Normal Human Cystic Fibrosis Transmembrane Conductance Regulator cDNA to the Airway Epithelium.* This request was published for comment in the **Federal Register** on November 2, 1992 (57 FR 49584).

The protocol was reviewed during the RAC meeting on December 3–4, 1992. By a vote of 17 in favor, 0 opposed, and no abstentions, the RAC recommended approval of the protocol with the following modifications: (1) The patient eligibility criterion requiring that patients are documented to be sterile will be replaced with a statement suggesting that all patients should exercise appropriate birth control methods, (2) include the statement, "There may be no long term benefit to patients from this procedure" in the Informed Consent Document, and (3) revise the title of the protocol to read as follows: *A Phase I Study, in Cystic Fibrosis (CF) Patients, of the Safety, Toxicity, and Biological Efficacy of a Single Administration of a Replication Deficient, Recombinant Adenovirus Carrying the cDNA of the Normal Human Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Gene in the Lung,* and (4) demonstrate that there is less than one replication-competent adenovirus particle per 20 milliliters of supernatant (standard dosage).

On February 4, 1993, Dr. Crystal submitted the modified sections of the protocol to ORDA except for the data requested in modification number (4). Dr. Crystal stated that a lot release has been established for each preparation. Lot release forms with the relevant data will be forwarded to ORDA and FDA simultaneously. Approval from these agencies must be obtained before the clinical experiment can proceed. This information was reviewed by the RAC Executive Secretary, and it was determined that it meets the request of the RAC. The following section may be added to Appendix D:

"Appendix D–XXXXI

"Dr. Ronald G. Crystal, National Institutes of Health, Bethesda, Maryland, may conduct experiments on 10 cystic fibrosis (CF) patients ≥ 21 years of age. Patients will receive an initial administration of the replication-deficient type 5 adenovirus vector, AdCFTR, to their left nares. If no toxicity is observed from intranasal administration, patients will receive a single administration of AdCFTR to the respiratory epithelium of their left large bronchi. Five groups of patients (2 patients per group) will be studied based on increased dosage administration of AdCFTR. This study will determine the: (1) *in vivo* safety and efficacy of the administration of AdCFTR into the respiratory epithelium; (2) efficacy of the correction of the biologic abnormalities of CF in the respiratory epithelium; (3) duration of the biologic correction; (4) efficacy of the correction of the abnormal electrical potential difference of the airway epithelial sheet; (5) clinical parameters relevant to the disease process; and (6) if humoral immunity develops against AdCFTR sufficient to prevent repeat administration."

I accept this recommendation, and Appendix XXXXI of the *NIH Guidelines* will be added accordingly.

C. Addition of Appendix D–XXXXII of the NIH Guidelines

In a letter dated December 7, 1992, Dr. Kenneth Culver, Iowa Methodist Medical Center, Des Moines, Iowa, and Dr. John C. Van Gilder, University of Iowa, Iowa City, Iowa, indicated the intention to submit a human gene therapy protocol to the RAC for formal review and approval. The title of this protocol is: *Gene Therapy for the Treatment of Malignant Brain Tumors with* In Vivo *Tumor Transduction with the Herpes Simplex Thymidine Kinase Gene/Ganciclovir System.* This request was published for comment in the **Federal Register** on February 12, 1993 (58 FR 8500).

The protocol was reviewed during the RAC meeting on March 1–2, 1993. By a vote of 19 in favor, 0 opposed, and no abstentions, the RAC recommended approval of the protocol with the following modifications: (1) Patient eligibility will be limited to those patients who have measurable residual tumor immediately following the post-operative procedure as demonstrated by imaging studies, i.e., MRI or CT scans. (2) Patient enrollment in the protocol will be limited to 15 patients. If a positive response is observed in any of the first 15 patients, the investigators may submit a request to treat an additional 15 patients. The total number of patients treated will be divided between Iowa Methodist Medical Center and the University of Iowa. (3) Following 3 injections of herpes simplex thymidine kinase (HS-tk) vector-producing cells (VPC), patients will be eligible for additional treatments only if they have demonstrated stable disease for a minimum of 6 months. The following section may be added to Appendix D:

"Appendix D–XXXXII

"Dr. Kenneth Culver, Iowa Methodist Medical Center, Des Moines, Iowa, and Dr. John Van Gilder, University of Iowa, Iowa City, Iowa, may conduct experiments on 15 patients ≥18 years of age with recurrent malignant primary brain tumors or lung, melanoma, renal cell carcinoma, or breast carcinoma, brain metastases who have failed standard therapy for their disease. Patient eligibility will be limited to those patients who have measurable residual tumor immediately following the post-operative procedure as demonstrated by imaging studies. The number of patients treated will be equally divided between the Iowa Methodist Medical Center and the University of Iowa. If a positive response is observed in any of the first 15 patients, the investigators may submit a request to treat an additional 15 patients.

"Following surgical debulking, patients will receive a maximum of 3 interlesional injections of the G1TkSvNa vector-producing cell line (VPC) to induce regression of residual tumor cells by ganciclovir (GCV) therapy. Patients who demonstrate stable disease for a minimum of 6 months following this treatment will be eligible for additional VPC injections and subsequent GCV therapy."

I accept this recommendation, and Appendix D–XXXXII of the *NIH Guidelines* will be added accordingly.

D. Addition of Appendix D–XXXXIII of the NIH Guidelines

In a letter dated December 31, 1992, Drs. Malcolm Brenner, Robert Krance, Helen E. Heslop, Victor Santana, and James Ihle of the St. Jude Children's Research Hospital, Memphis, Tennessee, submitted a human gene transfer protocol to the RAC for formal review and approval. The title of this protocol is: *Assessment of the Efficacy of Purging by Using Gene-Marked Autologous Marrow Transplantation for Children with Acute Myelogenous Leukemia in First Complete Remission.* This request was published for comment in the **Federal Register** on February 12, 1993 (58 FR 8500).

The protocol was reviewed during the RAC meeting on March 1–2, 1993. By a vote of 17 in favor, 0 opposed, and no abstentions, the RAC recommended approval of the protocol. The following section may be added to Appendix D:

"Appendix D–XXXXIII

"Drs. Malcolm Brenner, Robert Krance, Helen E. Heslop, Victor Santana, and James Ihle, St. Jude Children's Research Hospital, Memphis, Tennessee, may conduct experiments on 35 patients ≥1 year and ≤21 years of age at the time of initial diagnosis of acute myelogenous leukemia (AML). The investigators will use the two retroviral vectors, LNL6 and G1Na, to determine the efficacy of the bone marrow purging techniques: 4-hydroxyperoxicyclophosphamide and interleukin-2 (IL–2) activation of endogenous cytotoxic effector cells, in preventing relapse from the reinfusion of autologous bone marrow cells."

I accept this recommendation, and Appendix D–XXXXIII of the *NIH Guidelines* will be added accordingly.

E. Addition of Appendix D–XXXXIV of the NIH Guidelines

In a letter dated December 31, 1992, Drs. Helen E. Heslop, Malcolm Brenner, and Cliona Rooney of the St. Judes Children's Research Hospital, Memphis, Tennessee, submitted a human gene transfer protocol to the RAC for formal review and approval. The title of this protocol is: *Administration of Neomycin Resistance Gene Marked EBV Specific Cytotoxic T Lymphocytes to Recipients of Mismatched-Related or Phenotypically Similar Unrelated Donor Marrow Grafts*. This request was unpublished for comment in the **Federal Register** on February 12, 1993 (58 FR 8500).

The protocol was reviewed during the RAC meeting on March 1–2, 1993. By a vote of 19 in favor, 0 opposed, and no abstentions, the RAC recommended approval of the protocol. The following section may be added to Appendix D.

"Appendix D–XXXXIV

"Drs. Helen E. Heslop, Malcolm Brenner, and Cliona Rooney, St Jude Children's Research Hospital, Memphis, Tennessee, may conduct experiments of 35 patients ≤21 years of age who will be recipients of mismatched-related or phenotypically similar unrelated donor marrow grafts for leukemia. In this Phase I dose escalation study, spontaneous lymphoblastoid cell lines will be established that express the same range of Epstein-Barr Virus (EBV) encoded proteins as the recipient. These EBV-specific cell lines will be transduced with the LNL6 or G1Na retroviral vector and readministered at the time of bone marrow transplant. This study will determine: (1) survival and expansion of these EBV-specific cell lines *in vivo*, (2) the ability of these adoptively transferred cells to confer protection against EBV infection, and (3) appropriate dosage and administration schedules."

I accept this recommendation, and Appendix D-XXXXIV of the NIH Guidelines will be added accordingly.

F. Addition to Appendix D-XXXXV to the NIH Guidelines

In a letter dated December 23, 1992, Drs. Robert W. Wilmott and Jeffrey Whitsett, Children's Hospital Medical Center, Cincinnati, Ohio, and Dr. Bruce Trapnell, Genetic Therapy, Inc., in Gaithersburg, Maryland, indicated the intention to submit a human gene therapy protocol to the RAC for formal review and approval. The title of this protocol is: A Phase I study of Gene Therapy of Cystic Fibrosis Utilizing a Replication Deficient Recombinant Adenovirus Vector to Deliver the Human Cystic Fibrosis Transmembrane Conductance Regulatory cDNA to the Airways. This request was published for comment in the **Federal Register** on February 12, 1993 (58 FR 8500).

The protocol was reviewed during the RAC meeting on March 1–2, 1993. By a vote of 16 in favor, 0 opposed, and 2 abstentions, the RAC recommended approval of the protocol with the following modification: (1) the second administration of the adenovirus vector (Ad1CF2), and associated procedures, will be eliminated from the protocol. The RAC recommended that the investigators should attempt to obtain a level of sensitivity adequate to detect one replication-competent virus particle per patient dose, i.e., 20 milliliter of retroviral vector supernatant.

On March 18, 1993, Dr. Wilmott submitted the modified protocol to ORDA. The modified protocol was reviewed by the RAC Executive Secretary, and it was determined that it meets the request of the RAC. The following section may be added to Appendix D:

"Appendix D-XXXXV

"Drs. Robert W. Wilmott and Jeffrey Whitsett, Children's Hospital Medical Center, Cincinnati, Ohio, and Dr. Bruce Trapnell, Genetic Therapy, Inc., Gaithersburg, Maryland, may conduct experiments on 15 cystic fibrosis (CF) patients who have mild to moderate disease ≥ 21 years of age. The replication-deficient type 5 adenovirus vector, Av1CF2, will be administered to the nasal and lobar bronchial respiratory tract of patients. This study will demonstrate the: (1) expression of normal cystic fibrosis transmembrane conductance regulator (CFTR) nRNA *in vivo*, (2) synthesis of CFTR protein, and (3) correction of epithelial cell cAMP dependent Cl^- permeability. The pharmacokinetics of CFTR expression and ability to re-infect the respiratory tract with AvCF2 will be determined. Systemic and local immunologic consequences of Av1CF2 infection, the time of viral survival, and potential for recombination or complementation of the virus will be monitored."

I accept this recommendation, and Appendix XXXXV of the NIH Guidelines will be added accordingly.

G. Amendment to the "Points To Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects" Regarding the Use of Compassionate Plea

In a letter dated December 7, 1992, Dr. Ivor Royston of the San Diego Regional Cancer Center, San Diego, California, requested a compassionate plea approval for a human gene therapy protocol. This RAC established a working group to develop policy regarding compassionate plea exemptions.

The Points to Consider (March 1, 1990, 55 FR 7443) provide guidance to scientists and clinical investigators submitting human gene therapy/transfer protocols. During the RAC meeting on January 14, 1993, the committee adopted the following preliminary policy statement regarding the approval of human gene therapy protocols on an expedited basis. The following original statement included the following elements which are not listed in order of importance, but are simply meant to be inclusive of the issues that need to be addressed:

"1. NIH will strongly emphasize that the standard method of protocol submission is highly preferred.

"2. The RAC will consider single patient protocols.

"3. There will be no attempt to distinguish between research and treatment in the consideration of protocols.

"4. Regardless of the method of review, the criteria must be the same for all protocols.

"5. When time-sensitive circumstances prevail, the NIH will do an internal review.

"6. To the extent that it is legally and practically possible, the Director of NIH will ask NIH experts, RAC members, and other experts to participate in protocol review.

"7. Among other factors to be considered by the Director of NIH, is the consanguinity of the new protocol to existing protocols.

"8. The NIH will report to the RAC following its internal review.

"9. Protocols that are deferred or not approved by the RAC in its normal review process, are not eligible for expedited review.

"10. In the development of any documents that are a part of this policy statement, the terms, compassionate use and compassionate treatment, will be deliberately avoided."

This preliminary policy statement was published for comment in the **Federal Register** on February 12, 1993 (58 FR 8500).

During the March 1–2, 1993, meeting, the RAC reviewed the preliminary policy statement. By a vote of 16 in favor, 0 opposed, and no abstentions, the RAC recommended that the following section be added to the Points to Consider:

"VI. Procedures to be Followed for Expedited Review

"1. An investigator submitting a request to the NIH for expedited review of a gene transfer protocol must provide detailed information regarding the necessity of expedited review.

"2. No protocol shall be considered without Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) approval.

"3. At this time, all gene transfer protocols must be considered experimental.

"4. Regardless of the method of review, the *Points to Consider* must be the standard of review for all gene transfer protocols.

"5. Review of such protocols may include intramural NIH experts but must include extramural experts.

"6. Among other factor to be considered by the reviewers, is the similarity of the new protocol to previously approved protocols.

"7. The NIH will report to the RAC following expedited review and will include all of the materials on which the decision was based. The RAC will formally review the protocol at its next scheduled meeting. Patient privacy will be maintained.

"8. 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.

"9. As requested in the context of non-expedited review, none of the costs of the experimental protocol should be borne by the patient or the patient's family.

"10. Data on all patients undergoing gene transfer shall be provided to the RAC within six months of the procedure."

I accept this recommendation, and the *Points to Consider* of the *NIH Guidelines* will now contain this new addition.

H. Amendment to the Points To Consider Regarding the Separation of the Gene Marking Informed Consent Document From the Therapeutic Informed Consent Documents

During the September 14–15, 1992, RAC meeting, Dr. Leonard Post requested that when a gene transfer protocol is submitted as an addition to an IRB-approval clinical protocol, the principal investigator should submit two separate informed consent documents, one for the gene marking procedures and one for the therapeutic portion of the protocol. In the *Points to Consider, Part I–D—Informed Consent* (March 1, 1990, 55 FR 7446), a new sentence would be added to the introductory paragraph:

"When gene transfer is a procedure separate from the therapeutic protocol, an informed consent document should be submitted for both the gene marking and therapeutic procedures."

This request was published for comment in the **Federal Register** on February 12, 1993 (58 FR 8500).

The request was reviewed during the RAC meeting on March 1–2, 1993. By a vote of 17 in favor, 0 opposed, and no abstentions, the RAC recommended that the following sentence be added to the introductory paragraph of Section I–D—Informed Consent:

"When gene transfer is a procedure separate from a clinical protocol, informed consent documents should be submitted for both the gene transfer and clinical protocols."

I accept this recommendation and the *Points to Consider* of the *NIH Guidelines* will now contain this new addition.

II. Summary of Actions

A. Addition of Appendix D–XXXX to the NIH Guidelines

The following section is added to Appendix D:

"Dr. Michael J. Welsh, Howard Hughes Medical Institute Research Laboratories, University of Iowa College of Medicine, Iowa City, Iowa, may conduct experiments on 3 cystic fibrosis (CF) patients ≥ 18 years of age with mild to moderate disease. This Phase I study will determine the: (1) *in vivo* safety and efficacy of the administration of the replication-deficient type 2 adenovirus vector, Ad2/CFTR–1, to the nasal epithelium; (2) efficacy in correcting the CF chloride transport defect *in vivo;* and (3) effect of adenovirus vector dosage on safety and efficacy."

B. Addition of Appendix D–XXXXI to the NIH Guidelines

The following section is added to Appendix D:

"Dr. Ronald G. Crystal, National Institutes of Health, Bethesda, Maryland, may conduct experiments on 10 cystic fibrosis (CF) patients ≥ 21 years of age. Patients will receive an initial administration of the replication-deficient type 5 adenovirus vector, AdCFTR, to their left nares. If no toxicity is observed from intranasal administration, patients will receive a single administration of AdCFTR to the respiratory epithelium of their left large bronchi. Five groups of patients (2 patients per group) will be studied based on increased dosage administration of AdCFTR. This study will determine the: (1) *in vivo* safety and efficacy of the administration of AdCFTR into the respiratory epithelium; (2) efficacy of the correction of the biologic abnormalities of CF in the respiratory epithelium; (3) duration of the biologic correction; (4) efficacy of the correction of the abnormal electrical potential difference of the airway epithelial sheet; (5) clinical parameters relevant to the disease process; and (6) if humoral immunity develops against AdCFTR sufficient to prevent repeat administration."

C. Addition of Appendix D–XXXXII of the NIH Guidelines

The following section is added to Appendix D:

"Dr. Kenneth Culver, Iowa Methodist Medical Center, Des Moines, Iowa, and Dr. John Van Gilder, University of Iowa, Iowa City, Iowa, may conduct experiments on 15 patients ≥ 18 years of age with recurrent malignant primary brain tumors or lung, melanoma, renal cell carcinoma, or breast carcinoma brain metastases who have failed standard therapy for their disease. Patient eligibility will be limited to those patients who have measurable residual tumor immediately following the post-operative procedure as demonstrated by imaging studies. The number of patients treated will be equally divided between the Iowa Methodist Medical Center and the University of Iowa. If a positive response is observed in any of the first 15 patients, the investigators may submit a request to treat an additional 15 patients.

"Following surgical debulking, patients will receive a maximum of 3 intralesional injections of the G1TkSvNa vector-producing cell line (VPC) to induce regression of residual tumor cells by ganciclovir (GCV) therapy.

Patients who demonstrate stable disease for a minimum of 6 months following this treatment will be eligible for additional VPC injections and subsequent GCV therapy."

D. Addition of Appendix D–XXXXIII of the NIH Guidelines

The following section is added to Appendix D:

"Drs. Malcolm Brenner, Robert Krance, Helen E. Heslop, Victor Santana, and James Ihle, St. Jude Children's Research Hospital, Memphis, Tennessee, may conduct experiments on 35 patients ≥ 1 year and ≤ 21 years of age at the time of initial diagnosis of acute myelogenous leukemia (AML). The investigators will use the two retroviral vectors, LNL6 and G1Na, to determine the efficacy of the bone marrow purging techniques: 4-hydroxyperoxicyclophosphamide and interleukin-2 (IL–2) activation of endogenous cytotoxic effector cells, in preventing relapse from the reinfusion of autologous bone marrow cells."

E. Addition of Appendix D–XXXXIV of the NIH Guidelines

The following section is added to Appendix D:

"Drs. Helen E. Heslop, Malcolm Brenner, and Cliona Rooney, St Jude Children's Research Hospital, Memphis, Tennessee, may conduct experiments of 35 patients ≤21 years of age who will be recipients of mismatched-related or phenotypically similar unrelated donor marrow grafts for leukemia. In this Phase I dose escalation study, spontaneous lymphoblastoid cell lines will be established that express the same range of Epstein-Barr Virus (EBV) encoded proteins as the recipient. These EBV-specific cell lines will be transduced with LNL6 or G1Na and readministered at the time of bone marrow transplant. This study will determine: (1) survival and expansion of these EBV-specific cell lines *in vivo*, (2) the ability of these adoptively transferred cells to confer protection against EBV infection, and (3) appropriate dosage and adminstration schedules."

F. Addition to Appendix D–XXXXV to the NIH Guidelines

The following section is added to Appendix D:

"Drs. Robert W. Wilmott and Jeffrey Whitsett, Children's Hospital Medical Center, Cincinnati, Ohio, and Dr. Bruce Trapnell, Genetic Therapy, Inc., Gaithersburg, Maryland, may conduct experiments on 15 cystic fibrosis (CF) patients who have mild to moderate disease ≥ 21 years of age. The replication-deficient type 5 adenovirus vector, Av1CF2, will be administered to the nasal and lobar bronchial respiratory tract of patients. This study will demonstrate the: (1) expression of normal cystic fibrosis transmembrane conductance regulator (CFTR) mRNA *in vivo*, (2) synthesis of CFTR protein, and (3) correction of epithelial cell cAMP dependent C1 permeability. The pharmacokinetics of CFTR expression and ability to re-infect the respiratory tract with AvCF2 will be determined. Systematic and local immunologic consequences of Av1CF2 infection, the time of viral survival, and potential for recombination or complementation of the virus will be monitored."

G. Amendment to the "Points To Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Into the Genome of Human Subjects" Regarding the Use of Compassionate Plea

The following section is added to the *Points to Consider* of the *NIH Guidelines:*

"VI. Procedures to be Followed for Expedited Review

"1. An investigator submitting a request to the NIH for expedited review of a gene transfer protocol must provide detailed information regarding the necessity of expedited review.

"2. No protocol shall be considered without Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) approval.

"3. At this time, all gene transfer protocols must be considered experimental.

"4. Regardless of the method of review, the Points to Consider must be the standard of review for all gene transfer protocols.

"5. Review of such protocols may include intramural NIH experts but must include extramural experts.

"6. Among other factors to be considered by the reviewers, is the similarity of the new protocol to previously approved protocols.

"7. The NIH will report to the RAC following expedited review and will include all of the materials on which the decision was based. The RAC will formally review the protocol at its next scheduled meeting. Patient privacy will be maintained.

"8. 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.

"9. As requested in the context of non-expedited review, none of the costs of the experimental protocol should be borne by the patient or the patient's family.

"10. Data on all patients undergoing gene transfer shall be provided to the RAC within six months of the procedure."

H. Amendment to the Points To Consider Regarding the Separation of the Gene Marking Informed Consent Document From the Therapeutic Informed Consent Documents

In the Points to Consider, Part I–D—Informed Consent (March 1, 1990, 55 FR 7446), a new sentence would be added to the introductory paragraph:

"When gene transfer is a procedure separate from a clinical protocol, informed consent documents should be submitted for both the gene transfer and clinical protocols."

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, HIH 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: April 16, 1993.

Bernadine Healy,

Director, National Institutes of Health.

[FR Doc. 93–9503 Filed 4–22–93; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information

collection requests it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, April 9, 1993.

(Call PHS Reports Clearance Officer on 202–245–2100 for copies of request).

1. Grant Program for Scholarships for the Undergraduate Education of Professional Nurses (SUEPN)—Form—0915–0141—The Employment Verification Form is used to track compliance of nurse recipients during the obligated service period. *Respondents:* Individuals or households; Businesses or other for-profit; Non-profit institutions

Title	No. of respondents	No. of responses per respondent	Average burden per response
Employment Verification Form (Recipients)	300	1	.17 hours.
Employment Verification Form (Employers)	300	1	.08 hours.
Estimate Total Annual Burden			75 hours.]

2. National Survey of Physicians Concerning Perceptions of Drug Labeling and the Brief Summary—New—The purpose of this survey is to provide information for the Food and Drug Administration's Center for Drug Evaluation and Research labeling planning and development. A national survey of office-based practicing physicians will examine the perceived usefulness and effectiveness of communication of the information in prescription drug labeling and the summary of labeling included in prescription drug product advertising. *Respondents:* Businesses or other for-profit; *Number of Respondents:* 392; *Number of Responses per Respondent:* 1; *Average Burden per Response:* .3 hours; *Estimated Annual Burden:* 118 hours.

3. Reporting and Recordkeeping Requirements for Electronic Products Under Public Law 90–602—General Requirements—0915–0025—In order to protect the public from unnecessary exposure to radiation from electronic products, the Food and Drug Administration must collect certain information from manufacturers and dealers/distributors about electronic products they sell and install.

Note: FDA is in the process of amending the 5-year retention period from some dealers/distributors.

Respondents: Businesses or other-for-profit; Small businesses or organizations:

Title	Number of respondents	Number of responses per respondent	Average burden per response
Reporting Requirements for Electronic Products—General 21 CFR 1002, 1003, 1004, 1005 & 1010	1,635	14.5	3.94 hrs.
Recordkeeping Requirements for Electronic Products—General 21 CFR 1002	43,635	29.7	29.7 hrs.

Estimate Total Annual Burden—1,389,414.

4. Cancer Prevention Awareness; The Black College as a Resource; Medical and other Health Professional Schools—New—This data collection will aid the National Cancer Institute's efforts to effectively utilize historically black institutions in health promotion activities, especially focusing on cancer prevention. This data will also provide the NCI with a foundation for planning and developing further cancer prevention intervention research appropriate to the target population. *Respondents:* Individuals or households; Small businesses or organizations; *Number of Respondents:* 18,885; *Number of Responses per Respondent:* 1; *Average Burden per Response:* 0.1765 hours; *Estimated Annual Burden:* 4,661 hours.

5. Substance Abuse Prevention and Treatment (SAPT) Block Grant 45 CFR part 96—New—This interim final rule provides guidance for States regarding the SAPT Block Grant legislation. The rule implements the reporting and application requirements of Public Law 102–321 (42 U.S.C. 300x–21 to –35) by specifying the content of the State's annual report on an application for block grant funds. *Respondents:* State or local governments.

Title	Number of respondents	Number of responses per respondent	Average burden per response
Reporting:			
Recordkeeping 45 CFR 96.129(a)(13)	60	1	16 hrs.

Estimate Total Annual Burden—960 hours.

Note—The OMB approval for the application will be sought separate.

OMB Desk Officer: Shannah Koss.

Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated above at the following address: Human Resources and Housing Branch, New

Executive Office Building, room 3002, Washington, DC 20503.

Dated: April 19, 1993.

James Scanlon,

Director, Division of Data Policy, Office of Health Planning and Evaluation.

[FR Doc. 93-9518 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-17-M

Centers for Disease Control and Prevention Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HC (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-67776, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 58 FR 7569, dated February 8, 1993) is amended to reflect the transfer of functions for real property and space management from the Engineering Services Office, Office of Program Support, to the Office of the Director, Office of Program Support.

Section HC-B, Organization and Functions, is hereby amended as follows:

After the functional statement for the *Office of Program Support (HCA5), Office of the Director (HCA5A), Physical Security Activity (HCA5A2)*, insert the following:

Real Property and Space Management Activity (HCA5A3). (1) Conducts the Real Property and Space Management program throughout CDC, including the acquisition of leased space, the purchase and disposal of real property for CDC (with emphasis on current and long-range planning for the utilization of existing and future real property resources); (2) provides technical assistance in space planning to meet programmatic needs; (3) administers day-to-day management of leased facilities and ensures contract compliance by lessors; (4) provides technical assistance and prepares contract specifications for all repair and improvement projects in leased space; (5) maintains liaison with the General Services Administration Regional Offices; (6) performs all functions relating to leasing and/or acquisition of real property under CDC delegation of authority for leasing special purpose space; (7) coordinates the relocation of CDC personnel within owned and leased space.

Following the title *Engineering Services Office (HCA52)*, delete the functional statement in its entirety and insert the following:

(1) Operates, maintains, repairs, and modifies CDC's Atlanta area plant facilities; and conducts a maintenance and repair program for CDC's program support equipment;

(2) Carries out facilities planning functions for CDC, including new or expanded facilities, and a major repair and improvement program;

(3) Develops services for new, improved, and modified equipment to meet program needs;

(4) Provides technical assistance for and reviews maintenance and operation programs of field installations and recommends appropriate action; and

(5) Maintains liaison with the Division of Health Facilities Planning of the Office of the Assistant Secretary for Health.

Dated: April 14, 1993.

William L. Roper,

Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93-9494 Filed 4-22-93; 8:45 am]

BILLING CODE 4160-18-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. N-93-3614]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Angela Antonelli, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: April 6, 1993.

John T. Murphy,

Director, IRM Policy and Management Division.

Submission of Proposed Information Collection to OMB

Proposal: Evaluation of the Nehemiah Program.

Office: Policy Development and Research.

Description of the Need for the Information and its Proposed Use: The program provides funding to non-profit organizations in order to create homeownership opportunities for low and moderate-income households. Nehemiah funds are used to provide up to $15,000 per unit in zero interest deferred mortgages to first time homebuyers who purchase new or rehabilitated units developed by the non-profit institution. The data collection is in support of a Congressionally mandated evaluation of the Nehemiah Program.

Form Number: None.

Respondents: State or Local Governments and Non-Profit Institutions.

Frequency of Submission: One-Time.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information collection	276		1		1.13		312

Total Estimated Burden Hours: 312.
Status: New.
Contact: Joe Cater, HUD, (202) 708–3700, Angela Antonelli, OMB, (202) 395–6880.

Dated: April 6, 1993.

[FR Doc. 93–9564 Filed 4–22–93; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. N–93–3612]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comment on the subject proposals.

ADDRESSES: Interested persons are invited to submit comment regarding these proposals. Comments should refer to the proposal by name and should be sent to: Angela Antonelli, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposals for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35).

The Notices list the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: April 14, 1993.

John T. Murphy,
Director, IRM Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Flexible Subsidy/Capital Improvement Loan Programs, 24 CFR parts 219 Application Form.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: Section 201 of the Housing and Community Development Amendments of 1978 (Pub. L. 95–557) authorizes the provision of assistance to some HUD assisted projects. These include projects assisted under Section 236, Section 221(d)(3) and some Section 202 and Section 8 projects. Form HUD 9826 is used by owners when applying for Flexible Subsidy assistance under this program.

Form Number: HUD–9826.

Respondents: State or Local Governments, Businesses or Other For-Profit, Non-Profit Institutions and Small Businesses or Organizations.

Frequency of Submission: Annually.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD–9826	150		1		.5		75

Total Estimated Burden Hours: 75.
Status: New.
Contact: James J. Tahash, HUD, (202) 708–3944, Angela Antonelli, OMB, (202) 395–6880.

Dated: April 14, 1993.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Master Appraisal Report.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: The Master Appraisal Report form HUD–91322 series permits the listing of models covering types of individual homes proposed for construction. It also sets forth the general and specific conditions which must be met before a Firm Commitment for Mortgage Insurance can be endorsed by HUD.

Form Number: HUD–91322, 91322.1, 91322.2, and 91322.3.

Respondents: Businesses or Other For-Profit, Federal Agencies or Employees and Small Businesses or Organizations.

Frequency of Submission: On Occasion.

Reporting Burden.

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information collection	3,500		1		3		10,500

Total Estimated Burden Hours: 10,500.

Status: New.

Contact: Heidi Martin, HUD, (202) 708–2720, Angela Antonelli, OMB, (202) 395–6880.

Dated: April 14, 1993.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Supportive Housing Demonstration Program (FR–2878).

Office: Community Planning and Development.

Description of the Need for the Information and Its Proposed Use: The Grantee Annual Reports are needed by HUD to chart the accomplishments of the Transitional Housing and Permanent Housing components under the Supportive Housing Demonstration Program (SHDP). HUD will use the information for program monitoring, program evaluation and to report to Congress on the overall progress of the SHDP.

Form Number: HUD–40076A, HUD–40083A.

Respondents: State or Local Governments, and Non-Profit Institutions.

Frequency of Submission: Annually.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Report Preparation	1,078		1		20		21,560
Recordkeeping	1,078		1		45		48,510

Total Estimated Burden Hours: 70,070.

Status: Reinstatement.

Contact: James N. Forsberg, (202) 708–4300, Angela Antonelli, OMB, (202) 395–6880.

Dated: April 14, 1993.

[FR Doc. 93–9565 Filed 4–22–93; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. N–93–3613]

Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Angela Antonelli, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: April 7, 1993.

John T. Murphy,

Director, IRM Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Proposal: Public Housing Manager Certification Compliance—24 CFR 967.305.

Office: Public and Indian Housing.

Description of the Need for the Information and its Proposed Use: Each Public Housing Agency (PHA) is required to submit to HUD, with the proposed operating budget for each fiscal year, a list of its "Housing Manager' and Assistant Housing Manager" positions as reflected in the proposed budget. HUD needs this information to review the PHA's compliance with the provisions of the regulation.

Form Number: None.

Respondents: Non-Profit Institutions.

Frequency of Submission: Annually.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Information Collection	1,500		2.5		1		3,750

Total Estimated Burden Hours: 3,750.
Status: Reinstatement.
Contact: Odessa W. Burroughs, (202) 708-0790, Angela Antonelli, OMB, (202) 395-6880.

Dated: April 7, 1993.

[FR Doc. 93-9563 Filed 4-22-93; 8:45 am]

BILLING CODE 4210-01-M

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. N-93-3339; FR-3136-N-02]

FY 1992 NOFA for the Operating Assistance and Capital Improvement Loan Components Under the Flexible Subsidy Program; Announcement of Funding Awards

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

ACTION: Announcement of competition winners.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the NOFA for the Flexible Subsidy Program for Fiscal Year (FY) 1992. The announcement contains the names and addresses of the competition winners and the amounts of the awards.

FOR FURTHER INFORMATION CONTACT: Program Support Branch, Office of Multifamily Housing Management, 451 Seventh Street SW., Washington, DC 20410, telephone (202) 708-2654 (voice) or (202) 708-3938 (TDD for hearing-impaired). (These are not toll-free telephone numbers.)

SUPPLEMENTARY INFORMATION: The Department's Flexible Subsidy Program provides assistance to multifamily projects experiencing extreme financial difficulty. The Flexible Subsidy Program consists of two components:

(1) Operating Assistance

Operating assistance, provided in the form of a deferred loan and, in conjunction with other resources, is designed to restore or maintain the physical and financial soundness of eligible projects.

(2) Capital Improvement Loans

Capital improvement loans are provided for projects that need capital improvements to achieve physical soundness, and that cannot be funded from project reserve funds without jeopardizing other major repairs or replacements that are reasonably expected to be required in the near future.

The Flexible Subsidy Fund is comprised of excess rental receipts paid to HUD from owners of section 236 projects, interest earned on the fund, repayment of Operating Assistance loans made by the Department in past fiscal years, and amounts appropriated by Congress, if any, to carry out the purposes of the Flexible Subsidy Program.

On February 18, 1992 (57 FR 5948), the Department published a Notice of Funding Availability (NOFA) advising the public that a total of $83,000,000 in Flexible Subsidy funds was available for eligible projects, and invited owners of eligible projects to submit applications.

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, the Department is publishing, in this notice, the names and addresses of the projects and project owners that received funding awards under the FY 1992 Flexible Subsidy NOFA, and the amount of the awards. This information is set forth in Appendix A to this notice.

Dated: April 19, 1993.

James E. Schoenberger,

Associate General Deputy Assistant Secretary for Housing.

APPENDIX A—LIST OF FLEXIBLE SUBSIDY PROJECTS FUNDED PURSUANT TO THE FY 1992 NOFA

FHA No.	Project name/location	Owner's name/location	Program/amount awarded
Region: 01			
017-44109	Fairbanks, New Haven, CT	Fair Corporation, New Haven, CT	Operating Assistance 454,432.
017-555001	Liberty Square I, New Haven, CT	Liberty Square Hmes, Inc, New Haven, CT.	Operating Assistance 494,610.
017-55012	Liberty Square II, New Haven, CT	Liberty Square Hmes, Inc, New Haven, CT.	Operating Assistance 131,600.
017-55016	Meadowbrook I Apts, West Haven, CT	Meadowbrook I, Ltd., West Haven, CT	Operating Assistance 504,403.
017-55030	Meadowbrook II Apts, West Haven, CT	Meadowbrook II Joint Ven, West Haven, CT.	Operating Assistance 455,738.
017-55043	Meadowbrook III Apts, West Haven, CT	Meadowbrook III Joint Vt, West Haven, CT.	Operating Assistance 379,494.
0234-4167	Eastern Coop Homes, Springfield, MA	Eastern Coop Homes Inc., Springfield, MA.	Operating Assistance 514,411.
023-NI-027	Pine Grove, Taunton, MA	Mass Hsg Finance Agency, Tauton, MA.	Operating Assistance 805,686.
023-NI-105	Lacase Apartments, Holyoke, MA	Mass Hsg Finance Agency, Boston, MA.	Operating Assistance 995,500.
Region: 02			
012-55006	Rochester Highlands Apts, Rochester, NY.	Rochester Highlands Ltd., Rochester, NY.	Operating Assistance 1,094,445.
012-55013	Ellicott Community Redev, Buffalo, NY	Ellocott Con Red Corp, Buffalo, NY	Operating Assistance 1,250,850.
012-55105	Urban Park Apts, Rochester, NY	I.C. Hsg Dev Fund Co., Rochester, NY	Operating Assistance 2,717,078.
012-55175	Lefferets Heights Houses, Brooklyn, NY	Lefferts Hghts Hdfc, Inc., Brooklyn, NY	Operating Assistance 941,755.
014-11006	Wilcox Lane Apts, Canandaligua, NY	Wilcox Lane Sen Cit Hsg, Canandaigua, NY.	Operating Assistance 173,200.
031-44021	Stephen Manor, Asbury, NJ	St Stephen Urb Dev Corp, Ashbury Park, NJ.	Operating Assistance 517,600.
031-55078	Roosevelt Village, Cartaret, NJ	Roosevelt Vel J/V, Carlsbad, CA	Operating Assistance 379,363.
031-NI-003	Zion Towers, Newark, NJ	B'Nai Zion, Newark, NJ	Operating Assistance 1,622,560.
031-NI-040	Colt Arms, Paterson, NJ	Colt Arms Assoc, Paterson, NJ	Operating Assistance 457,800.

APPENDIX A—LIST OF FLEXIBLE SUBSIDY PROJECTS FUNDED PURSUANT TO THE FY 1992 NOFA—Continued

FHA No.	Project name/location	Owner's name/location	Program/amount awarded
031-SH017	Wesley Towers, Newark, NJ	Wesley Towers Corp, Newark, NJ	Operating Assistance 2,233,680
035-35019	Burlington Manor, Bridgeton, NJ	Burlington Manor Assoc, Carlsbad, CA	Operating Assistance 170,331.
035-35023	Magellan Manor, Altantic City, NJ	Magellan Manor Assoc, Carlsbad, CA	Operating Assistance 233,078.
035-44038	Philadelphia Village, Egg Harbor, NJ	Philadelphia Vil Apts., Carlsbad, CA	Operating Assistance 301,336.
035-55001	Brights Villa South, Atlantic City, NJ	Rev. Horace Burton, Atlantic City, NJ	Operating Assistance, 825,022.
035-55002	Brights Villa North, Atlantic City, NJ	St. James AME Church, Atlantic City, NJ.	Operating Assistance, 824,657.
Region: 03			
000-55027	Sursum Corda, Washington, DC	Sursum Corda Coop, Washington, DC	Operating Assistance, 4,781,153.
033-440522	Riverview II Apartments, Pittsburgh, PA	Riverview Apts II, Inc. Pittsburgh, PA	Operating Assistance, 848,560.
033-55007	East Liberty Gardens, Pittsburgh, PA	East Liberty Housing, Inc., Pittsburgh, PA.	Operating Assistance, 539,328.
033-55020	Lemington Heights, Pittsburgh, PA	Metro Pittsburgh Hg Corp, Pittsburgh, PA.	Operating Assistance, 385,800.
045-44004	Oakwood Terrace, Charleston, WV	Kanawha Valley Hmes, Inc., Charleston, WV.	Capital Improvement, 1,119,018.
Region: 04			
053-44801	Vanderbilt Apartments, Asheville, NC	Vanderbuilt Apts, Inc., Asheville, NC	Operating Assistance, 1,050,052.
054-44801	Christopher Towers, Columbia, SC	The Navigator Corp, Columbia, SC	Operating Assistance, 157,829.
056-44009	Torres De Carolina, Carolina, PR	Carolina Towers Coop, Carolina, PR	Operating Assistance, 579,500.
061-35125	Villa Marie Apts, Augusta, GA	Caritas Corp, Augusta, GA	Operating Assistance, 897,349.
061-44088	Bethel Towers Apts, Atlanta, GA	Allen Bird, Carlsbad, CA	Capital Improvement, 225,000.
061-44097	Tall Pines Apartments, Lagrange, GA	Larry Chkoreff, Atlanta, GA	Capital Improvement, 348,750.
061-44803	Epworth Towers, Atlanta, GA	Kenneth Weber, Atlanta, GA	Operating Assistance, 840,725.
061-55019	London Towne Houses, Atlanta, GA	Fondon Towne Houses, Inc., Atlanta, GA.	Operating Assistance, 1,475,321.
061-SH004	Wesley Woods Towers, Atlanta, GA	Wesley Homes, Inc., Atlanta, GA	Operating Assistance, 1,990,160.
063-SH017	Cathedral Towers, Jacksonville, FL	The Cathedral Foundation, Jacksonville, FL.	Operating Assistance, 1,990,532.
063-SH033	Cathedral Townhouse, Jacksonville, FL	The Cathedral Foundation, Jacksonville, FL.	Operating Assistance, 2,518,634.
066-35129	Broward Gardens Apts., Ft. Lauderdale, FL.	Broward Gardens Assoc., Ft. Lauderdale, FL.	Operating Assistance, 464,661.
083-35017	Knights of St. John's, Louisville, KY	Kingits of St. John Corp., Louisville, KY	Operating Assistance, 880,748.
083-35044	Riverside Apartments, Booneville, KY	Owsleg County Hsg Assoc., Booneville, KY.	Operating Assistance, 276,580.
083-35061	Campton Methodist Hsg I, Campton, KY.	Campton Methodist Hsg I, Campton, KY.	Capital Improvement, 275,000.
083-44054	Dudley Court Apts, Paducah, KY	So Ctrl Conf Assoc of KY, Nashville, TN.	Capital Improvement, 1,021,581.
083-44077	Smoketown Apartments, Louisville, KY	Smoketown Hsg Imprv Corp, Louisville, KY.	Capital Improvement, 161,834.
083-44083	Abel Court Apartments, Bowling Green, KY.	Seventh Day Adventist, Nashville, TN	Capital Improvement, 448,630.
083-44085	Jackson Woods Apts, Louisville, KY	New Directions Hsg Corp, Louisville, KY.	Capital Improvement, 486,484.
083-44802	Chapel House, Louisville, KY	Chapel House, Inc., Louisville, KY	Capital Improvement, 549,295.
086-35015	Haynes Garden Apts, Nashville, TN	Seventh Day Adventist, Nashville, TN	Operating Assistance, 2,138,457.
Region: 05			
042-SH005	Council Gardens I & II, Cleveland, OH	Council Gardens, Cleveland, OH	Operating Assistance, 203,679.
044-SH004	Rochdale Court, Detroit, MI	Rochdale Court Coop, Detroit, MI	Capital Improvement, 935,291.
046-55002	Parktown Cooperative, Cincinnati, OH	Parktown Coop Homes, Inc, Cincinnati, OH.	Operating Assistance, 2,294,313.
048-55016	Glenburn Green Coop, Dayton, OH	Glenburn Green Coop, Inc, Huber Heights, OH.	Operating Assistance, 468,946.
047-44051	Woodbridge Commons I, Lansing, MI	Woodbridge Commons Coop, Lansing, MI.	Operating Assistance, 748,216.
047-44069	Woodbridge Commons II, Lansing, MI	Woodbridge Commons Coop, Lansing, MI.	Operating Assistance, 830,812.
047-44901	New Horizon Village, Kalamazoo, MI	New Horizon Village Coop, Kalamazoo, MI.	Operating Assistance, 1,520,056.
047-NI-003	Oak Meadows, Albion, MI	Albion Community, Albion, MI	Operating Assistance, 808,000
071-44070	North Park Tower Coop, Chicago, IL	North Park Tower, Chicago, IL	Operating Assistance, 1,179,883.
071-55108	Noble Square Coop, Chicago, IL	Noble Square Coop, Chicago, Il	Operating Assistance, 3,806,312.
073-44091	Parc Lorraine, Richmond, IN	Parc Lorraine Coop, Inc, Richmond, IN	Operating Assistance, 827,984.
073-44310	Retreat Cooperative, Indianapolis, IN	Retreat Cooperative, Inc, Indianapolis, IN.	Operating Assistance, 693,013.
073-SH004	Bremen Manor, Bremen, IN	Michigan Benevolent Soc, Breman, IN	Operating Assistance, 191,285.
092-35004	Key Row-Wheaton, Wheaton, MN	Rev. Timothy Wenzel, Wheaton, MN	Operating Assistance, 381,743.
092-44207	Westminster Place Apts, St Paul, MN	Westminster Place, St. Paul, MN	Operating Assistance, 397,303.

APPENDIX A—LIST OF FLEXIBLE SUBSIDY PROJECTS FUNDED PURSUANT TO THE FY 1992 NOFA—Continued

FHA No.	Project name/location	Owner's name/location	Program/amount awarded
Region: 06			
059–35039	Cooper Road Plaza, Shreveport, LA	Post 525, Shreveport, LA	Operating Assistance, 879,265.
064–35054	Live Oak Manor Apts, Abbeville, LA	Live Oak Masonic Hg Corp, Abbeville, LA.	Operating Assistance, 2,305,130.
064–35070	Daggs Read Apartments, Hammond, LA.	St. James Ame Church, Hammond, LA	Operating Assistance, 1,131,050.
112–55050	Southport II Apts, Dallas, TX	Southport Charitable Tr, Dallas, TX	Operating Assistance, 486,469.
113–35005	Prince Hall Garden Apts, Fort Worth, TX.	Herbert Reece, Fort Worth, TX	Operating Assistance, 572,820.
114–35038	Columbus Village Apts, Hearn, TX	Columbus–80, Hearn, TX	Operating Assistance, 960,619.
115–35015	Cliff Maus Village Apts, Corpus Christi, TX.	Cliff Maus Village Trust, Corpus Christi, TX.	Operating Assistance, 1,112,358.
115–35035	Guild Park Apts, San Antonio, TX	San Antonio News Guild, San Antonio, TX.	Operating Assistance, 875,440.
115–35109	Guadalupe Haciendas Apts, Alice, TX	Guadalupe Haciendas Hsg, Alice, TX	Operating Assistance, 660,578.
Region: 07			
074–35003	Des Moines Area Council, Des Moines, IA.	Des Moines Area Con, Inc, Des Moines, IA.	Operating Assistance, 1,052,292.
074–44015	Homes of Oakridge, Des Moines, IA	Home of Oakridge, Inc., Des Moines, IA.	Operating Assistance, 1,143,269.
084–44008	Nowlin Hall, Kansas City, MO	Nowlin Hall, Inc., Kansas City, MO	Operating Assistance, 1,641,185.
084–55015	Highleah Townhouses I, Independence, MO.	Frances Breen, Independence, MO	Operating Assistance, 163,706.
084–55016	Highleah Townhouses II, Independence, MO.	Frances Breen, Independence, MO	Operating Assistance, 373,834.
084–55017	Highleah Townhouses III, Independence, MO.	Frances Breen, Independence, MO	Operating Assistance, 425,340.
084–55028	Highleah Townhouses IV, Independence, MO.	Frances Breen, Independence, MO	Operating Assistance, 644,773.
085–44064	San Luis Apartment, St. Louis, MO	San Luis Apartments, St. Louis, MO	Capital Improvement, 460,441.
103–SH004	Lincoln Manor, Lincoln, NE	Lincoln Manor, Inc., Lincoln, NE	Operating Assistance, 443,995.
Region: 08			
091–35077	Hill Center Apartments, Salem, SD	Hill Ctr Joint Venture, Salem, SD	Capital Improvement, 61,704.
093–44047	Havre Eagles Manor, Havre, MT	Havre Eagles Manor, Inc., Havre, MT	Operating Assistance, 445,429.
101–35018	Shorter Arms Apt, Denver, CO	Shorter Arms Church Hsg, Denver, CO	Operating Assistance, 511,262.
101–35024	Durango Housing, Durango, CO	Durango Housing Corp, Durango, CO	Operating Assistance, 334,165.
101–44002	Sakura Square, Denver, CO	Sakura Square, Denver, CO	Operating Assistance, 1,503,195.
101–44026	Golden Spike Apartments, Denver, CO	Co. Vet and Retired Rail, Denver, CO	Operating Assistance, 3,689,228.
Region: 09			
121–44195	El Bethel Arms, San Francisco, CA	El Bethel Arms, Inc., San Francisco, CA.	Operating Assistance, 1,525,383.
121–44208	Freedom West I, San Francisco, CA	Freedom West Hmes I Coop, San Francisco, CA.	Operating Assistance, 1,402,895.
121–44272	Ammel Park Coop, San Francisco, CA	Ammel Park Coop Hms, Inc., San Francisco, CA.	Operating Assistance, 678,099.
121–44423	Freedom West II, San Francisco, CA	Freedom West Hms II Coop, San Francisco, CA.	Operating Assistance, 883,461.
121–SH040	Jones Memorial Homes I, San Francisco, CA.	Jones Memorial Hmes, Inc., San Francisco, CA.	Operating Assistance, 120,868.
Region: 10			
127–35004	M.L. King, Jr., Apts, Seattle, WA	Empire-Kenyon Assoc, Seattle, WA	Operating Assistance, 3,760,871.

[FR Doc. 93–9566 Filed 4–22–93; 8:45 am]
BILLING CODE 4210–27–M

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–93–1917; FR–3350–N–28]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: April 23, 1993.

ADDRESS: For further information, contact James Forsberg, Department of Housing and Urban Development, room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–4300; TDD number for the hearing- and speech-impaired (202) 708–2565,

(these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: April 16, 1993.

Don I. Patch,

Acting Deputy Assistant Secretary for Grant Programs.

[FR Doc. 93–9376 Filed 4–22–93; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Meeting; Miles City, MT

AGENCY: Bureau of Land Management, Montana, Miles City District, Interior.

ACTION: Notice of Meeting.

SUMMARY: The Miles City District Grazing Advisory Board will meet Tuesday, May 25, 1993 at 10 a.m. The meeting will be held in the conference room at the Miles City District Office, Bureau of Land Management, Garryowen Road, Miles City, Montana 59301.

The agenda for the meeting will include:

(1) Animal Damage Control.

(2) Big Dry Resource Management Plan.

(3) Range Improvement Funding.

(4) Range Improvement Program Briefing for New Members.

The meeting is open to the public and the Board can set aside time to hear public comments. The public may make oral statements before the Board or file written statements for the Board to consider. Depending on the number of persons wishing to make a statement, a per person time limit may be established. Summary minutes of the meeting will be available for public inspection and reproduction during regular business hours within 30 days following the meeting.

FOR FURTHER INFORMATION CONTACT: District Manager, Miles City District, Bureau of Land Management, P.O. Box 940, Miles City, Montana 59301 or phone (406) 232–4331.

Darrel G. Pistorious,

Acting District Manager.

[FR Doc. 93–9576 Filed 4–22–93; 8:45 am]

BILLING CODE 4310–DN–M

[Docket No. ES–020–03–4210–05, FL–ES–04156; FL–ES–041959]

Realty Action; Classification of Public Lands for Recreation and Public Purposes; County of Walton

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action for the classification of public lands for lease/conveyance pursuant to the Recreation and Public Purposes Act.

SUMMARY: The following described public lands in Walton County, Florida have been examined and found suitable for lease or conveyance pursuant to the Recreation and Public Purposes Act, as amended, 43 U.S.C. 869 et seq., and the regulations promulgated thereunder, title 43 Code of Federal Regulations, part 2912

Tallahassee Meridian, Florida

T. 3S., R. 19W.
Sec. 24, Lot 24.
Totalling 0.49 acres.

T. 3S., R. 18 W.
Sec. 36, Lots 193–200 and 225–233.
Totalling 19.52 acres.

The Walton County Board of County Commissioners plan to use these lands for recreational areas. The lands are not needed for Federal purposes. Lease or conveyance is consistent with current Bureau of Land management land use planning and disposal is deemed to be in the public interest.

The lease/patent, when issued, shall be subject to the provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior, and to the following reservations to the United States:

1. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals.

2. The terms and conditions as stipulated within the Environmental Assessment and the formal consultation with the U.S. Fish and Wildlife Service pursuant to section 7 of the Endangered Species Act of December 18, 1973, 43 U.S.C. 1536, as amended.

3. All valid existing rights documented on the official public land records at the time of lease/patent issuance.

4. Any other reservations that the authorized officer determines appropriate to ensure public access and proper management of Federal lands and interests herein.

EFFECTIVE DATE: Upon publication of this notice in the **Federal Register** the lands will be segregated from all forms of appropriation under the public and land laws, including the general mining laws, except for lease or conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. June 7, 1993, interested persons or parties may submit comments regarding the proposed lease/conveyance or classification of the lands to the District Manager, Jackson District Office, 411 Briarwood Drive, Suite 404, Jackson, MS 39236. Any adverse comments will be reviewed by the District Manager. In the absence of any adverse comments, the classification will become effective on June 22, 1993.

FOR FURTHER INFORMATION CONTACT: Mark H. Davis, Assistant District Manager, Jackson District Office, 411 Briarwood Drive, Suite 404, Jackson, MS 39206, (601) 977–5400.

Dated: April 16, 1993.

Robert V. Abbey,

District Manager.

[FR Doc. 93–9458 Filed 4–22–93; 8:45 am]

BILLING CODE 4210–05–M

[CO–942–93–4730–12]

Colorado: Filing of Plats of Survey

April 9, 1993.

The plats of survey of the following described land, will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10 a.m., April 9, 1993.

The plat representing the dependent resurvey of portions of the north boundary, subdivisional lines, and Tract 39, and the subdivision of sections 3, 4, and 9, T. 3 N., R. 96 W., Sixth Principal Meridian, Colorado, Group No. 926, was accepted January 14, 1993.

The plat representing the dependent resurvey of portions of the south and west boundaries, a portion of the subdivisional lines and a portion of certain claim lines, T. 6 N., R. 93 W., Sixth Principal Meridian, Colorado, Group No. 952, was accepted February 2, 1993.

The plat representing the dependent resurvey of a portion of the south boundary, a portion of the subdivisional lines, and a portion of certain claim lines, T. 6 N., R. 94 W., Sixth Principal Meridian, Colorado, Group No. 952, was accepted February 2, 1993.

The plat representing the dependent resurvey of portion of the subdivisional lines, and certain claim lines, and the subdivision of sections 26 and 35, T. 4 N., R. 92 W., Sixth Principal Meridian, Colorado, Group No. 953, was accepted January 14, 1993.

The plat representing the dependent resurvey of the south half of the line between sections 23 and 24 and the west half of the east half of the line between sections 23 and 24 and the subdivision of certain claim sections, T. 2 N., R. 77 W., Sixth Principal Meridian, Colorado, Group No. 955, was accepted March 1, 1993.

The supplemental plat, showing the removal of Tract 38 in the E1/2NE1/4 of section 7, and correcting the tie from the A.M.C. of Tract 39 to the north 1/4 Cor. of section 7, T. 8 S., R. 96 W., Sixth Principal Meridian, Colorado, was accepted February 23, 1993.

These surveys were executed to meet certain administrative needs of this Bureau. The plat representing the dependent resurvey of the east two miles of the south boundary and the east mile of the north boundary, T. 7 S., R. 77 W., Sixth Principal Meridian, Colorado, Group No. 769, was accepted March 1, 1993.

The plat (in three sheets), representing the dependent resurvey of portions of the south and west boundaries, subdivisional lines, and mineral survey No. 19534, and the subdivision of certain sections. T. 7 S., R. 76 W., Sixth Principal Meridian, Colorado, Group No. 769, was accepted March 1, 1993.

The plat (in three sheets), representing the dependent resurvey of portions of the south and west boundaries, subdivisional lines, and the metes-and-bounds survey of Homestead Entry Survey No. 328, and the subdivision of certain sections, T. 7 S., R. 75 W., Sixth Principal Meridian, Colorado, Group No. 769, was accepted March 1, 1993.

The plat representing the dependent resurvey of portions of the east and north boundaries and the subdivisional lines and the subdivision of sections 2 and 12, Frac. T. 2 N., R. 88 W., Sixth Principal Meridian, Colorado, Group No. 920, Colorado, was accepted March 1, 1993.

The plat, representing the dependent resurvey of a portion of the subdivisional lines, and the metes-and-bounds survey of Public Land Tract 57, T. 39 N., R. 3 E., New Mexico Principal Meridian, Colorado, Group No. 1033, was accepted February 3, 1993.

These surveys were executed to meet certain administrative needs of the U.S. Forest Service.

Darryl A. Wilson

Chief, Cadastral Surveyor for Colorado.

[FR Doc. 93-9444 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-TB-M

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit and Habitat Conservation Plan for Sunland Communities, Inc., a Proposed Residential Development (Tract TT 14265) Near Victorville, San Bernardino County, CA

AGENCY: Fish and Wildlife Service, Interior

ACTION: Notice.

SUMMARY: Sunland Communities, Inc. (Sunland) has applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to section 10(a) of the Endangered Species Act (Act). The proposed permit would authorize the incidental take of the threatened desert tortoise (*Gopherus agassizii*). The Service has prepared an environmental assessment (EA) for the incidental take permit application. This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the permit application, Habitat Conservation Plan, and EA should be received on or before May 24, 1993.

ADDRESSES: Comments regarding the adequacy of the documents should be addressed to Mr. Craig Faanes, Field Supervisor, U.S. Fish and Wildlife Service, Ventura Office, 2140 Eastman Avenue, suite 100, Ventura, California 93003.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Hohman, U.S. Fish and Wildlife Service, 2140 Eastman Avenue, Suite 100, Ventura, California 93003 (805/644-1766). Individuals wishing copies of the documents for review should immediately contact the above individual.

SUPPLEMENTARY INFORMATION: Section 9 of the Act and implementing regulations prohibits the "taking" of a threatened species like the desert tortoise. However, the Service, under limited circumstances, may issue permits to take threatened species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for threatened species are in 50 CFR 17.32.

Sunland proposes to construct a residential development on a 160-acre parcel, which is located in western Victorville, San Bernardino County, California. The parcel comprises the western ½ of the eastern ½ of section 11 in Township 5 North, Range 5 West (San Bernardino Base Meridian). The proposed residential development and improvement to roads on its borders will permanently eliminate up to 160 acres of threatened species habitat. Sunland proposes to mitigate for this incidental take via several on-site and off-site mitigation measures. Such measures include off-site acquisition of 320 acres of desert tortoise habitat within California Department of Fish and Game's (Department) crucial habitat for the desert tortoise and surrounded by Bureau of Land Management's Category 1 habitat for the desert tortoise, conveyance of these lands to the Department, transfer of $18,000 to the Department to provide fencing around the off-site mitigation lands, a management endowment in the amount of $27,840 ($87/acre) to the Department to manage the conveyed lands in perpetuity for the desert tortoise, and various on-site measures to avoid take of the desert tortoise to the maximum extent possible during construction of the residences.

The EA considers the environmental consequences of the proposed action and the no action alternative. Sunland considered a third alternative to set aside those portions of the parcel that were inhabited by tortoises and to not develop these portions. This alternative was rejected. The proposed action would result in the loss of a portion of a population of tortoises already fragmented by development in and around the city of Victorville. The proposed action would also result in the preservation and enhancement of 320 acres of desert tortoise habitat in the Department's crucial habitat and surrounded by the Bureau's Category 1 habitat for the desert tortoise. Although the no action alternative would not permit the take of the desert tortoise on the proposed project site, the illegal collection of tortoises as pets and for food, vandalism, death from vehicle kills, predation from domestic and feral pets, fragmentation of habitat in an urban setting, and other human activities would prevent the long-term survival of desert tortoises on this parcel.

Notice: Availability of Environmental Assessment and Receipt of an Application for an Incidental Take Permit for Sunland Communities, Inc., Proposed Residential Development in Western Victorville, San Bernardino County, California

Dated: April 16, 1993.

William E. Martin,

Acting Regional Director, U.S. Fish and Wildlife Service, Portland Oregon.

[FR Doc. 93-9493 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-55-M

National Park Service

Delaware Water Gap National Recreation Area

AGENCY: Delaware Water Gap National Recreation Area Citizens Advisory Commission, National Park Service, DOI.

ACTION: Notice of Meeting.

SUMMARY: This notice sets forth the dates for two public forums of the Delaware Water Gap National Recreation Area Citizens Advisory Commission.

Date: May 26, 1993.

Time: 7 p.m.

Location: Monroe County Courthouse, Jury Assembly Room, 7th and Monroe Streets, Stroudsburg, PA.

Date: June 9, 1993.

Time: 7 p.m.

Location: Pike County Administration Building, Commissioners Meeting Room, 506 Broad Street, Milford, PA.

Agenda: The agenda will be devoted to the Park Service policy and legislation on U.S. Highway Route 209. Opportunities for public comment to the Commission will be provided.

FOR FURTHER INFORMATION CONTACT: Hal J. Grovert, Acting Superintendent; Delaware Water Gap National Recreation Area, Bushkill, PA 18324; 717-588-2435.

SUPPLEMENTARY INFORMATION: The Delaware Water Gap National Recreation Area Citizens Advisory Commission was established by Public Law 101-573 to advise the Secretary of the Interior and the United States Congress on matters pertaining to the management and operation of the Delaware Water Gap National Recreation Area, as well as on other matters affecting the Recreation Area and its surrounding communities.

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 Delaware Water Gap National Recreation Area Citizens Advisory Commission, P.O. Box 284, Bushkill, PA 18324. Minutes of the meeting will be available for inspection four weeks after the meeting at the permanent headquarters of the Delaware Water Gap National Recreation Area located on River Road 1 mile east of U.S. Route 209, Bushkill, Pennsylvania.

John R. Reynolds,

Regional Director, Mid-Atlantic Region.

[FR Doc. 93-9491 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-70-M

Lakeshore Road Reconstruction Lake Mead National Recreation Area Record of Decision

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, Public Law 91-190, and specifically to the regulations promulgated by the Council on Environmental Quality at 40 CFR 1505.2, the Department of the Interior, National Park Service (NPS) has prepared a Record of Decision on the Final Environmental Impact Statement for Lakeshore Road Reconstruction, Lake Mead National Recreation Area.

The NPS will implement the proposal, set forth as Alternative B in the Draft Environmental Impact Statement issued in November, 1991 (56 FR 61047), and as modified in the Final Environmental Impact Statement issued in February, 1993 (58 FR 7244).

Copies of the Record of Decision may be obtained either from the Superintendent, Lake Mead National Recreation Area, 601 Nevada Highway, Boulder City, Nevada 89005, telephone number (702) 293-8920 or the Western Regional Office, National Park Service, Division of Planning, Grants and Environmental Quality, 600 Harrison St., Suite 600, San Francisco, CA 94107-1372.

Dated: April 7, 1993.

Lewis Albert,

Acting Regional Director, Western Region.

[FR Doc. 93-9492 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-70-M

General Management Plan Manzanar National Historic Site, California; Intent to Prepare an Environmental Impact Statement

Summary: The National Park Service will prepare a General Management Plan/Environmental Impact Statement (GMP/EIS) for Manzanar National Historic Site, California and initiate the scoping process for this document. This notice is in accordance with 40 CFR 1501.7 and 40 CFR 1508.22, of the regulations of the President's Council on Environmental Quality for the National Environmental Policy Act of 1969, Public Law 91-190.

Background: The GMP is mandated by Public Law 102-248, which established the unit in March 1992. The purpose of the GMP/EIS will be to state the management philosophy for the historic site and provide strategies for addressing major issues facing the site consistent with management objectives. Two types of strategies will be presented in the GMP: (1) Those required to properly manage cultural and natural resources, and (2) those required to provide for safe, accessible and appropriate use of those resources. Based on these strategies, the GMP will identify the programs, actions and support facilities needed for their implementation.

Persons wishing to comment or express concerns on the management issues and future management direction of Manzanar National Historic Site should address these to the Regional Director, Western Region, National Park Service, 600 Harrison Street, Suite 600, San Francisco, California 94107-1372. Questions regarding the plan should be addressed to Dan Olson, Park Planner, address as above, telephone (415) 744-3968. Comments on the scoping of the proposed GMP/EIS should be received no later than June 30, 1993.

A public scoping meeting on the GMP/EIS has been scheduled April 23, 1993, at the American Legion Hall, Highway 395, Independence, California from 7:30-3:30 p.m. Additional public scoping sessions will be scheduled as needed and notice given in the press.

The responsible official is Stanley T. Albright, Regional Director, Western Region, National Park Service. The draft GMP/EIS is expected to be available for public review in early 1994, and the final GMP/EIS and Record of Decision completed by the end of 1994.

Dated: April 6, 1993.

Lewis Albert,

Acting Regional Director.

[FR Doc. 93-9498 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-70-M

Lake Clark National Park Subsistence Resource Commission

AGENCY: National Park Service, Interior.

ACTION: Subsistence Resource Commission meeting.

SUMMARY: The Superintendent of Lake Clark National Park and Preserve and the Chairperson of the Subsistence Resource Commission for Lake Clark National Park announce a forthcoming meeting of the Lake Clark National Park Subsistence Resource Commission

The following agenda items will be discussed:

(1) Introduction of commission members and guests.

(2) Introduction of Superintendent.

(3) Superintendent's welcome.
(4) Old Business:
a. Approval of minutes from last meeting.
b. Review of SRC function and purpose.
c. Update progress on subsistence hunting plan roster regulation.
(5) New Business:
a. New regional council structure and SRC charter.
b. Public and other agency's comments.
(6) Hunting plan recommendations work session.

DATES: The meeting will be held Tuesday, May 11, 1993. The meeting will begin at 10 a.m. and conclude around 5 p.m.

LOCATION: The meeting will be held at the Lake Clark National Park field headquarters in Port Alsworth, Alaska.

FOR FURTHER INFORMATION CONTACT: Ralph Tingey, Superintendent, 4230 University Drive, Suite 311, Anchorage, AK 99508. Phone (907) 271-3751.

SUPPLEMENTARY INFORMATION: The Subsistence Resource Commissions are authorized under title VIII, section 808, of the Alaska National Interest Lands Conservation Act, Public Law 96-487, and operate in accordance with the provisions of the Federal Advisory Committees Act.

Paul F. Haertel,
Acting Regional Director.

[FR Doc. 93-9490 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-70-M

Trail of Tears National Historic Trail Advisory Council; Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act, Public Law 92-463, that a meeting of the Trail of Tears National Historic Trail Advisory Council will be held May 27-28, 1993, at 8:30 a.m., at the Opryland Hotel, 2800 Opryland Drive, Nashville, Tennessee.

The Trail of Tears National Historic Trail Advisory Council was established pursuant to Public Law 100-192 establishing the Trail of Tears National Historic Trail to advise the National Park Service on such issues as preservation of trail routes and features, public use, standards for posting and maintaining trail markers, as well as administrative matters.

The matters to be discussed include:

—Plan Implementation Status
—Trail Association Role
—Cooperative Agreements Negotiation
—Fundraising

The meeting will be open to the public. However, facilities and space for accommodating members of the public are limited, and persons will be accommodated on a first-come, first-served basis. Any member of the public may file a written statement concerning the matters to be discussed with David Gaines, Trail Manager.

Persons wishing further information concerning this meeting, or who wish to submit written statements may contact David Gaines, Trail Manager, Trail of Tears National Historic Trail, National Park Service, Southwest Region, P.O. Box 728, Santa Fe, New Mexico 87504-0728, telephone 505/988-6888. Minutes of the meeting will be available for public inspection four weeks after the meeting at the office of the Trail Manager, located in room 358, Pinon Building, 1220 South St. Francis Drive, Santa Fe, New Mexico.

Dated: April 15, 1993.

Mary R. Bradford,
Deputy Regional Director, Southwest Region.

[FR Doc. 93-9489 Filed 4-22-93; 8:45 am]

BILLING CODE 4310-70-M

INTERNATIONAL TRADE COMMISSION

Sanction for Breaches of Commission Protective Order

AGENCY: U.S. International Trade Commission.

ACTION: Sanction for breaches of Commission protective order.

SUMMARY: Notice is hereby given of the sanction imposed by the Commission for breaches of the administrative protective order issued in *Fresh Kiwifruit from New Zealand*, Inv. No. 731-TA-516 (Final). The Commission has decided to sanction Mr. John Lindsey, Esq., for inadvertently providing his client with a document containing business proprietary information covered by the protective order, and for issuing instructions to a paralegal of his firm that resulted in the transmission of documents containing business proprietary information to additional persons not authorized to receive such information.

ADDRESSES: Copies of the public letter of reprimand are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-252-2000.

FOR FURTHER INFORMATION CONTACT: Andrea C. Casson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-3105. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-2000.

Authority: The authority for this action is conferred by section 777c(1)(B) of the Tariff Act of 1930 (19 U.S.C. 1677f(c)(1)(B)) and by Rule 207.7(d) of the Commission's Rules of Practice and Procedure (19 CFR § 207.7(d)).

Issued: April 20, 1993.

By order of the Commission.

Paul R. Bardos,
Acting Secretary.

[FR Doc. 93-9640 Filed 4-21-93; 11:26 am]

BILLING CODE 7020-02-P

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32219]

The Kansas City Southern Railway Company—Control Exemption—Graysonia, Nashville and Ashdown Railroad Company

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the prior approval requirements of 49 U.S.C. 11343-45 the acquisition of control by The Kansas City Southern Railway Company (KCS) of Graysonia, Nashville and Ashdown Railway Company (GNA), through stock ownership, subject to standard labor protective conditions. KCS is wholly owned by Kansas City Southern Industries, Inc. (KCSI), a noncarrier holding company that currently controls no other Commission-regulated rail carriers. KCSI, KCS, and K&M NEWCO jointly have pending in Finance Docket No. 32167 an application to control MidSouth Corporation. KCS has placed all of its shares of GNA's stock in an independent voting trust to avoid a common control violation, pending the effective date of this exemption.

DATES: This exemption will be effective on May 23, 1993. Petitions to stay must be filed by May 10, 1993, and petitions to reopen must be filed by May 18, 1993.

ADDRESSES: Send pleading referring to Finance Docket No. 32219 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423 and

(2) Petitioners' representative: Jay M. Nadlman, Kansas City Southern Industries, Inc. 114 West Eleventh Street, Kansas City, MO 64105-1804.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder (202) 927–5610 [TDD for hearing impaired: (202) 927–5721]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Decided: April 15, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,

Secretary

[FR Doc. 93–9554 Filed 4–22–93; 8:45 am]

BILLING CODE 7035–01–P

[Finance Docket No. 32277]

RailTex, Inc.—Continuance in Control Exemption—the Salt Lake City Southern Railroad Co.

Railtex, Inc. (RailTex), a noncarrier, has filed a notice of exemption to continue in control of the Salt Lake City Southern Railway Company (SLCS) upon SLCS becoming a class III rail carrier. SLCS, a noncarrier, has concurrently filed a notice of exemption in Finance Docket No. 32276, Salt Lake City Southern Railroad Company Inc.—Acquisition and Operation Exemption—Line between Mount and Salt Lake City, UT, to operate approximately 25 miles of rail line located between Mount and Salt Lake City, UT, including the 1.25-mile Loverdahl Spur. SLCS expected that transaction to be consummated on or after the March 31, 1993, effective date of the exemption.

RailTex also controls 11 other class III rail carriers operating in 14 States.[1] RailTex has certified that: (1) The SLCS will not connect with any other railroads in the RailTex corporate family; (2) the continuance in control is not part of a series of anticipated transactions that would connect the railroads with each other or any other railroad in their corporate family; and (3) the transaction does not involve a class I carrier. The transaction is therefore exempt from the prior approval requirements of 49 U.S.C. 11343. *See* 49 CFR 1180.2(d)(2).

As a condition to use of this exemption, any employees adversely affected by the transaction will be protected by the conditions set forth in New York Dock Ry.—Control—Brooklyn Eastern Dist., 360 I.C.C. 60 (1979).

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 automatically stay the transaction. Pleadings must be filed with the Commission and served on: Kelvin J. Dowd, Esq., Slover & Loftus, 1224 Seventeenth Street NW., Washington, DC 20036.

Decided: April 19, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9553 Filed 4–22–93; 8:45 am]

BILLING CODE 7035–01–M

[1] Those rail carriers are Chesapeake and Albermarle Railroad Company, Inc., Indiana Southern Railroad, Inc., North Carolina & Virginia Railroad Company, Inc., Mid Michigan Railroad Company, Inc., Missouri & Northern Arkansas Railroad, Austin & Northwestern Railroad Company, Inc., South Carolina Central Railroad Company, Inc., Dallas, Garland, & Northeastern Railroad, San Diego & Imperial Valley Railroad, New Orleans Lower Coast Railroad, Michigan Shore Railroad, Inc. The property of those carriers is located in Alabama, Arkansas, California, Georgia, Indiana, Kansas, Louisiana, Michigan, Missouri, New Mexico, North Carolina, South Carolina, Texas, and Virginia.

[Finance Docket No. 32271]

Maine Coast Railroad Corp.; Modified Rail Certificate

On March 18, 1993, Maine Coast Railroad Corporation (MECO) filed a notice under 49 CFR part 1150, Subpart C—Modified Certificate of Public Convenience and Necessity, to operate the State of Maine's 33.60-mile Lower Road, extending between milepost 29.40, at Rock Junction in Brunswick, ME, and milepost 63.00 in Augusta, ME.

Maine Central Railroad Company was authorized to abandon and Springfield Terminal Railway Company was authorized to discontinue service over the Lower Road in Docket No. AB–83 (Sub-No. 9), Maine Central Railroad Company and Springfield Terminal Railway Company—Abandonment and Discontinuance—In Cumberland, Sagadahoc and Kennebec Counties, ME (not printed), served January 8, 1990. The Maine Department of Transportation acquired the Lower Road in February 1991.

The notice filed by MECO also includes the Cobbossecontee Branch, connecting to the Lower Road in Gardiner, ME, and extending about 1 mile to its end. In its notice, MECO claimed that the State of Maine owns the Cobbossecontee Branch as well and that the Commission had authorized its abandonment in the referenced proceeding. In fact, the cited decision does not mention the Cobbossecontee Branch. By letter filed April 13, MECO contends that the Cobbossecontee Branch was not included in the abandonment application because it was "spur" or "industrial" track excepted from Commission jurisdiction under 49 U.S.C. 10907. It has not been established that the Cobbossecontee Branch's status has changed so that the Commission now has jurisdiction over its operation. Accordingly, this modified rail certificate does not cover the Cobbossecontee Branch.

The Commission will serve a copy of this notice on the Association of American Railroads (Car Service Division), as agent of all railroads subscribing to the car-service and car-hire agreement, and on the American Short Line Railroad Association.

Dated: April 19, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9555 Filed 4–22–93; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 32276]

Salt Lake City Southern Railroad Co., Inc.; Acquisition and Operation Exemption; Line Between Mount and Salt Lake City, UT

Salt Lake City Southern Railroad Company, Inc. (SLCS) has filed a notice of exemption to acquire certain limited ownership interests in and to operate as a common carrier approximately 25 miles of rail line owned by Union Pacific Railroad Company (UP).[1] UP had previously conveyed certain right-of-way and trackage interest in the line to the Utah Transit Authority (UTA), but had retained a permanent easement for the freight operations.[2] SLCS will become a class III rail carrier. Parties expected to consummate the transaction after the March 31, 1993, effective date of this notice.

The line involved in the transaction extends from milepost 775.19, at the Salt Lake County/Utah County boundary line, to milepost 798.74, at

[1] This exemption also includes SLCS' acquisition of incidental trackage rights from UP over about 1183 yards of track at the end of the Loverdahl Subdivision, near Midvale, UT.

[2] By decision served December 31, 1992, in Finance Docket No. 32186, Utah Transit Authority—Acquisition Exemption—Line of Union Pacific Railroad Company, the Commission ruled that it does not have jurisdiction over the transfer of certain of UP's physical assets to UTA, where UTA would perform only intrastate passenger service and no freight service, and UP would retain and convey to a Freight Operator a permanent easement for the freight operations.

Ninth South Street in Salt Lake City, UT, and includes the 1.25-mile Loverdahl Spur, connecting at milepost 790.52.[3]

This proceeding is related to Finance Docket No. 32277, RailTex, Inc.—Continuance in Control Exemption—The Salt Lake City Southern Railroad Company, wherein RailTex, Inc., parent company of SLCS, has concurrently filed a notice of exemption for its continuance in control of SLCS when SLCS becomes a rail carrier upon consummation of the transaction described in this notice.

Any comments must be filed with the Commission and served on: Kelvin J. Dowd, Slover & Loftus, 1224 Seventeenth St., NW., Washington, DC 20036.

This notice is filed under 49 CFR 1150.31. 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 automatically stay the transaction.

Decided: April 19, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.

Secretary.

[FR Doc. 93-9552 Filed 4-22-93; 8:45 am]

BILLING CODE 7035-01-M

[3] Although in Finance Docket No. 32186, Loverdahl Spur had been described as a 1.4-mile line rather than a 1.25-mile line, the spur in this notice appears to refer to that same spur.

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division, of Wage Determinations, 200 Constitution Avenue, NW., room S-3014, Washington, DC 20210.

New General Wage Determination Decisions

The numbers of the decisions added to the Government Printing office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" are listed by Volume and State.

Volume I

Vermont
VT93-14 (April 23, 1993)

Volume III

Idaho
ID93-6 (April 23, 1993)

Withdrawn General Wage Determination Decision

This is to advise all interested parties that the Department of Labor is withdrawing, from the date of this notice, General Wage Determination No. TN930041, dated Feb. 19, 1993.

Agencies with construction pending projects, to which this wage decision would have been applicable, should utilize the project determination procedure by submitting a SF-308. (See Regulations, 29 CFR part 1, § 1.5.) Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.6(c)(2)(i)(A), when the opening of bids is within ten (10) days of this notice, the contract specifications need not be affected.

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing office document entitled "General Wage Determination Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Florida
FL93-17 (Feb. 19, 1993)
FL93-45 (Feb. 19, 1993)
Massachusetts
MA93-2 (Feb. 19, 1993)
Pennsylvania
PA93-9 (Feb. 19, 1993)
Tennessee
TN93-4 (Feb. 19, 1993)
TN93-17 (Feb. 19, 1993)
TN93-19 (Feb. 19, 1993)

Volume II

Illinois
IL93-1 (Feb. 19, 1993)

IL93–2 (Feb. 19, 1993)
IL93–3 (Feb. 19, 1993)
IL93–4 (Feb. 19, 1993)
IL93–5 (Feb. 19, 1993)
IL93–6 (Feb. 19, 1993)
IL93–7 (Feb. 19, 1993)
IL93–8 (Feb. 19, 1993)
IL93–13 (Feb. 19, 1993)
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IL93–15 (Feb. 19, 1993)
IL93–16 (Feb. 19, 1993)
IL93–17 (Feb. 19, 1993)
IL93–18 (Feb. 19, 1993)

Indiana
IN93–2 (Feb. 19, 1993)

Kansas
KS93–16 (Feb. 19, 1993)

Texas
TX93–13 (Feb. 19, 1993)

Wisconsin
WI93–5 (Feb. 19, 1993)

Volume III

Idaho
ID93–1 (Feb. 19, 1993)

Montana
MT93–2 (Feb. 19, 1993)

Utah
UT93–7 (Feb. 19, 1993)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under the Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from:

Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC This 16th day of April 1993.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 93–9348 Filed 4–22–93; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Local Arts Agencies Advisory Panel (Local Arts Agency Development Section) will be held on May 19, 1993 from 2 p.m.–5:30 p.m., May 20 from 9 a.m.–5 p.m., and May 21 from 9 a.m.–3 p.m. in Room M–14 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

This meeting will be open to the public on a space available basis. The topics will include application review of Leadership Training and Services, Planning and Stabilization, and an overview of the program.

Any interested person may observe meetings, or portions thereof, which are open to the public, and may be permitted to participate in the discussions at the discretion of the meeting chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TTY 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5439.

Dated: April 15, 1993.

Yvonne M. Sabine,

Director, Panel Operations, National Endowment for the Arts.

[FR Doc. 93–9457 Filed 4–22–93; 8:45 am]

BILLING CODE 7537–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Trade Policy Staff Committee (TPSC); Initiation of a Review To Consider Designation of the Russian Federation as a Beneficiary Developing Country Under the Generalized System of Preferences (GSP); Solicitation of Public Comments Relating to the Designation Criteria

AGENCY: Office of the United States Trade Representative.

ACTION: Solicitation of public comment with respect to the eligibility of the Russian Federation (Russia) for the Generalized System of Preferences (GSP) program.

SUMMARY: The purpose of this notice is to announce the initiation of a review to consider whether Russia satisfies criteria for designation as a beneficiary developing country under the GSP program, and to solicit public comment relating to the designation criteria.

FOR FURTHER INFORMATION CONTACT: GSP Subcommittee, Office of the United States Trade Representative, 600 17th Street, NW., room 517, Washington, DC 20506. The telephone number is (202) 395–6971. Public versions of all documents related to this review will be available for review by appointment with the USTR Public Reading Room shortly following filing deadlines. Appointments may be made from 10 a.m. to noon and 1 p.m. by calling (202) 395–6186.

SUPPLEMENTARY INFORMATION: As a successor state to the Soviet Union, Russia is currently statutorily ineligible for designation as a beneficiary developing country for purposes of the Generalized System of Preferences (GSP) (19 U.S.C. 2462 (b)). On April 5, 1993, the President announced his intention to propose the elimination of this statutory bar.

In anticipation of the elimination of this bar, and in order to provide for possible designation as soon as possible thereafter, the Trade Policy Staff Committee (TPSC) has initiated a review to determine if Russia meets the designation criteria of the GSP law and should be designated as a beneficiary. The GSP is provided for in the Trade Act of 1974, as amended (19 U.S.C. 2461–2465). The designation criteria are listed in 19 U.S.C. 2462(a), 2462(b) and 2462(c). Interested parties are invited to submit comments regarding the eligibility of Russia for designation as a GSP beneficiary. The designation criteria mandate determinations related to participation in commodity cartels, preferential treatment provided by beneficiaries to other developed countries, expropriation without compensation, enforcement of arbitral awards, international terrorism, and internationally recognized worker rights. Other practices taken into account include market access for goods and services, investment practices and intellectual property rights.

An original and fourteen (14) copies of comments regarding Russia's eligibility may be submitted, in English, to the Chairman of the GSP Subcommittee, Trade Policy Staff Committee, 600 17th Street, NW., room 517, Washington, DC 20506. Comments

must be received no later than 5 p.m. on May 14, 1993.

Information and comments submitted regarding this notice will be subject to public inspection by appointment with the staff of the USTR Public Reading Room, except for information granted "business confidential" status pursuant to 15 CFR 2003.6. If the document contains business confidential information, an original and fourteen (14) copies of a nonconfidential version of the submission along with an original and (14) copies of the confidential version must be submitted. In addition, the document containing confidential information should be clearly marked "confidential" at the top and bottom of each and every page of the document. The version which does not contain business confidential information (the public version) should also be clearly marked at the top and bottom of each and every page (either "public version" or "non-confidential").

Frederick L. Montgomery,

Chairman, Trade Policy Staff Committee.

[FR Doc. 93–9525 Filed 4–22–93; 8:45 am]

BILLING CODE 3190–01–M

SECURITIES AND EXCHANGE COMMISSION

Forms Under Review by Office of Management and Budget

Agency Clearance Officer: John J. Lane, (202) 272–5407.

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of Consumer Affairs and Information Services, 450 Fifth Street, NW., Washington, DC 20549.

New

Rule 485a, File No. 270–68

Proposed Amendments

Rule 415, File No. 270–68
Form N–2, File No. 270–21

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission has submitted for OMB approval a proposed amendment to rule 415 and new rule 485a under the Securities Act of 1933 ("Act"), and amendments to Form N–2 under the Investment Company Act of 1940 ("Investment Company Act"). The amendment to rule 415 under the Act would permit continuous or delayed offerings by closed-end investment companies making periodic repurchase offers pursuant to rule 23c–3 under the Investment Company Act. Proposed rule 485a would provide for automatic effectiveness of post-effective amendments and new registration statements filed by closed-end investment companies making periodic repurchase offers under rule 23c–3. The proposed amendments to Form N–2 relate to the proposed new offering and registration procedures.

Form N–2 is the form on which closed-end management investment companies register their securities under the Act, and register as investment companies under the Investment Company Act. The staff estimates that approximately five post-effective amendments or registration statements would be filed annually by closed-end investment companies making periodic repurchase offers pursuant to rule 23c–3 that are not currently offering their shares. The staff also estimates that the time necessary for each such investment company to comply with the requirements of the relevant form would be approximately 1,630 hours.

Rule 415, as proposed, would enable closed-end investment companies that make periodic repurchase offers pursuant to rule 23c–3 to offer securities on a continuous or delayed basis. Rule 485a, as proposed, would provide for the automatic effectiveness of post-effective amendments and registration statements filed by such closed-end investment companies for the purpose of registering additional shares. No separate burden hours are allocated to compliance with these two rules since their burden hours are accounted for under Form N–2.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even representative survey or study of the cost of the SEC rules and forms.

Direct general comments to Gary Waxman at the address below. Direct any comments concerning the accuracy of the estimated average burden hours for compliance with SEC rules and forms to John J. Lane, Associate Executive Director, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, and Gary Waxman, Clearance Officer, Office of Information and Regulatory Affairs, Office of Management and Budget (Paperwork Reduction Project 3235–0026 [Form N–2] and 3235–0074 [Rules 415 and 485a]), room 3208, New Executive Office Building, Washington, DC 20503.

Dated: April 16, 1993.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9562 Filed 4–22–93; 8:45 am]

BILLING CODE 8010–01–M

Forms Under Review by Office of Management and Budget

Agency Clearance Officer: John J. Lane, (202) 272–5407

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of Consumer Affairs and Information Services, 450 Fifth Street, NW., Washington, DC 20549

Amendment:

Form N–1A, File No. 270–21
Form N–14, File No. 270–297
Rule 34b–1, File No. 270–305

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") has submitted for OMB approval amendments to Forms N–1A and N–14 and Rule 34b–1 under the Investment Company Act of 1940 ("1940 Act").

Form N–1A is the registration statement for use by open-end management investment companies, except small business investment companies and insurance company separate accounts. There are approximately 2700 registrants using Form N–1A. The average additional burden imposed by the amendments is estimated to be 4.3 hours per registrant, for a new total burden of 1059.6 hours per registrant.

Form N–14 is the registration form used by investment companies to register under the 1933 Act securities to be issued in mergers and other forms of business combination. By cross-referencing a number of the items in Form N–1A, Form N–14 requires disclosure of the same performance information regarding the management investment companies involved in the transaction. Approximately 95 registrants filed Form N–14 in 1992, with an estimated compliance time of 2,499 hours per registrant. The maximum additional burden imposed by the amendments is estimated to be one hour, for a total of 2,500 hours.

Rule 34b–1 under the 1940 Act deems to be materially misleading any investment company sales literature filed with the Commission which includes therein any information that purports to show the investment performance of the fund unless it also includes performance data calculated in a manner prescribed by Rule 482 under

the 1933 Act. This requirement is intended to permit the Commission staff to review this sales literature for compliance with the antifraud provisions of the federal securities laws. The rule imposes an annual reporting burden of 3,444 hours on about 287 respondents, each with approximately five responses, for a total of about 1,435 responses. The Commission anticipates that the amendments to rule 34b–1 will not change the burdensomeness of the rule.

The estimated average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the cost of Commission rules and forms.

Direct general comments to Gary Waxman at the address below. Direct any comments concerning the accuracy of the estimated average burden hours for compliance with Commission rules and forms to John J. Lane, Associate Executive Director, 450 Fifth Street NW., Washington, DC 20549–6004, and Gary Waxman, Clearance Officer, Office of Management and Budget, Paperwork Reduction Project (3235–0307 for Form N–1A, 3235–0336 for Form N–14, and 3235–0346 for rule 34b–1), room 3208, NEOB, Washington, DC 20543.

Dated: April 16, 1993.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9561 Filed 4–22–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Cincinnati Stock Exchange, Inc.

April 16, 1993.

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:

Nuveen Maryland Premium Income Municipal Fund
Shares of Beneficial Interest, $.01 Par Value (File No. 7–10553)
Nuveen Massachusetts Premium Income Municipal Fund
Shares of Beneficial Interest, $.01 Par Value (File No. 7–10554)
Nuveen New Jersey Premium Income Municipal Fund 2
Shares of Beneficial Interest, $.01 Par Value (File No. 7–10555)
Nuveen Pennsylvania Premium Income Municipal Fund 2
Shares of Beneficial Interest, $.01 Par Value (File No. 7–10556)
Nuveen Virginia Premium Income Municipal Fund
Shares of Beneficial Interest, $.01 Par Value (File No. 7–10557)
Oneita Industries, Inc.
Common Stock, $.25 Par Value (File No. 7–10558)
Paragon Trade Brands, Inc.
Common Stock, $.01 Par Value (File No. 7–10559)
Parker & Parsley Petroleum Co.
Common Stock, $.01 Par Value (File No. 7–10560)
PEC Israel Economic Corp.
Common Stock, $1.00 Par Value (File No. 7–10561)
Piccadilly Cafeterias, Inc.
Common Stock, No Par Value (File No. 7–10562)
Pillowtex Corp.
Common Stock, $.01 Par Value (File No. 7–10563)
Preferred Income Management Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–10564)
Rhone-Poulenc S.A.
American Depositary Shares (Rep. ¼ Sh. of an Ord. Sh. A) (File No. 7–10565)
Salomon Brothers High Income Fund, Inc.
Common Stock, $.001 Par Value (File No. 7–10566)
St. John Knits, Inc.
Common Stock, No Par Value (File No. 7–10567)
Storage Equities, Inc.
Cum. Pfd. Ser. B, $.01 Par Value (File No. 7–10568)
Sunamerica, Inc.
$2.78 Depositary Shares (rep. 1/50 Sh. Ser. D Mand. Conv. Prem. Div. Pfd. Stk.) (File No. 7–10569)
Tejas Gas Corp.
Depositary Shares (rep. 1/10 Sh. 9.96% Cum. Pfd. Stk., $1.00 Par Value (File No. 7–10570)
United American Healthcare Corp.
Common Stock, No Par Value (File No. 7–10571)
Van Kampen Merritt Strategic Sector Municipal Trust
Comm. Shares of Beneficial Interest (rep. 1/10 Sh. 8½% Cum. Pfd. Stk. Ser. N) (File No. 7–10572)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before May 7, 1993, written data, views and arguments concerning the above-referenced applications. 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 applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are 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. 93–9475 Filed 4–22–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Inc.

April 16, 1993.

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:

General Growth Properties
Common Stock, $.10 Par Value (File No. 7–10551)
Starter Corporation
Common Stock, $.01 Par Value (File No. 7–10552)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before May 7, 1993, 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. 93–9476 Filed 4–22–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35-25797]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

April 16, 1993.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by May 10, 1993, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Texas Utilities Company (70-8072)

Texas Utilities Company ("Texas Utilities"), 2001 Bryan Tower, Dallas, Texas 75201, a Texas corporation and public-utility holding company exempt from registration by order pursuant to section 3(a)(1) of the Act, has filed an application under sections 3(a)(1), 9(a)(2) and 10 of the Act. Texas Utilities proposes to acquire all of the issued and outstanding common shares of Southwestern Electric Service Company ("SESCO"), a Texas electric utility company, subject to SESCO's shareholder approval at a meeting to be held on April 29, 1993. The acquisition will be accomplished by an Agreement and Plan of Merger ("Merger Agreement") dated as of January 23, 1993, between Texas Utilities, TUA, Inc. ("Acquisition Sub"), a Texas wholly owned subsidiary of Texas Utilities created for the purpose of engaging in the merger, and SESCO.

TU Electric, Texas Utilities' principal subsidiary, is engaged in the generation, purchase, transmission, distribution, and sale of electric energy in the north central, eastern, and western portions of Texas, with a population estimated at 5.5 million. TU Electric provides electric service in 91 counties and 372 municipalities in Texas, including Dallas, Fort Worth, Arlington, Irving, Plano, Waco, Mesquite, Grand Prairie, Wichita Falls, Odessa, Midland, Carrollton, Tyler, Richardson, and Killeen. At September 30, 1992, Texas utilities reported total consolidated assets of $19.2 billion, and for the twelve month period ending September 30, 1992, Texas Utilities reported operating revenues of approximately $4.9 billion and consolidated net income of approximately $699 million. As of December 31, 1992, Texas Utilities had 217,316,054 shares outstanding of common stock, no par value.

SESCO is engaged in the purchase, transmission, distribution, and sale of electricity wholly within Texas. SESCO's service area is essentially surrounded by that of TU Electric, and consists of 40 towns and communities located in ten counties in central and east Texas. SESCO provides electric service to approximately 40,000 industrial, commercial, and retail customers. SESCO owns no electric generating facilities, and currently receives 100% of its power and energy from TU Electric.

At September 30, 1992, SESCO had total assets of approximately $64 million. For the twelve months ended September 30, 1992, SESCO reported revenues of $68.2 million and net income available for common stock of $3.2 million. As of December 31, 1992, SESCO had outstanding capital stock consisting of 660,296 shares of common stock, $1 par value. SESCO redeemed its preferred stock on February 26, 1993.

As of the Effective Time, as defined, SESCO will be merged into the Acquisition Sub, the separate existence of Acquisition Sub will cease, and SESCO will be the surviving corporation as a new wholly-owned subsidiary of Texas Utilities. The Merger Agreement provides that each common shareholder of SESCO (other than persons who have perfected their dissenter's rights in the manner provided under the Texas Business Corporation Act ("TBCA"), will have the right to elect to receive, in exchange for each share of SESCO common stock, either $93.00 cash or 2.2 shares of Texas Utilities common stock, subject to certain conditions. Texas Utilities states that no fractional shares of its stock will be issued in the merger.

The Merger Agreement limits the aggregated amount of cash payable in connection with the merger (including amounts paid to dissenting shareholders or in lieu of fractional shares) to no more than 20% of the consideration for the merger (or such lower percentage as may be required to ensure the tax-free treatment of the merger). Such cash consideration will be prorated among the holders of SESCO common stock unconditionally electing to receive cash if, in the aggregate, the shares with respect to which such elections are made, multiplied by $93.00, exceed the available cash consideration less offsets for the value of fractional shares and shares for which holders have perfected their dissenter's rights under the TBCA. It is intended that the merger qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, and Texas Utilities states that the transaction is expected to be tax-free to holders of SESCO common stock to the extent they elect to receive Texas Utilities' common stock.

Texas Utilities also seeks an order of exemption under section 3(a)(1) from all provisions of the Act, except section 9(a)(2), following the proposed transactions. Texas Utilities states that it and each of its public-utility subsidiaries will be predominantly intrastate in character and will carry on their business substantially in Texas, the state in which each is incorporated.

Eastern Utilities Associates, et al. (70-8161)

Eastern Utilities Associates, ("EUA"), a registered holding company, and its wholly owned nonutility subsidiary company, EUA Cogenex Corporation ("Cogenex") (collectively, "Applicants"), both located at P.O. Box 2333, Boston, Massachusetts 02107, have filed an application-declaration under Sections 6(a) 7, 9(a), 10, and 12(b) of the Act and Rules 43, 45, and 50(a)(5) thereunder.

By order dated October 24, 1991 (HCAR No. 25396), the Commission authorized Applicants to finance Cogenex's business in an amount, in addition to Cogenex's approximately $94.4 million permanent capitalization as of December 31, 1992 not to exceed $100 million from the following sources: (1) up to an aggregate of $50 million from EUA in any combination of short-term borrowings, capital contributions, or proceeds from sales of common stock to EUA; (2) up to $35 million from the issuance and sale of additional long-term unsecured notes; and (3) up to $50 million of short-term borrowings under the EUA system credit lines. This financing authorization expires on December 31, 1993.

For the period ending December 31, 1995, Applicants propose the following. Cogenex requests authorization to undertake various financing transactions in an amount not to exceed $100 million from one or any combination of the sources listed below: (1) Up to an aggregate of $50 million from EUA in an any combination of capital contributions or short term borrowings ("EUA Investments"); (2) up to $50 million from the issuance and sale of additional long-term unsecured notes ("New Notes"); and (3) up to $50 million of short-term borrowings under the EUA system credit lines. EUA proposes to (1) make investments in Cogenex, in addition to its existing investments in Cogenex, in an aggregate amount up to $50 million in one or any combination of EUA Investments; (2) borrow up to $25 million under the EUA system credit lines; and (3) continue to guarantee Cogenex's borrowings under the EUA system credit lines. Should it become necessary in order to obtain more favorable financing for the New Notes, EUA also proposes to guarantee, or to provide an equity maintenance agreement for, all or a portion of the obligations of Cogenex regarding the New Notes.

The borrowings authorized for EUA and Cogenex under EUA's existing credit lines will be evidenced by notes which may be issued and renewed during the period ending December 31, 1995. Such notes will mature in not more than one year from their respective dates of issuance, and the principal amount of notes authorized and outstanding at any one time outstanding will not exceed $25 million for EUA and $50 million for Cogenex. The existing credit line arrangements, which expire on June 30, 1993, include borrowing at the prime rate or money market rate, together with a commitment fee equal to ¼ of 1% multiplied by the credit line, if applicable. Notes bearing interest at the prime rate will be prepayable at any time without premium. Notes bearing interest at available money market rates, will not be prepayable.

Cogenex will use the net proceeds from the financing transactions listed above for one or any combination of the following—to pay, reduce, or renew short-term borrowings from banks or short-term loans from EUA and for working capital and general corporate purposes, including construction expenditures for plant and equipment. Cogenex states that the proceeds or any part thereof of the New Notes may be temporarily invested in securities meeting the requirements of section 9(c)(i) of the Act or of Rules 40(a)(1) or 40(a)(2) thereunder.

Cogenex requests that the Commission, pursuant to paragraph (a)(5) of Rule 50, grant an exception from that Rule with respect to the New Notes, so that it may carry out the negotiation of the terms of the New Notes itself, with one or more institutional investors, or to engage a placement agent, for a fee, to negotiate the terms of and place the New Notes with institutional purchasers. It may do so.

Arkansas Power & Light Company (70–8171)

Arkansas Power & Light Company ("AP&L"), 425 West Capitol, 40th Floor, Little Rock, Arkansas 72201, an electric utility subsidiary company of Entergy Corporation, a registered holding company, has filed a declaration under Sections 6(a) and 7 of the Act and Rule 50(a)(5) thereunder.

By orders dated May 25, 1983 and June 6, 1983 (HCAR Nos. 22952 and 22966, respectively), AP&L was authorized to participate in arrangements for the issuance of $45 million aggregate principal amount of Independence County, Arkansas ("County") 11⅛% Pollution Control Revenue Bonds, 1983 Series ("1983 Bonds"). The 1983 Bonds were issued for the purpose of reimbursing AP&L for the cost of, or financing, and refinancing the cost of, on a tax-exempt basis, the acquisition, construction, installation and equipping of certain sewage disposal and/or pollution control facilities ("Facilities") at AP&L's Independence Steam Electric Generating Station ("Station") in the County.

AP&L now proposes to refinance the 1983 Bonds by entering into a loan agreement ("Agreement") with the County so that the County will issue, at one time or from time to time through December 31, 1994, up to $45 million aggregate principal amount of one or more new series of tax-exempt revenue bonds ("Tax-Exempt Bonds") pursuant to one or more trust indentures ("Indenture") between the County and one or more trustees ("Trustee"). In addition, AP&L proposes to guarantee payment on the Tax-Exempt Bonds by: (1) Entering into a Letter of Credit and Reimbursement Agreement for the issuance of a letter of credit; (2) providing an insurance policy on the Tax-Exempt Bonds; and/or (3) issuing collateral bonds.

Under the Agreement, the County would loan the proceeds from the sale of the Tax-Exempt Bonds (which are not expected to exceed $45 million) to AP&L, and AP&L would use the proceeds of the loan, net of any underwriters discounts or other expenses, to redeem prior to maturity the 1983 Bonds. AP&L will repay the loan in installments sufficient to pay the principal or purchase price of, the premium, if any, and the interest on the Tax-Exempt Bonds as the same became due and payable. The term of the Agreement will coincide with the maturity of the Tax-Exempt Bonds, which will mature not less than five years nor later than 40 years from the first day of the month in which they are initially issued. Under the Agreement, AP&L will be obligated to pay: (1) The fees and charges of the Trustee and any registrar or paying agent under the Indenture and, if any, the remarketing agent and the tender agent; (2) all expenses incurred by the County in connection with its rights and obligations under the Agreement; (3) all expenses necessarily incurred by the County or the Trustee under the Indenture in connection with the transfer or exchange of Tax-Exempt Bonds; and (4) certain other miscellaneous fees and expenses, as specified in the Agreement. The Indenture may provide for redemption of the Tax-Exempt Bonds upon the occurrence of certain events and/or pursuant to a mandatory sinking fund or other mandatory redemption provisions and, in such cases, AP&L's loan repayments under the Agreement would be sufficient to meet these obligations.

The Tax-Exempt Bonds will be subject to optional redemption, at the direction of the AP&L, in whole or in part at the redemption prices (expressed as percentages of principal amount) and at the times, set forth in the Indenture, plus accrued interest to the redemption date. In the event that maturity of the Tax-Exempt Bonds is accelerated because of the occurrence of certain events, as described in the Indenture, AP&L's payments under the Agreement shall be sufficient to pay the principal of, and the premium, if any, and interest on, such Tax-Exempt Bonds when due. AP&L would most likely meet such requirements through the issuance of other debt such as first mortgage bonds, but could in the alternative use cash on hand, internally generated funds, short-term borrowings and/or funds from the issuance of such other securities as may be appropriate and as may be approved by the appropriate regulatory authorities.

The Agreement and the Indenture may provide for a fixed interest rate and/or for an adjustable interest rate for the Tax-Exempt Bonds. If the Tax-Exempt Bonds have an adjustable interest rate, the interest rate during the first rate period would be determined by negotiation between AP&L and the

purchasers. Thereafter, for each rate period, the interest rate on such Tax-Exempt Bonds would be that rate (subject to a specified maximum rate) which will be sufficient to remarket the Tax-Exempt Bonds at their principal amount.

If the Tax-Exempt Bonds bear an adjustable interest rate, the Agreement and the Indenture would provide that holders of Tax-Exempt Bonds would have the right to tender or be required to tender their Tax-Exempt Bonds and have them purchased at a price equal to the principal amount thereof, plus any accrued and unpaid interest thereon, on dates specified in, or established in accordance with, the Indenture. Under the Agreement, AP&L would be obligated to pay amounts equal to the amounts to be paid by the remarketing agent or the tender agent pursuant to the Indenture for the purchase of Tax-Exempt Bonds so tendered, less any other monies available for that purpose, including the proceeds of the sale of such tendered Tax-Exempt Bonds by the remarketing agent.

In order to guarantee payment on the Tax-Exempt Bonds, obtain a more favorable rating thereon and, thus, improve their marketability, AP&L may arrange for the issuance of an irrevocable letter of credit for an amount of up to $51.75 million from a bank ("Bank") in favor of the Trustee. In such event, payments with respect to principal, premium, if any, interest and purchase obligations in connection with the Tax-Exempt Bonds coming due during the term of such letter of credit would be secured by, and payable from funds drawn under, the letter of credit. In order to induce the Bank to issue such letter of credit, AP&L would enter into a Letter of Credit and Reimbursement Agreement ("Reimbursement Agreement") with the Bank pursuant to which AP&L would agree to reimburse the Bank for all amounts drawn under such letter of credit within a specified period after the date of the draw and with interest thereon.

It is anticipated that the Reimbursement Agreement would require the payment by AP&L to the Bank of annual letter of credit fees and perhaps an up-front fee. Any such letter of credit may expire or be terminated prior to the maturity date of the Tax-Exempt Bonds and, in connection with such expiration or termination, the Tax-Exempt Bonds may be made subject to mandatory redemption or purchase on or prior to the date of expiration or termination of such letter of credit, possibly subject to the right of owners of Tax-Exempt Bonds not to have their Tax-Exempt bonds redeemed or purchased. Provision may be made for extension of the term of such letter of credit or for the replacement thereof, upon its expiration or termination, by another letter of credit from the bank or a different bank.

In addition or as an alternative to the security provided by a letter of credit, AP&L proposes to: (1) Provide an insurance policy in an amount not to exceed $45 million for the payment of the principal of and/or interest and/or premium on the Tax-Exempt Bonds; and/or (2) provide security for holders of Tax-Exempt Bonds and/or the Bank equivalent to the security afforded to holders of First Mortgage Bonds outstanding under AP&L's Mortgage by obtaining the authentication of and pledging a new series of First Mortgage Bonds ("Collateral Bonds") under the Mortgage as it may be supplemented.

Collateral Bonds would be delivered to the Trustee under the Indenture and/or the Bank to evidence and secure AP&L's obligation to repay the loan made by the County under the Agreement and AP&L's obligation to reimburse the Bank under the Reimbursement Agreement.

The Collateral Bonds could be issued in several ways. First, if the Tax-Exempt Bonds bear a fixed-interest rate, Collateral Bonds could be issued in a principal amount equal to the principal amount of such Tax Exempt Bonds and bear interest at a rate equal to the rate of interest on such Tax-Exempt Bonds. Second, the Collateral Bonds could be issued in a principal amount equivalent to the principal amount of such Tax-Exempt Bonds plus an amount equal to interest on those Bonds for a specified period. In such a case, Collateral Bonds would bear no interest. Third, Collateral Bonds could be issued in a principal amount equivalent to the principal amount of such Tax-Exempt Bonds or in such amount plus an amount equal to interest on those Bonds for a specified period, but carry a fixed interest rate that would be lower than the fixed interest rate of the Tax-Exempt Bonds. Fourth, Collateral Bonds could be issued in a principal amount equivalent to the principal amount of Tax-Exempt Bonds at an adjustable rate of interest, varying with such Tax-Exempt Bonds but having a cap above which the interest on Collateral Bonds could not raise.

The terms of the Collateral Bonds relating to maturity, interest payment dates, if any, redemption provisions and acceleration will correspond to the terms of the Tax-Exempt Bonds. Upon issuance, the terms of the Collateral Bonds will not vary during the life of such series except for the interest rate in the event the Collateral Bonds bear interest at an adjustab'e rate.

It is contemplated that the Tax-Exempt Bonds may be sold by the County pursuant to arrangements with an underwriter or a group of underwriters or by private placement in a negotiated sale or sales. AP&L will not be party to the underwriting or placement arrangements; however, the Agreement will provide that the terms of the Tax-Exempt Bonds, and their sale by the County, shall be satisfactory to AP&L.

AP&L states that it shall not use the proceeds from the Agreement to enter into refinancing transactions unless. (1) The estimated present value savings derived from the net difference between interest or dividend payments on a new issue of comparable securities and those securities refunded is, on an after tax basis, greater than the present value of all repurchasing, redemption, tendering and issuing costs, assuming an appropriate discount rate, determined on the basis of the then estimated after=tax cost of capital of Entergy and its subsidiaries, consolidated; or (2) AP&L shall have notified the Commission of the proposed refinancing transaction (including the terms thereof) by post-effective amendment hereto and obtained the appropriate supplemental authorization.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9477 Filed 4–22–93; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

PCF Venture Capital Corp. (License #09–09–0313); License Surrender

Notice is hereby given that PCF Venture Capital Corporation ("PCF"), a California corporation, has surrendered its license to operate as a small business investment company under the Small Business Investment Act of 1958, as amended ("the Act"). PCF was licensed by the Small Business Administration on May 4, 1983.

Under the authority vested by the Act and pursuant to the regulations promulgated thereunder, the surrender of the license was accepted on February 15, 1993, and accordingly, all rights, privileges, and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 19, 1993.

Wayne S. Foren,

Associate Administrator for Investment.

[FR Doc. 93–9459 Filed 4–22–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended April 16, 1993

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: 48748.
Date filed: April 12, 1993.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: May 10, 1993.
Description: Application of Sitra Cargo System S.A., pursuant to section 402 of the Act and Subpart Q of the Regulations applies for a foreign air carrier permit authorizing it to engage in scheduled foreign air transportation of property and mail between Lima, Peru and Miami, Florida.

Docket Number: 48754.
Date filed: April 15, 1993.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 30, 1993.
Description: Application of Delta Air Lines, Inc., pursuant to section 401 of the Act and Subpart Q of the Regulations applies for a new or amended certificate of public convenience and necessity to permit Delta to provide foreign air transportation between New York, New York and London, England (including Heathrow Airport).

Docket Number: 48755.
Date filed: April 16, 1993.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: May 14, 1993.
Description: Application of Continental Airlines, Inc., pursuant to section 401 of the Act and Subpart Q of the Regulations, applies for a certificate of public convenience and necessity to authorize Continental to provide scheduled foreign air transportation of persons, property and mail between Cleveland, Ohio, and London, England. Continental also requests the right to combine service as the points on this route segment with service at other points Continental is authorized to serve by certificates or exemptions, consistent with applicable international agreements.

Docket Number: 48756.
Date filed: April 16, 1993.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: May 14, 1993.
Description: Application of Continental Airlines, Inc., pursuant to section 401 of the Act and Subpart Q of the Regulations, applies for a certificate of public convenience and necessity to authorize Continental to provide scheduled foreign air transportation of persons, property and mail between Newark, New Jersey, and Manchester, and England. Continental also requests the right to combine service as the points on this route segment with service at other points Continental is authorized to serve by certificates or exemptions, consistent with applicable international agreements.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 93–9537 Filed 4–22–93; 8:45 am]

BILLING CODE 4910–62–M

Federal Aviation Administration

[Summary Notice No. PE–93–18]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before May 10, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule docket (AGC–10), Petition Docket No. _____, 800 Independent Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Mr. Frederick M. Haynes, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3939.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, April 16, 1993.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 26176
Petitioner: AMR Combs
Sections of the FAR Affected: 14 CFR 135.165(a)(1) and (a)(6), and (b)(1), (b)(6), and (b)(7)
Description of Relief Sought: To extend the termination date of Exemption No. 5334 to allow AMR Combs to operate certain airplanes equipped with one high-frequency communications system in extended overwater operations.

Docket No.: 27187
Petitioner: Cessna Aircraft Co.
Sections of the FAR Affected: 14 CFR 21.325(b)(1) and (3)
Description of Relief Sought: To allow Cessna Aircraft Co. to issue export approvals using the Delegation Option Authorization CE–1 and CE–3 for Class I, II, and III products located outside the United States.

Docket No.: 27207
Petitioner: Universal West Indies, S.A.R.L.
Sections of the FAR Affected: 14 CFR 91.9

Description of Relief Sought: To allow Universal West Indies, to operate its own DC–6A cargo airplane, N4163Q, at increased zero fuel and landing weights.

Dispositions of Petitions

Docket No.: 25091
Petitioner: Allied-Signal Aerospace Company
Sections of the FAR Affected: 14 CFR 21.325(b)(1) and (3)
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 4830, which allows export airworthiness approvals to be issued for Class I, II, and III products under Production Certificate No. 413, at Rolls-Royce Limited in East Kilbride, Scotland. *Grant, April 8, 1993, Exemption No. 4830C*

Docket No.: 25126
Petitioner: Executive Air Fleet, Inc.
Sections of the FAR Affected: 14 CFR 91.191(a)(4), 135.165(a)(1), 135.165(a)(5), 135.165(a)(6), 135.165(b)(5), 135.165(b)(6), 135.165(b)(7)
Description of Relief Sought/ Disposition: To extend the termination date of exemption No. 4821, which allows Executive Air Fleet and certain corporations and individuals contracting with Executive Air Fleet for management services to operate airplanes in extended overwater operations that are equipped with only one operational long-rang navigation system (LRNS), and one operational high-frequency (HF) communication system. *Grant, April 9, 1993, Exemption No. 4821C*

Docket No.: 25630
Petitioner: Director of Transportation of the State of Hawaii
Sections of the FAR Affected: 14 CFR 45.29(h)
Description of Relief Sought/ Disposition: To allow persons operating within the state of Hawaii to operate their aircraft without displaying 12-inch nationality and registration marks when penetrating the inner boundary of the Hawaiian Coastal Air Defense Identification Zone (ADIZ). *Grant, April 8, 1993, Exemption No. 5632*

Docket No.: 25716
Petitioner: Flamenco Airways, Inc.
Sections of the FAR Affected: 14 CFR 43.3(g)
Description of Relief Sought/ Disposition: To allow the pilots employed by Flamenco to remove and reinstall aircraft cabin seats and to install an FAA-approved stretcher in Britian Norman, Model BN2A, aircraft operated by Flamenco. *Grant, April 7, 1993, Exemption No. 5631*

Docket No.: 25983
Petitioner: Federal Express Corporation
Sections of the FAR Affected: 14 CFR 121.613 and 121.625
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 5392, which relieves Federal Express to the extent that those sections are interpreted to hold that weather reports or forecasts, or any combination thereof, contain conditional statements that the weather may be below authorized minimums at the estimated time of arrival at the primary or alternate airport and do not satisfy the appropriate dispatch requirements of those sections. *Grant, April 7, 1993, Exemption No. 5392A*

Docket No.: 26832
Petitioner: Phoenix Air Group, Inc.
Sections of the FAR Affected: 14 CFR 135.267
Description of Relief Sought: To allow a properly certified Phoenix flight crew, consisting of two pilots, to exceed 10 hours of flight time and 14 hours of duty time during 24 consecutive hours under certain conditions and limitations. *Denial, April 9, 1993, Exemption No. 5634*

Docket No.: 26977
Petitioner: Ms. Laura K. Beck
Sections of the FAR Affected: 14 CFR 61.65 (f) and (g), 61.123 (d) and (e)
Description of Relief Sought: To allow her to receive a commercial rotorcraft-helicopter pilot certificate and instrument-helicopter rating in lieu of the written and flight testing requirements, even though Ms. Beck is not a rated military pilot or former military pilot who has been on active flying status within the previous 12 months. *Denial, April 9, 1993, Exemption No. 5635*

Docket No.: 26978
Petitioner: Mr. Kenneth S. Burchell
Sections of the FAR Affected: 14 CFR 61.65 (f) and (g), 61.123 (d) and (e)
Description of Relief Sought: To allow Mr. Burchell to receive a commercial rotorcraft-helicopter pilot certificate and instrument-helicopter rating in lieu of the written and flight testing requirements, even though Mr. Burchell is not a rated military pilot or former military pilot who has been on active flying status within the previous 12 months. *Denial, April 9, 1993, Exemption No. 5636*

Docket No.: 27032
Petitioner: Horizon Air
Sections of the FAR Affected: 14 CFR 121.358
Description of Relief Sought: To allow Horizon Air to operate three Fokker F–28 Mark 1000 (F–28–1000) aircraft that are not equipped with approved low-altitude windshear system equipment, or in the alternative would permit Horizon Air to operate aircraft until December 31, 1995, in order to install predictive windshear radar, which is being evaluated but which is not yet approved. *Denial, April 7, 1993, Exemption No. 5633*

Docket No.: 27120
Petitioner: Flight Training International, Inc.
Sections of the FAR Affected: 14 CFR 61.55(b)(2), 61.56(b)(1), 61.57 (C) and (D), 61.58(C) (1) and (d), 61.63(c)(2) and (d)(2) and (3), 61.67(d)(2), 61.157(d)(1) and (2), and appendix A or part 62.
Description of Relief Sought: To allow Flight Training International, Inc. to use FAA-approved simulators to meet certain training and testing requirements of part 61 of the FAR. *Grant, April 9, 1993, Exemption No. 5629*

[FR Doc. 93–9556 Filed 4–22–93; 8:45 am]
BILLING CODE 4910–13–M

[Summary Notice No. PE–93–19]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before May 10, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the

Chief Counsel, Attn: Rule Docket (AGC-10), Petition Docket No. _____, 800 Independence Avenue SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3132.

FOR FURTHER INFORMATION CONTACT: Mrs. Jeanne Trapani, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-7624.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on April 14, 1993.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 21882.
Petitioner: China Airlines Limited.
Sections of the FAR Affected: 14 CFR 61.77 and 63.23.
Description of Relief Sought: To extend the termination date of Exemption No. 4849, which allows China Airlines Limited's airmen, who operate two U.S.-registered Boeing 747-SP Aircraft N4508H and N4522V, to receive special purpose pilot and flight engineer airmen certificates, without meeting the requirement to hold a current certificate or license issued by a foreign contracting State to the Convention on International Civil Aviation.

Docket No.: 23980.
Petitioner: United States Hang Gliding Assn., Inc.
Sections of the FAR Affected: 14 CFR 91.309 and 103.1.
Description of Relief Sought: To amend Exemption No. 4144 to allow an increase of the weight limit for single-place, powered ultralight vehicles to 360 pounds, empty weight, and to allow an increase of the weight limit for two-place, powered ultralight vehicles to 496 pounds, empty weight, for ultralight vehicles that are used for aero-towing purposes.

Docket No.: 26176.
Petitioner: AMR Combs.
Sections of the FAR Affected: 14 CFR 135.165(a)(6), (b)(1), (b)(6), and (b)(7).
Description of Relief Sought: To extend the termination date of Exemption No. 5334 to allow AMR Combs to operate certain airplanes equipped with one high-frequency communications system in extended overwater operations.

Docket No.: 26811.
Petitioner: National Avionics.
Sections of the FAR Affected: 14 CFR 145.47(b).
Description of Relief Sought: To allow National Avionics to share the use of another repair station's airframe technical data to maintain the limited airframe privileges of National Avionics.

Docket No.: 27124.
Petitioner: Vertiflite Air Services, Inc.
Sections of the FAR Affected: 14 CFR 141.35(d).
Description of Relief Sought: To allow Vertiflite Air Services, Inc.'s Chief Flight Instructor, Mr. James Craig Folger, to teach an approved commercial helicopter course to the public although he does not meet the flight time requirements in § 141.35(d).

Dispositions of Petitions

Docket No.: 25552.
Petitioner: State of Alaska.
Sections of the FAR Affected: 14 CFR 45.29(h).
Description of Relief Sought/ Disposition: To allow persons operating aircraft within, to, or from the State of Alaska to fly their aircraft across the inner boundaries of the Alaskan Air Defense Identification Zone without displaying temporary or permanent registration marks at least 12-inches high. *Partial Grant, April 2, 1993, Exemption No. 5630.*

Docket No.: 26412.
Petitioner: The Soaring Society of America, Inc.
Sections of the FAR Affected: 14 CFR 61.118.
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 5303 to allow the Soaring Society of America, Inc., to permit private pilots to log the flight time accumulated while towing gliders for its chapter members. *Grant, April 1, 1993, Exemption No. 5303A.*

Docket No.: 27188.
Petitioner: Knighthawk Air Express Ltd.
Sections of the FAR Affected: 14 CFR 61.77(a).
Description of Relief Sought/ Disposition: To allow the petitioner's pilots to be issued special purpose pilot certificates to perform pilot duties on a civil airplane of U.S. registry, a Falcon 20D, Registration No. N950RA, without that airplane meeting the passenger seating configuration and payload capacity requirements. *Grant, March 1, 1993, Exemption No. 5608.*

Docket No.: 27196.
Petitioner: Tower Air, Inc.
Sections of the FAR Affected: 14 CFR 121.434(e).
Description of Relief Sought/ Disposition: To allow Tower Air, Inc., on certain flights, to use flight attendants who have not completed operating experience under part 121 of the FAR. *Grant, March 30, 1993, Exemption No. 5628.*

[FR Doc. 93-9535 Filed 4-22-93; 8:45 am]
BILLING CODE 4910-13-M

Airway Science Grant Proposals; Solicitation

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Solicitation for Airway Science Grant Proposals.

SUMMARY: This Notice cancels the Notice of Solicitation for Airway Science (AWS) Grant Proposals, 57 FR 9586, March 19, 1992, and re-announces the availability of competitive grant funding under the Federal Aviation Administration (FAA) Airway Science Grant Program. The FAA is authorized by Public Laws 101-516 and 102-143 to solicit competitive proposals for AWS grants from accredited public or nonprofit private colleges and universities with recognized FAA AWS Curriculum programs. FAA previously announced in the **Federal Register** the availability of $5,036,834 in AWS grant funding with the Federal share of any grant project not to exceed 50 percent of the cost of the project. Public Law 101-516 provided $1,275,834 of the total available funds and established the maximum Federal share at 50 percent. Public Law 102-143 provided the remaining $3,761,000 in grant funding also with a maximum Federal share of 50 percent. However, Public Law 102-388 revised the Federal share of projects funded under the AWS Grant Program to a maximum of 65 percent. The law further stated that such Federal share shall be considered as having taken effect on October 1, 1991. As a result, this Notice states (1) the maximum Federal share of projects totalling $1,275,834 funded under Public Law 101-516 shall not exceed 50 percent and, (2) the maximum Federal share of projects funded with the remaining available $3,761,000 provided under Public Law 102-143 shall not exceed 65 percent.

The FAA expects to award most, if not all, of an available $5,036,834 in the

form of grants, to a select member of recognized AWS institutions. A portion of the available funds will be awarded to eligible minority institutions with recognized AWS curricula. Awards will range up to a maximum of $300,000.

The grant funds may be used for the purchase, lease with intent to purchase, or construction of academic buildings and associated facilities to be used in direct support of an FAA recognized AWS curriculum. In addition, grant funds may be used for nonexpendable instructional materials or instructional equipment to be used in the actual teaching of the AWS curriculum. No Federal grant funds shall be used for salaries, operating expenses, research and development, travel, construction fees, indirect costs, office supplies or other expendable items, automobiles, aircraft, maintenance agreements, printing costs, promotional and marketing materials or equipment, general purpose parking lots, land, commercial airport facilities, taxiways, runways, or any project in support of a commercial activity.

Priority consideration will be given to grant applications submitted by institutions which have not received noncompetitive grant awards under the AWS Grant Program since Fiscal Year 1991 and to applications requesting funds in support of receive sites under the AWS Network.

FOR FURTHER INFORMATION CONTACT: Virginia Hancock Krohn, Manager, Airway Science Grant Program, Federal Aviation Administration, Office of Training and Higher Education, AHT–30, room PL–100, 400 7th St. SW., Washington, DC 20590, Telephone: (202) 366–7003.

CLOSING DATE: Six identical copies of the Proposal must be received by the FAA no later than July 16, 1993 (4 p.m. e.d.t.). One copy of the proposal must contain original signatures on the cover sheet. Applications received after the closing date and time will not be accepted.

Proposals Submitted by Mail: A mailed proposal must be sent to the address listed above. Applicants are strongly encouraged to use registered or first class mail. Any grant application received after 4 p.m. e.d.t. on the closing date will be treated as a late application and will not be considered for a grant award.

Proposals Submitted By Messengers: A hand delivered proposal must be taken to the FAA at the address listed above. The office of the AWS Grant Program Manager will accept hand delivered proposals between the hours of 8 a.m. and 4 p.m. e.d.t., except weekends and Federal Holidays. A hand delivered proposal will not be accepted after 4 p.m. e.d.t., on the closing date.

Each institution will be notified when its application is received. No supplemental materials received after 4 p.m. e.d.t., on the application deadline date will be considered unless such material is requested by the FAA.

Background

The FAA is engaged in a comprehensive program to modernize the Nation's airway system to meet the challenge of aviation growth in the coming decades. The modernization program takes advantage of current technological advances to increase the capacity of the Nation's airway system while reducing relative costs to the Nation's taxpayers.

The FAA recognizes the increasing complexity of technical and managerial skills that will be needed to accommodate the technological advances in equipment, systems, and configurations being planned and implemented throughout the aviation industry. The FAA sponsors the AWS curriculum to assure that future aviation work force needs are adequately met.

In 1982, the FAA, in collaboration with the University Aviation Association, developed and recommended a specific college-level AWS curriculum. The AWS curriculum was designed (1) to satisfy academic and accreditation requirements, (2) to easily adapt to existing aviation-related programs, and (3) to allow individual educational institutions the option of offering any of five areas of concentration.

The five areas of concentration of the AWS curriculum are: (1) Airway science management, (2) airway computer science, (3) aircraft systems management, (4) airway electronic systems, and (5) aviation maintenance management.

The FAA currently recognizes 53 institutions which offer approved AWS curricula. The AWS curriculum directly supports the human resource needs of both the FAA and the aviation industry by producing graduates with the necessary knowledge and skills to pursue aviation-related technical careers in the public and private sectors. Interested institutions which do not already offer recognized AWS curricula, may contact the FAA for further information.

References

For further background information, refer to the following **Federal Register** Notices: 48 FR 116872, March 18, 1983 (FAA proposed AWS curriculum demonstration project plan), 48 FR 32490, July 15, 1983 (Office of Personnel Management approval of the FAA demonstration final plan), 49 FR 22903, June 1, 1984, 50 FR 37612, September 16, 1985, 52 FR 3195, February 2, 1987, 54 FR 8617, March 1, 1989, and 56 FR 22504, May 15, 1991 (notices announcing the competitive criteria employed by the FAA in selecting AWS grant recipients under previous solicitations).

The Airway Science Grant

Authority

This solicitation represents a continuation of the FAA's AWS Grant Program. This program funds projects at selected institutions of higher education which have evidenced a commitment to the agency's AWS curriculum program. The grants are authorized by Public Laws 101–516, 102–143, and 102–388 with a total amount of $5,036,834 available for competitive grant awards. The funds may be used for allowable direct costs in the following categories, to the extent that such items are in direct support of aviation and/or computer courses in the required core or area of concentration of an institution's recognized AWS curriculum option(s): (a) The purchase, lease with intent to purchase, or construction of academic buildings and associated facilities, and (b) nonexpendable instructional materials and equipment to be used in the actual teaching of the AWS curriculum. Monies are not available for salaries, operating costs, research and development, travel, consultant fees, indirect costs, office supplies or other nonexpendable equipment, automobiles, aircraft, maintenance agreements, printing and marketing materials or equipment, general purpose parking lots, land, commercial airport facilities, taxiways, runways, or any project in support of commercial activities.

Eligibility

Eligible institutions must be accredited public and non-profit colleges and universities in the United States and its possessions. To be eligible, an applicant institution must have an established FAA-recognized AWS curriculum in place and available to students. The curriculum must have been recognized by the FAA no later than December 31, 1992.

Priority Consideration

Priority consideration will be given to applications submitted by institutions which have not received noncompetitive funding under the

Airway Science Grant Program since Fiscal Year 1991. In addition, in support of FAA's commitment to the development of the Airway Science Network, the FAA will give priority consideration to projects which include the development of distance learning receive sites.

Disqualification

Applications which do not include all the information including forms required by this Notice of Solicitation will be disqualified.

Proposal Format and Content

Each FAA-sponsored, AWS grant project is subject to the provisions of applicable FAA regulations and OMB Circulars A–21, A–73, A–88, A–110, and A–128 or A133. Proposals must contain the following information in the order listed.

1. Cover Sheet

Type the title "Airway Science Grant Proposal" near the top of the Cover Sheet. Type the legal name of the proposed grantee institution, its mailing address, and IRS Employer Identification Number in the center of the Cover Sheet. Type the names, titles, telephone numbers and FAX numbers of the Project Manager and of an official authorized to sign for the institution in the lower left and right corners, respectively, of the Cover Sheet. The Cover Sheet of one copy of the proposal must bear the original signatures of the above individuals and dates of signatures. The signature of the authorized individual signifies institutional endorsement of the proposal, cognizance of the eligibility and limitation requirements, and a commitment to provide the specific support, including fiscal obligations, for the proposed activities in the event of grant award.

2. Application Forms

Submit the standard forms listed below with each grant application. These forms may be obtained by writing to the AWS Grant Program Manager at the address listed above.

(1) Standard Form 424 (Rev. 4–88), Application for Federal Assistance,

(2) FAA/AWS, Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and Drug-Free Workplace Requirements.

3. Table of Contents

Includes a table of contents with page numbers.

4. Project Summary

Include a concise summary of the proposed project. State the goals and objectives and the long-range benefits of the project and the associated costs including cost sharing figures. The summary should not exceed two (2) double-spaced typewritten pages and must be informative to other people in AWS or related fields. The project summary will be sent to persons requesting information on the grant project if it is selected by the FAA to be funded.

5. Narrative

The Narrative should be clearly written and not exceed forty (40) double-spaced typewritten pages in length. The Narrative must contain the following:

(a) Introduction

Present a brief description of the institution, including: Historical background, full time graduate and undergraduate student enrollment, student body profile, location (rural, urban, etc.), fields of emphasis and degrees awarded. This information will be used for information/statistical purposes only.

(b) AWS Background

Describe the evolution of the institution's involvement in the AWS Program. Provide a detailed discussion of the institution's current recognized AWS program. Provide information and statistics on the occupational areas for which AWS students are preparing within the aviation industry and the FAA. Provide the following information in "easy to read" chart format (1) recognized AWS curriculum options, (2) recognition dates by curriculum option, (3) declared and expected majors by AWS option for current and next five academic years by minority, female, others, and total, (4) number of degrees awarded by AWS option for the last five academic years or since the date of recognition whichever is least, (5) number of degrees expected to be awarded by AWS option for the next five years. (The above requested information may be presented in several different charts). Provide a discussion explaining any substantial increases in AWS enrollment over the next five years.

Describe the institution's aviation degree options other than AWS. Provide a chart(s) for the institution's other aviation degree options which contains the same information requested for the AWS Program as explained above.

Describe current and planned institutional activities to recruit AWS students with emphasis on minority and female recruitment activities, to meet the projected five year enrollment projects. Include annual AWS recruitment expenditures.

Include an institutional organizational chart to show how the AWS Program fits into the institutional structure.

Submit one copy of an official course catalog and/or other brochure(s) showing the AWS course offerings to students during the 1992–1993 academic year. If the institution's AWS curriculum was recognized after the start of the 1992–1993 academic year, provide a discussion of the status of the program and plans to incorporate the AWS curriculum in official publications of available courses offered by the institution for the upcoming academic year.

(c) Strategic Plan

Present a 5-year Strategic Plan for the institution's AWS Program. Discuss the components of the plan and how the institution anticipates achieving the goals and objectives of the Strategic Plan. Justify the feasibility of the plan in relation to the projected work force needs of the aviation industry and FAA, over-all direction of the institution, and the availability of resources necessary for plan accomplishment.

Note: This is a strategic plan for the institution's AWS Program, not a strategic plan for the proposed grant project.

(d) Project Plan

Discuss the proposed Project Plan with stated goals and objectives emphasizing those associated with the increased/enhanced educational benefits the project will provide AWS students (see below). Relate the project plan to the Strategic Plan. Present a detailed discussion from project design to conclusion on the components of the Project Plan and the activities and tasks necessary to bring the project to a successful conclusion. (The project is completed when the measurements discussed under the Evaluation Plan have been applied and analyzed. This should occur within 18 months of the time the facility and/or equipment becomes available to students). Indicate institutional planning activities which may have already occurred and when they occurred. (See reference to allowable cost sharing activities under section 5(f), Budget Plan).

Explain how the project will directly support the aviation and/or computer courses in the required core and the area(s) of concentration of an institution's recognized AWS curriculum options. Identify these courses by title.

Note: The grant project must be in direct support of an institution's recognized AWS courses and not intended for the development of new recognized AWS curriculum options. Provide a detailed discussion on the project in terms of the immediate and long-range increased/enhanced educational benefits it will provide for AWS students. Justify the proposed grant project in terms of the institution's AWS enrollment figures included in section 5(b) and the number of AWS students who will benefit from the project.

Provide a milestone chart for the project commencing with the official award of the grant. (This occurs when the grant agreement is signed by both the institution and the FAA). Describe and explain the mechanism that will be used to manage and monitor the progress of the project in terms of the milestones and budget expenditures.

Applicants may submit photographs, architectural drawings, site plans, or other visual representations that would aid the reviewing panel in understanding the proposed project.

(e) Project Personnel Plan

Identify and describe the relevant skills of those individuals who will have major responsibilities for the proposed grant project. Include a discussion of their relevant skills in terms of the project and the amount of time each person will be required to devote to the project. Discuss the role of the Project Manager. Provide information indicating the grant manager has appropriate qualifications, well defined responsibilities, sufficient time, and adequate academic and institutional authority and support to effectively manage the project.

Discuss the number and qualifications of faculty necessary to adequately utilize the funded facility/equipment in teaching of AWS courses after conclusion of project. Indicate if these individuals are current faculty members or must be hired. If the latter, provide a discussion on the institution's commitment to provide necessary faculty positions and planned activities to staff the positions.

(f) Budget Plan

The proposal must contain a Budget Plan in the following format which includes a detailed itemization of proposed expenditures for direct costs associated with the project.

Item	Fed $	% Non-Fed $	% Total
(a) Facilities			
(1) Construction			
(2) Renovation			
(b) Equipment			
(1) Flight			
(2) Air Traffic Control			
(3) Electronics			
(4) Maintenance			
(5) Computers			
(6) Meteorology			
(7) Office equipment			
(8) Classroom equipment			
(9) Distance Learning			
(10) Resource materials			
(c) Travel [1]			
(d) Consultant services[1]			
(e) Salaries[1] (non-teaching)			
(f) Other direct costs[1]			
Total			

[1] Costs directly related to grant project, though not qualified for Federal funding.

Each budget subcategory must contain line item entries of allowable costs and be subtotalled. (See OMB Circular A–21 for discussion of allowable costs.) The line item entries must be allocated appropriately between Federal and non-Federal funding. FAA grant funds may only be dedicated to the subcategories under categories "a" and "b". Cost sharing funds include allowable grant project costs or the value of in-kind contributions (categories "a" thru "f") essential to the completion of the project which are incurred by the institution or donated by an outside source. Cost sharing costs do not include costs associated with the institution's AWS program outside of the grant project. Federal costs may not occur prior to the official award of the grant. Nonfederal funds may occur from the planning stages commencing with the date of this solicitation through the evaluation period but, do not include operating and administrative costs, faculty teaching costs, or the development time for an institution's grant application.

Note: If an institution is resubmitting a grant application for a project which was initially submitted in response to the Notice of Solicitation, 57 FR 9585, March 19, 1992, eligible planning costs only may have occurred between March 19 and June 30, 1992. Institutions will be held accountable for all cost sharing obligations. All cost sharing expenditures must be identified by the grant project and traceable under the institution's financial management system.

A sample itemized budget is available from the AWS Grant Program Manager upon request. Budgets which do not include an itemization of expenditures by appropriate subcategory will be disqualified. Budgets which include construction activities with only a general cost per square foot will be disqualified. Do not include budget categories included in the example for which the institution has no entries.

Discuss and identify the sources of non-Federal funding and show evidence that the funds will be available, i.e., provide a letter of commitment for funds which will be given to the institution by an outside source.

(g) Institutional Need

Provide a detailed justification for the requested grant funding in terms of the institution's financial need. Provide information on the institution's budgeted funds dedicated to the AWS program for the current academic year. Indicate funding levels for salaries, operating expenses, and capital improvements. Explain activities to locate other funding sources to support the proposed grant project and the overall AWS program. Include a

discussion on FAA sponsored AWS grants previously awarded to the institution including funding level, project, date of award, expenditures to date, and project status.

(h) Evaluation/Assessment Plan

Provide a project Evaluation/Assessment Plan. The Plan must include a strategy and measurement component for each goal and objective of the grant project. The actual evaluation/assessment may be performed by the institution's staff or in collaboration with outside consultants within 18 months of the time the project facility and/or equipment is available to students. The results of the completed evaluation/assessment will determine whether the goals and objectives of the project have been achieved, the impact of the project upon the AWS program at the institution, and will assist the FAA in determining if similar projects should be funded at other AWS institutions. These results shall be submitted to the FAA as part of the final project report.

(6) Letter of Endorsement

Attach a letter of endorsement, signed by an appropriate official of the institution, that contains: (a) An endorsement of the proposed project; (b) a description of how the proposed project supports the institution's long range goals and objectives in AWS; and (c) a commitment to provide the institutional resources necessary to meet cost sharing obligations, complete the proposed project, maintain the facilities and equipment to an acceptable standard, and continue financial support for the AWS Curriculum Program after the grant funds have been expended.

Reporting Requirements

Until the proposed project is completed, the FAA requires that each award institution prepare a semi-annual Project Report, not to exceed twenty (20) double-spaced typewritten pages in length. The Project Report shall be submitted to the FAA semi-annually based on the award date of the grant. The report should include a discussion of project progress, highlights and accomplishments, personnel changes and a status report on expenditures and account balances for each of the line items presented in the approved Budget Plan.

In addition, a Final Project must be submitted to the FAA within 90 days of the project completion. The Final Project Report shall include summaries of project activities, accomplishments, Budget Plan expenditures, and a detailed discussion on the results of the implemented Evaluation Plan. The FAA anticipates that FAA representatives will make site visits to each grant institution during the lifetime of the project.

Proposal Review

All proposals will be reviewed by the FAA to determine eligibility and compliance with the requirements of the solicitation. All accepted applications will be placed into one of two competitive classes: (1) Minority institutions (see June 1, 1984, 49 FR 22903) and (2) majority institutions. Each will be reviewed, evaluated, and ranked within its assigned competitive class against the evaluation criteria by an evaluation panel of educational and/or aviation specialists. The evaluators may represent either the public or private sector, including: academia, private industry and/or the Federal Government. The recommendations of the panel will be used by the FAA in the selection of applicants for grant awards.

Grant Award

Grant awards will be made within each competitive class. Individual grant awards within a competitive class will not exceed $300,000. The FAA does not intend to fund all proposed projects nor necessarily all components of a proposed project and expects to award at least 20 grants. Priority consideration for grant award will be given to applications submitted by institutions which have not received noncompetitive funding under the Airway Science Grant Program since Fiscal Year 1991. In addition, the FAA will give priority consideration to projects which include the development of receive sites in support of the AWS Network. The FAA will award grants against Federal AWS grant funds appropriated under Public Law 101–516 with a maximum Federal share of 50% prior to awarding grants against funds appropriated under Public Law 102–143 with a maximum Federal share of 65%.

Institutions will be notified of their selections to receive grants. A grant is not considered officially awarded until a grant agreement has been approved and signed by both the FAA and the institution.

Evaluation Criteria

The evaluation criteria are designed to enable the reviewing panel and FAA officials to effectively evaluate the relative merit of submitted proposals. The proposals will be scored on a 100-point scale and will be evaluated based on the following factors:

1. *Institutional Commitment* (15 points maximum)

Each proposal will be evaluated as to the extent of the institution's commitment to the AWS Program, in relation to the date of curriculum recognition and overall size of program, as follows:

(a) Number of recognized AWS curriculum options. (2 points maximum)
(b) Number of students pursuing AWS degrees. (2 points maximum)
(c) Number of AWS degrees awarded since curriculum recognition. (2 points maximum)
(d) Recruitment activities including outreach programs for minority and female students. (2 points maximum)
(e) Projected growth of AWS Program over next 5 years. (2 points maximum)
(f) Amount of institutional cost sharing funds provided toward the project. (2 points maximum)
(g) Demonstrated continued support and growth of the institution's AWS Program. (2 points maximum)
(h) Quality of Letter of Endorsement. (1 point maximum)

2. *Strategic Plan* (15 points maximum)

The quality and feasibility of the Strategic Plan will be evaluated in terms of the following:

(a) Well defined goals and objectives. (3 points maximum)
(b) Institution's current AWS Program. (3 points maximum)
(c) Institution's demonstrated understanding of the activities necessary to achieve the goals and objectives. (3 points maximum)
(d) Demonstrated knowledge of the aviation industry and projected work force needs. (3 points maximum)
(e) Identification of resources, including fiscal, instructional, and administrative, necessary for achievement of planned goals. (3 points maximum)

3. *Project Plan* (20 points maximum)

The Project Plan will be evaluated as follows:

(a) Well defined goals and objectives. (2 points maximum)
(b) Relationship between the project and the strategic plan. (2 points maximum)
(c) Evidence that institution has good understanding of activities and tasks required to bring project to conclusion. (2 points maximum)
(d) Appropriateness of proposed facilities and/or equipment in terms of project goals and objectives and requirement of the AWS curriculum. (2 points maximum)

(e) Extent to which project directly supports recognized curriculum. (2 points maximum)
(f) Increased/enhanced education benefits to students. (2 points maximum)
(g) Appropriateness of the project in terms of institution's current AWS Program including current and projected five year enrollment. (2 points maximum)
(h) Number of AWS students to benefit from the project. (2 points maximum)
(i) Extent to which milestones are realistic and attainable. (2 points maximum)
(j) Extent to which adequate management mechanisms provide for the effective administrative, technical, and financial direction of the project. (2 points maximum)

4. *Project Personnel* (10 points maximum)

The professional qualifications and experience of the institution's proposed personnel, especially the AWS grant project director, and other key officials who will be involved in the proposed AWS grant project, will be evaluated as follows:

(a) Qualifications and experience of the grant project manager. (2 points maximum)
(b) Qualifications and experience of the other grant project personnel in relation to the goals and objectives of the project. (2 points maximum)
(c) How well the institution scheduled and allocated grant project personnel time to perform duties associated with project. (2 points maximum)
(d) How well AWS grant project personnel responsibilities are defined. (2 points maximum)
(e) Adequate faculty on board to utilize facilities and/or equipment *or* institutional commitment to provide necessary faculty positions and adequate staffing plan developed. (2 points maximum)

5. *Budget Plan* (10 points maximum)

The Budget Plan will be evaluated as follows:

(a) Proposed expenditures itemized by budget subcategory and mathematical calculations correct. (2 points maximum)
(b) Entries detailed and consistent with project narrative. (3 points maximum)
(c) Budget figures appropriate for goods and services being procured. (3 points maximum)
(d) Extent to which the applicant demonstrates that non-Federal funds required for the project are available. (2 points maximum)

6. *Institutional Need* (15 points maximum)

Each proposal will be evaluated on the following:

(a) An overall financial need for funding. (5 points maximum)
(b) Consequences to the institution's AWS Program if Federal funding not obtained. (5 points maximum)
(c) Amount of AWS grant funding previously awarded to the institution. (5 points maximum)

7. *Evaluation/Assessment Plan* (15 points maximum)

The Evaluation Plan will be evaluated to determine the extent to which it demonstrates the following:

(a) Plan is adequately tied to goals and objectives of the project. (5 points maximum)
(b) Strategy and measurement components are appropriate for stated project goals and objectives. (5 points maximum)
(c) Evaluation will produce information which would be useful to other institutions in implementing similar projects. (5 points maximum)

Issued in Washington, DC, on April 16, 1993.

Belinda R. Zamer,

Deputy Director, Office of Training and Higher Education.

[FR Doc. 93–9557 Filed 4–22–93; 8:45 am]

BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee Meeting on Air Traffic Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the FAA's Aviation Rulemaking Advisory Committee on air traffic issues.

DATES: The meeting will be held on May 11, 1993, at 9:30 a.m.

ADDRESSES: The meeting will be held at the Aircraft Owners & Pilots Association, 421 Aviation Way, Frederick, MD.

FOR FURTHER INFORMATION CONTACT: Mr. Aaron Boxer, Air Traffic Rules and Procedures Service, Federal Aviation Administration, telephone: 202–267–8783.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Aviation Rulemaking Advisory Committee on air traffic issues to be held on May 11, 1993, at the Aircraft Owners & Pilots Association, 421 Aviation Way, Frederick, MD. The agenda for this meeting will include:

- Discussion of the FAA's task to develop an advisory circular on the operation of unmanned airspace vehicles;
- Status of the advisory circular on pilot procedures at non-towered airports;
- Status of the Mode S ground sensor evaluation study; and
- A status of the request to assign the Mode C veil petition to the committee.

Attendance is open to the interested public but will be limited to the space available. The public may present written statements to the committee at any time by providing 30 copies to the Assistant Executive Director, or by bringing the copies to him at the meeting. In addition, sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading "FOR FURTHER INFORMATION CONTACT."

Issued in Washington, DC, on April 19, 1993.

Aaron Boxer,

Assistant Executive Director for Air Traffic Issues, Aviation Rulemaking Advisory Committee.

[FR Doc. 93–9534 Filed 4–22–93; 8:45 am]

BILLING CODE 4910–13–M

Federal Highway Administration

Environmental Impact Statement: Davis and Weber Counties, UT

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Revised notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public of an expansion to the study area for an environmental impact statement (EIS) which is being prepared for a proposed highway project in Davis and Weber Counties, Utah.

FOR FURTHER INFORMATION CONTACT: Tom Allen, U.S. Department of Transportation, Federal Highway Administration, 2520 West 4700 South, Suite 9A, Salt Lake City, Utah, 84118, Telephone: (801) 963–0184; R. James Naegle, Utah Department of Transportation, 4501 South 2700 West, Salt Lake City, Utah 84119, Telephone (801) 965–4160; or Lynn Zollinger, Utah Department of Transportation, District

One Office, P.O. Box 12580, 169 Wall Avenue, Ogden, Utah, 84404, Telephone (801) 399–5921.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Utah Department of Transportation, will prepare an EIS on a proposal to improve highway US-89 from I-15 Interchange at Farmington to the intersection at Harrison Boulevard, in South Ogden, Utah. This represents a total distance of approximately 12.9 miles. A new interchange is being added at Burke Lane which will provide access to the Farmington area west of I-15. This Burke Lane access will cross the Union Pacific railroad tracks and terminate at either Clark Lane (100 North) or 650 West Street.

Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand, and increased safety measures. Alternatives under consideration include: (1) A "No Action" alternative, (2) A low-cost Transportation System Management alternative (intersection improvements, traffic signal installation and coordination, etc.), (3) Mass transit, (4) Signalized expressway, (5) Limited access expressway, (6) Freeway, (7) A combination of alternatives. Incorporated into and studied with the build alternatives will be alignment and grade variations which would provide for mitigation in sensitive areas.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed or are known to have an interest in this proposal. A series of informational public meetings will be held as necessary during the project development process. A formal scoping meeting and an official public hearing will also be held. Public notice of the time and place of the meetings and hearing will be given. The draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: April 14, 1993.

Donald P. Steinke,

Division Administrator, Salt Lake City, Utah.

[FR Doc. 93–9574 Filed 4–22–93; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

April 16, 1993.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Special Request: The Department of the Treasury is requesting review and approval of the information collection described below by April 23, 1993 in order to meet congressional report date of May 8, 1993. In accordance with 5 CFR part 1320.18, a copy of this form will accompany this notice for public review. All comments must be received by COB April 22, 1993.

Internal Revenue Service

OMB Number: New

Form Number: SWR–1600

Type of Review: New collection

Title: Real Estate Appraiser Industry Review

Description: A collection of a limited number of business practices exercised by individual real estate appraisal companies.

Respondents: Businesses or other for-profit, small businesses or organizations

Estimated Number of Respondents: 50

Estimated Burden Hours Per Respondent: 30 minutes

Frequency of Response: Other (one time)

Estimated Total Reporting Burden: 25 hours

Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Department Reports, Management Officer.

OMB No. 1545–XXXX

Expires _____

Real Estate Appraiser Industry Review

Company Name _____

1. How many years has this company been in business in Austin?

_____

2. Is this company a corporation, partnership, or sole proprietor? corporation partner sole

3. What type of appraisals does the company perform? Commercial or Residential? Commercial Residential

4. What is your Federal Employer Identification Number?

_____

5. How many research/and support personnel are associated with your company? _____

6. How many are treated as "independent contractors" for tax purposes? _____

7. How many appraisers are associated with your business on a regular and recurring basis?

_____

8. How many of your appraisers are treated for tax purposes as "independent contractors"?

_____

9. When did the company begin treating the appraisers as "independent contractors"? _____

10. Have the appraisers who are treated as "independent contractors" been issued Form 1099 each year?

_____

11. Does the president/owner hold either a rating of MAI or SRA?

_____

12a. How many of the appraisers in your ofice have a rating of MAI?

_____

12b. How may of the appraisers in your office have a rating of SRA?

_____

Paperwork Reduction Act Notice.—We ask for the information on this form to carry out the Internal Revenue laws of the United States. Your response is voluntary. The time needed to complete this form will vary depending on individual circumstances. The estimated average time is 30 minutes. If you have suggestions for making this form more simple, we would be happy to hear from you. You can write to both the Internal Revenue Service, Attention: Reports Clearance Officer, T:FP, Washington, DC 20224 and the Office of Management and Budget Paperwork Reduction Project (1545–XXXX),

Washington, DC 20503. Do not send the form to either of these offices. Instead, send the form to either or following address: Internal Revenue Service, 9430 Research Boulevard, suite 303, Austin, TX 78759.

[FR Doc. 93-9481 Filed 4-22-93; 8:45 am]

BILLING CODE 4830-01-M

Public Information Collection Requirements Submitted to OMB for Review

April 16, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Special Request: The Department of the Treasury is requesting review and approval of the Internal Revenue Service information collection, described below, by April 29, 1993. IRS's Value Tracking Core Business System developed requirements to obtain information regarding walk-in service sites and why some taxpayers choose them over toll-free service, and the likelihood of public acceptance of expanded use by IRS of Voice Response Units. These requirements could be efficiently met by this survey. Accordingly, the survey was modified to accommodate them.

Internal Revenue Service

OMB Number: New
Form Number: None
Type of Review: New collection
Title: Survey of Individual Taxpayers' Interaction with TPS Toll-Free Assistance
Description: These telephone interviews with the public are being conducted to obtain data on the Taxpayer Service toll-free telephone system. The data will be used in developing an approach to establish a more efficient level of service for the IRS's toll-free telephone system.
Respondents: Individuals or households
Estimated Number of Respondents: 31,315
Estimated Burden Hours Per Respondent:
Pretest—80 hours
Screener Instrument—736 hours
Interview of "taxpayers who called and got through"—214 hours
Interview of "taxpayers who called but did not get through"—90 hours
Interview of "taxpayers who never called"—160 hours
Interview of "taxpayers who walked in"—70 hours
Frequency of Response: Other (one-time)
Estimated Total Reporting: 1,350 hours
Clearance Officer: Garrick Shear (202) 622-3869, Internal Revenue Service, Room 5571, 111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports, Management Officer.

[FR Doc. 93-9482 Filed 4-22-93; 8:45 am]

BILLING CODE 4830-01-M

Public Information Collection Requirements Submitted to OMB for Review

Date: April 19, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545-0458.
Form Number: IRS Form 4852.
Type of Review: Revision.
Title: Substitute for Form W-2, Wage and Tax Statement or Form 1099R, Distributions from Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, etc.
Description: In the absence of a Form W-2 or 1099R from the employer or payer, Form 4852 is used by the taxpayer to estimate gross wages, pensions, annuities, retirement or IRA payments received as well as income or FICA tax withheld during the year. It is attached to the return for processing.
Respondents: Individuals or households.
Estimated Number of Respondents: 1,300,000.
Estimated Burden Hours Per Respondent: 18 minutes.
Frequency of Response: Annually.
Estimated Total Reporting Burden: 390,000 hours.
OMB Number: 1545-0597.
Form Number: IRS Form 4598.
Type of Review: Revision.
Title: Form W-2 or 1099 Not Received or Incorrect.
Description: Employers and/or payers are required to furnish Forms W-2 or 1099 to employees and other payees. This three part form is necessary for the resolution of taxpayer complaints concerning the non-receipt of or incorrect Forms W-2 or 1099.
Respondents: Individuals or households, State or local governments, Farms, Businesses or other for-profit, Federal agencies or employees, Small businesses or organizations.
Estimated Number of Respondents: 850,000.
Estimated Burden Hours Per Respondent: 15 minutes.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 212,500 hours.
Clearance Officer: Garrick Shear (202) 622-3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Department Reports, Management Officer.

[FR Doc. 93-9530 Filed 4-22-93; 8:45 am]

BILLING CODE 4830-01-M

Public Information Collection Requirements Submitted to OMB for Review

Date: April 19, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Special Reqest: The Department of the Treasury is requesting review and approval of the Internal Revenue Service information collection, described below, by May 21, 1993. All comments must be received by COB May 14, 1993.

Internal Revenue Service

OMB Number: New.
Form Number: None.
Type of Review: New collection.
Title: 1993 Value Tracking Focus Groups with Taxpayers.
Description: The IRS needs taxpayer input into proposed changes in technologies that will dramatically alter the way they interact with the Service. We propose to obtain this input by conducting a series of focus group interviews with individual and small business taxpayers in five U.S. cities.
Respondents: Individuals or households, Businesses or other for-profit, Small businesses or organizations.
Estimated Number of Respondents: 1,000.
Estimated Burden Hours Per Respondent:
Screening Questionnaire—5 minutes
Focus Group Sessions—3 hours
Frequency of Response: Other (one-time data collection)
Estimated Total Reporting: 683 hours.
Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports, Management Officer.
[FR Doc. 93–9531 Filed 4–22–93; 8:45 am]
BILLING CODE 4830–01–M

Public Information Collection Requirements Submitted to OMB for Review

April 16, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Special Request: The Department of the Treasury is requesting review and approval of the Internal Revenue Service information collection, described below, by April 22, 1993. The completion of the application of approval was delayed by several iterations of designs for the answer sheet returns, and by the design of the focus group moderator's guide. It was also necessary to make corresponding modifications to the human factors laboratory testing questionnaire.

Internal Revenue Service

OMB Number: New
Form Number: None
Type of Review: New collection
Title: Focus Group and Human Factors Lab Testing of Answer Sheet Style Form 1040 Package
Description: Focus Group and Human Factors Lab tests are needed to finalize the design of an answer sheet tax form for the Tax Systems Modernization Program. Approximately 96 people will be involved in the focus group test, 360 in the lab tests. This request is for a single series of tests to be conducted in April 1993.
Respondents: Individuals or households
Estimated Number of Respondents: 1,200
Estimated Burden Hours Per Respondent:
Focus Group Tests—295 hours, 41 minutes
Human Factors Lab Tests—1,180 hours, 48 minutes
Non-selected—59 hours, 31 minutes
Frequency of Response: Other (one-time test series)
Estimated Total Reporting: 1,464 hours
Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports, Management Officer
[FR Doc. 93–9479 Filed 4–22–93; 8:45 am]
BILLING CODE 4830–01–M

Public Information Collection Requirements Submitted to OMB for Review

April 16, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the Submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Special Request: The Department of the Treasury is requesting a less-than 60-day review and approval of the information collection described below All comments must be received not later than COB May 19, 1993.

Internal Revenue Service

OMB Number: New
Form Number: None
Type of Review: New collection
Title: Opinion Survey of Bankruptcy Chapter 7 Case Trustees by Internal Revenue Service/Department of Justice Compliance 2000 Task Force.
Description: The affected public is the 16,000 bankruptcy trustees required to file Form 1041 who are appointed by the Executive Office of the United States Trustees, Department of Justice. They are self employed. The survey will determine the effectiveness of current materials and procedures to develop new strategies for customer service.
Respondents: Businesses or other for-profit, small businesses or organizations
Estimated Number of Respondents: 1,600
Estimated Burden Hours Per respondent: 20 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 533 hours
Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports, Management Officer.
[FR Doc. 93–9480 Filed 4–22–93; 8:45 am]
BILLING CODE 4830–01–M

DEPARTMENT OF TREASURY

Customs Service

Copyright, Trademark, and Trade Name Recordations

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

SUMMARY: Effective January 1, 1993, hard copy issuances (dated January 1, 1993 or later) of U.S. Customs Service recordations of trademarks, copyrights and trade names can be viewed in any Customs Reading Room.

FOR FURTHER INFORMATION CONTACT: John F. Atwood, Chief, Intellectual Property Rights Branch, (202) 482–6960.

Dated: April 15, 1993.

John F. Atwood,

Chief, Intellectual Property Rights Branch.

[FR Doc. 93–9471 Filed 4–22–93; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF THE TREASURY

Customs Service

Application for Recordation of Trade Name: "NLC, INC."

ACTION: Notice of Application for Recordation of Trade Name.

SUMMARY: Application has been filed pursuant to section 133.12, Customs Regulations (19 CFR 133.12), for the recordation under section 42 of the Act of July 5, 1946, as amended (15 U.S.C. 1124), of the trade name NLC, INC.," used by NLC, Inc., a corporation organized under the laws of the State of Missouri, located at 319 West Main Street, P.O. Box 348, Jackson, Missouri 63755.

The application states that the trade name is used in connection with arc welding accessories which are sold under the trademark "LENCO" and include electrode holders, ground clamps, cable connectors, lugs, splicers and chipping hammers, resistance spot welders and computer controlled welding trainers.

Before final action is taken on the application, consideration will be given to any relevant data, views, or arguments submitted in writing by any person in opposition to the recordation of this trade name. Notice of the action taken on the application for recordation of this trade name will be published in the **Federal Register**.

DATE: Comments must be received on or before June 22, 1993.

ADDRESSES: Written comments should be addressed to U.S. Customs Service, Attention: Franklin Court, Intellectual Property Rights Branch, 1301 Constitution Avenue, NW., (Suite 4000), Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Gina D'Onofrio, Intellectual Property Rights Branch, 1301 Constitution Avenue, NW., Washington, DC 20229 (202–482–6960).

Dated: April 16, 1993.

John F. Atwood,

Chief, Intellectual Property Rights Branch.

[FR Doc. 93–9558 Filed 4–22–93; 8:45 am]

BILLING CODE 4820–02–M

Internal Revenue Service

Information Reporting Program Advisory Committee; Open Membership Application Period

AGENCY: Internal Revenue Service, Treasury.

ACTION: Announcement of Open Membership Application Period for the Information Reporting Program Advisory Committee.

SUMMARY: In 1991 the Internal Revenue Service (IRS) established the Information Reporting Program Advisory Committee (IRPAC). The primary purpose of IRPAC is to provide an organized public forum for discussion of relevant information reporting issues between the officials of the IRS and representatives of the payer community. IRPAC offers constructive observations about current or proposed policies, programs, and procedures, and when necessary, suggests ways to improve the operation of the Information Reporting Program. IRPAC is currently comprised of 18 representatives from various segments of the private sector payer community. Thirteen of these appointments to IRPAC will expire at the end of 1993. Additional members will be selected for two-year terms beginning in January 1994.

SUPPLEMENTARY INFORMATION: IRPAC reports to the Executive Director, Information Reporting Program (IRP), who is the executive responsible for information reporting and is charged with its system-wide planning and improvement. IRPAC is instrumental in providing advice to enhance the IRP Program. Increasing participation by external stakeholders in the planning and improvement of the tax system will help achieve the goals of increasing voluntary compliance and reduction of burden. IRPAC members are not paid for their time or services, but consistent with Federal regulations, they will be reimbursed for their travel and lodging expenses to attend a two-day meeting twice each year.

The IRS is interested in representation from different areas of the payer community (e.g., banking, payroll services, securities, life insurance, data processing, etc.). Anyone wishing to be considered for membership on IRPAC should so advise the IRS. Please complete the following questionnaire and forward it to Ms. Kate LaBuda of the IRP Planning Staff, at the address below.

ADDRESSES: Internal Revenue Service, EX:I:P, 1111 Constitution Avenue, NW., room 2013, Washington, DC 20224.

DATE: Completed questionnaires should be received by IRS by May 29, 1993. Applications received after this date will not be considered. An acknowledgment letter will be sent upon receipt of each application.

FOR FURTHER INFORMATION CONTACT: Kate LaBuda at 202–622–3404 (not a toll-free number).

Dated: April 7, 1993.

John Devlin,

Executive Director, Information Reporting Program.

Information Reporting Program Advisory Committee Membership Application Questionnaire

The following questions must be answered by anyone interested in becoming a member of the Information Reporting Program Advisory Committee (IRPAC). Applications must be received in that office by May 29, 1993. Those received after this date will not be considered. All applications received will be acknowledged. Questions should be directed to Kate LaBuda at 202–622–3404, and your reply should be returned to: Ms. Kate LaBuda, EX:I:P, Information Reporting Program Planning Staff, Internal Revenue Service, room 2013, 1111 Constitution Avenue, NW., Washington, DC 20224.

1. Name:
2. Title:
3. Company or Organization Name:
4. Business Address:
5. Business Phone:
6. Fax Number:
7. Home Address:
8. Home Phone:
9. If you are applying on behalf of an organization or association other than your employer, please state the name, and address of that organization. Also, provide a letter of reference from that organization stating that you are nominated on their behalf. This letter should contain the name of a contact and this contact's phone number.
10. List professional credentials (e.g., Ph.D., CPA, Enrolled Agent, Attorney, Accountant, etc.)

11. Check the one segment of the Information Reporting Program (IRP) payer community to which the organization that you represent, and your experience, most closely relate:

_____ Large Financial Institution
_____ Small Financial Institution
_____ Real Estate
_____ Transmitter/Forms Developer
_____ Software Developer
_____ Insurance: Property & Casualty
_____ Insurance: Life
_____ Securities
_____ Payroll
_____ State & Local Governments
_____ Corporate Compliance
_____ Small Business Compliance
_____ General Compliance
_____ Employee Plans
_____ Trust Company
_____ Corporate Transfer Agent/ Utilities
_____ Other (Please specify. _____)

12. List the number of years of IRP-related experience you have, and specific sources of this IRP experience. (Account for all years of IRP experience claimed.)

13. Identify organizations to which you belong and any relevant leadership positions you have held.

14. List any previous IRS employment (please state position/s, title/s, and length of time in each position):

15. Please propose two topic ideas that you feel would be appropriate for discussion by IRPAC. Include a short description (two sentences) of each topic.

The Following Three Items Are Required For An FBI Name Check.

16. Date of Birth:
17. Place of Birth:
18. Other names ever used:

The Following Items Are Required For An IRS Tax Check. (Please Note That a Tax Check Is Not a Tax Audit.)

I hereby authorize the Internal Revenue Service to perform the standard Federal Advisory Committee member tax check, (pursuant to 26 U.S.C. 6103; 5 U.S.C. 1303; Executive Orders 9397, 11222, 10450; CFR 5.2; 31 CFR part O, Treasury Department Order Nos. 82 (Revised) and 150–87) and to provide this information to the Assistant Secretary (Administration) of the Treasury Department.

I understand that the purpose of such tax check and income tax filing record check is to promote public confidence in the integrity of the Treasury Department and its administration of the Federal tax system. I have been advised that my Social Security Number is required to identify my tax records accurately. I also understand that this tax check must be completed prior to my appointment to this Federal Advisory Committee and I hereby voluntarily provide the following information:

19. Social Security Number:

20. Spouse's name and SSN (if married and filing jointly):

21. Name(s) and address(es) under which tax returns were filed for the past three years.

The Following Item Is Required Because of The Foreign Agents Registration Act (FARA), As Amended.

22. I presently _____am / _____am not required to register as an agent of a foreign principal under FARA, as amended.

Note: Pursuant to 18 U.S.C. sec. 219, an individual who is required to register as an agent of a foreign principal under FARA is prohibited from serving on IRPAC. By executing this questionnaire, you agree that (1) if you are required to register as an agent of a foreign principal under the FARA before your term commences on IRPAC, you will terminate any and all such agencies prior to beginning your tenure and will provide appropriate verification therefor; and (2) you will immediately resign from IRPAC if you become such an agent at any time during your term.

Certification

23. I certify that, to the best of my knowledge and belief, all of my statements are true, correct, complete, and made in good faith. I also agree to the background checks setforth herein.

_____

Signature

_____

Date

[FR Doc. 93–9488 Filed 4–22–93; 8:45 am]

BILLING CODE 4830–01–U

Office of Thrift Supervision

[AC–16: OTS No. 0743]

Macon Building and Loan Association, Macon, MO; Approval of Conversion Application

Notice is hereby given that on March 30, 1993, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of Macon Building and Loan Association, Macon, Missouri, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Midwest Regional Office, Office of Thrift Supervision, 122 West John Carpenter Freeway, suite 600, Irving, Texas, 75261–9027.

Dated: April 19, 1993.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 93–9470 Filed 4–23–93; 8:45 am]

BILLING CODE 6720–01–M

[AC–15: OTS No. 3127]

St. Francis Bank, F.S.B., Milwaukee, WI; Approval of Conversion Application

Notice is hereby given that on March 30, 1993, the Deputy Assistant Director, Corporation Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of St. Francis Bank, F.S.B., Milwaukee, Wisconsin to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 111 Wacker Drive, suite 800, Chicago, Illinois 60601–4360.

Dated: April 19, 1993.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 93–9469 Filed 4–22–93; 8:45 am]

BILLING CODE 6720–01–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 77
Friday, April 23, 1993

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).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10 a.m. on Tuesday, April 27, 1993, to consider the following matters:

Summary Agenda

No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Reports of actions approved by the standing committees of the Corporation and by officers of the Corporation pursuant to authority delegated by the Board of Directors.

Discussion Agenda

Memorandum and resolution re: Proposed amendments to Part 337 of the Corporation's rules and regulations, entitled "Unsafe and Unsound Banking Practices," which would revise the capital category definitions used in the Corporation's regulations governing the acceptance of brokered deposits so that those definitions would conform to the definitions used in regulations implementing section 38 of the Federal Deposit Insurance Act.

Memorandum and resolution re: Final amendments to the Corporation's rules and regulations in the form of a new Part 363 regarding independent annual audits and reporting requirements.

Memorandum and resolution re: Risk-Related Premium System—Determination of Capital Group Assignments.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call (202) 898-6745 (Voice); (202) 898-3509 (TTY), to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898-6757.

Dated: April 20, 1993.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 93-9609 Filed 4-20-93; 8:45 am]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2), notice is hereby given that at its open meeting held at 2:30 p.m. on Tuesday, April 20, 1993, the Corporation's Board of Directors determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required the withdrawal from the agenda for consideration at the meeting, on less than seven days' notice to the public, of a memorandum and resolution regarding final amendments to the Corporation's rules and regulations in the form of a new Part 363 regarding independent annual audits and reporting requirements.

By the same majority vote, the Board determined that no notice earlier than April 15, 1993, of the change in the subject matter of the meeting was practicable.

Dated: April 21, 1993.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 93-9667 Filed 4-21-93; 12:37 pm]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its closed meeting held at 2:26 p.m. on Tuesday, April 20, 1993, the Corporation's Board of Directors determined, on motion of Director Jonathan L. Fiechter (Acting director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of matters relating to assistance agreements with insured institutions.

The Board further determined, by the same majority vote, that no earlier notice of the changes in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(9)(B), and 552 (c)(4), (c)(6), (c)(9)(B), and (c)(10)).

Dated: April 21, 1993.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 93-9668 Filed 4-21-93; 12:37 pm]

BILLING CODE 6714-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Wednesday, April 28, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20511.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. 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.

Date: April 20, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-9632 Filed 4-21-93; 10:30 am]

BILLING CODE 6210-01-M

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

Notice of a Meeting

The Board of Governors of the United States Postal Service, pursuant to its Bylaws (39 CFR 7.5) and the Government in the Sunshine Act (5 U.S.C. Section 552b), hereby gives notice that it intends to hold a meeting at 9 a.m. on Tuesday, May 4, 1993, in Nashville, Tennessee. The meeting is open to the public and will be held at the Loews Vanderbilt Plaza Hotel, 2100 West End Avenue, in the Belmont/Centennial Ballroom. The Board expects to discuss the matters stated in the agenda which is set forth below. Requests for information about the meeting should be addressed to the Secretary of the Board, David F. Harris, at (202) 268–4800.

There will also be a session of the Board on Monday, May 3, 1993, but it will consist entirely of briefings and is not open to the public.

Agenda

Tuesday Session

May 4—9 a.m. (Open)

1. Minutes of the Previous Meeting, April 5–6, 1993.
2. Remarks of the Postmaster General and CEO. (Marvin Runyon)
3. Quarterly Report on Service Performance. (Ann McK. Robinson, Vice President, Consumer Advocate)
4. Quarterly Report on Financial Performance. (Leonard J. Sichel, CFO and Vice President, Finance and Planning; and M. Richard Porras, Controller)
5. Annual Report on Finance and Planning. (Leonard J. Sichel, CFO and Vice President, Finance and Planning; and M. Richard Porras, Controller)
6. Annual Report on Employee Relations. (William J. Henderson, Vice President, Employee Relations)
7. Report on the Tennessee Customer Services District. (Andrew Walker, Manager, Tennessee Customer Services District)
8. Tentative Agenda for the June 7–8, 1993, meeting in Washington, DC.

David F. Harris,

Secretary.

[FR Doc. 93–9652 Filed 4–21–93; 12:43 pm]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: (58 FR 21333 April 20, 1993)

STATUS: Closed meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: Friday, April 16, 1993.

CHANGE IN THE MEETING: Additional meeting.

A closed meeting will be held on Friday, April 23, 1993, at 2:30 p.m. to consider the following items:

Institution of administrative proceedings of an enforcement nature.
Institution of injunctive actions.
Settlement of injunctive actions.
Opinions.

Commissioner Roberts, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

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: Christine Sakach at (202) 272–2300.

Dated: April 20, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–9597 Filed 4–20–93; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of April 26, 1993.

An open meeting will be held on Tuesday, April 27, 1993, at 3:30 p.m., in Room 1C30, followed by a closed meeting.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meetings. 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 option, 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 a closed session.

The subject matter of the open meeting scheduled for Tuesday, April 27, 1993, at 3:30 p.m., will be:

1. Consideration of whether to issue a release proposing amendments to the Commission's multijurisdictional disclosure system (MJDS) for Canadian issuers, including proposals relating to the eligibility requirements for use of certain forms under the MJDS reconciled to U.S. generally accepted accounting principles in certain filings. For further information, please contact Paul M. Dudek at (202) 272–3246.
2. Consideration of whether to issue a release adopting further rule and form changes to facilitate capital formation by small businesses and the transition of small business into the reporting system of the Securities Exchange Act of 1934. These rule and form changes include a number of revisions to the integrated registration and reporting disclosure system for small business issuers, including a new Securities Act registration statement format for offerings of less than $10 million and revisions to Regulation D which would modify certain disclosure references contained therein. Revisions to the definitions of "small business" for purposes of the Regulatory Flexibility Act would also be make. For further information, please contact Richard K. Wulff at (202) 272–2644.

The subject matter of the closed meeting scheduled for Tuesday, April 27, following the 3:30 p.m. open meeting, will be:

Institution of administrative proceedings of an enforcement nature.
Institution 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: George Kramer at (202) 272–2000.

Dated: April 20, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–9598 Filed 4–20–93; 4:54 am]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 58, No. 77
Friday, April 23, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1 and 3

Registration of Floor Traders; Mandatory Ethics Training for Registrants; Suspension of Registrants Charged With Felonies

Correction

In rule document 93-8798 beginning on page 19575 in the issue of Thursday, April 15, 1993, make the following corrections:

§ 1.66 [Corrected]

1. On page 19590, in the first column, in § 1 66, in paragraph (b)(1), the subparagraph designated "(11)" at the bottom of the page should read "(ii)".

§ 3.34 [Corrected]

2. On page 19593, in the third column, in § 3.34(d)(2), in the third line, "who has been duly registered" should read "who has not been duly registered".

§ 3.41 [Corrected]

3. On page 19594, in the second column, in § 3.41(a), in the first line, "§ 3 42" should read "§ 3.42".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Child Welfare Act; Receipt of Designated Tribal Agents for Service of Notice

Correction

In notice document 93-6926 beginning on page 16450 in the issue of Friday, March 26, 1993, make the following correction:

On page 16457, in the third column, in the listing for the Quinault Tribe of the Quinault Reservation, in the second line, "Box 198," should read "Box 189,".

BILLING CODE 1505-01-D

RESOLUTION TRUST CORPORATION

List of Thrifts and Banks in RTC and FDIC Conservatorship and Receivership

Correction

In notice document 93-8175 beginning on page 18234 in the issue of Thursday, April 8, 1993, make the following correction:

1. On page 18276, after the table, insert the following text:

By Order of the Executive Committee.

Dated at Washington, DC, this 2d day of April, 1993.

Resolution Trust Corporation.

John M. Buckley, Jr.,

Secretary.

[FR Doc. 93-8175 Filed 4-7-93; 8:45 am]

BILLING CODE 6714-01-M

BILLING CODE 1505-01-D

federal register

Friday
April 23, 1993

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910 et al.

Occupational Exposure to Cadmium; Correction; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915 and 1928

[Docket No. H–057a]

Occupational Exposure to Cadmium; Correction

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule; correction and amendment.

SUMMARY: The Occupational Safety and Health Administration is correcting errors in the entire Occupational Exposure to Cadmium Final Rule which appeared in the **Federal Register** on September 14, 1992 (57 FR 42101) and adding new provisions on Occupational Health to cover the agriculture industry. Regulations covering the agriculture industry were inadvertently omitted from the September 14 rule.

EFFECTIVE DATE: December 14, 1992.

FOR FURTHER INFORMATION CONTACT: Mr. James Foster, Occupational Safety and Health Administration. Office of Information and Public Affairs, room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone: 202–219–8151.

SUPPLEMENTARY INFORMATION:

Background

OSHA has promulgated a standard to reduce occupational exposure to all forms of cadmium in the general, agriculture and maritime industries. A separate standard for the construction industry was also published. Both standards establish a time-weighted-average permissible exposure limit (TWA PEL) of 5 micrograms per cubic meter of air (5 μg/m³) and an action level (AL) of 2.5 μg/m³.

Need for Correction

During the proofreading process of these regulations, technical and typographical errors were discovered. This notice is being published to correct these errors. With the exception of the explanation and related correction below these corrections are essentially self-explanatory.

The amendments in this document rectify the technical failure to print the standard for the agricultural industries (29 CFR Part 1928), and reflect OSHA's consistent intention to cover the general, agricultural and maritime industries (57 FR 42333; 55 FR 4121; February 6, 1990).

OSHA deleted the saccharin solution aerosol qualitative fit test protocol from the Cadmium final rule based upon a misreading of a comment submitted by the Maryland Occupational Safety and Health Administration (MOSH). The comment suggested the deletion of a reference to disposable dust respirators from the saccharin solution protocol in page 4131 Appendix C of the proposed Cadmium standard, 55 FR 4052 (February 6, 1990), since the standard prohibited the use of such respirators unless equipped with high efficiency filters. MOSH deemed the deletion to be necessary to avoid confusion. OSHA mistakenly deleted the entire protocol instead of only eliminating the reference to disposable dust respirators from the saccharin solution protocol. OSHA is correcting the preamble to the final rule and Appendix C by reinstating the deleted protocol and eliminating the reference to disposable dust respirators from the saccharin solution protocol to accurately reflect MOSH's comment.

OSHA also corrected the final rule by deleting the word "within" from a very narrow and specific portion of the medical surveillance program concerning the timing of follow-up biological monitoring examinations of veteran employees. Such examinations must be conducted "approximately one year" after the employees' initial biological monitoring results are determined (57 FR 42352). This correction was made in order to reflect the intent of the preamble and to prevent possible misinterpretation.

Correction of Publication

The following corrections are made in the final rule for Occupational Exposure to Cadmium published in the **Federal Register** on September 14, 1992 (57 FR 42101).

1. On page 42102, the CFR heading for the document is corrected to read, "29 CFR Parts 1910, 1915, 1926, and 1928".

2. On page 42102, first column, third paragraph, lines 11 through 15 are corrected to read, "has also established separate engineering control air limits (SECAL) of either 15 μg/m³ or 50 μg/m³ as the lowest feasible levels above the PEL that can be achieved by engineering and work practice controls."

3. On page 42102, second column, second paragraph after the heading, "A. General", lines 5 and 6, is corrected to read, "at 29 CFR 1910.1027 for general industry, § 1915.1027 for maritime, § 1928.1027 for agriculture and § 1926.63 for the construction industry.".

4. On page 42103, third column, first full paragraph after the heading, "C. Regulation", line 2, is corrected to read, "standard is also found in section 8(c)".

5. On page 42109, second column, second full paragraph, line 13, is corrected to read, "lethal concentration of cadmium was".

6. On page 42109, third column, line 2, is corrected to read "this exposure level, there is".

7. On page 42110, third column, first full paragraph, line 28, is corrected to read, "proteinuria (Exs. 8–86–B, p. 63; 4–54). In"

8. On page 42113, third column below table V–2, paragraph "iv. Jarup et al.", line 15, the word "had" is corrected to read "have".

9. On page 42114, second column, table V–3., left most column, the sixth entry is corrected to read, ">15,000".

10. On page 42115, third column, line 1, is corrected to read, "Cr the proportion of cases of β_2–M".

11. On page 42115, third column, first full paragraph, lines 12, 13 and 14 are corrected to read "using the model: log (B_2–M) =[a×age]+[b×cumulative dose]+[c]. Elinder".

12. On page 42115, third column, third full paragraph, lines 13 and 14 are corrected to read, "working lifetime (1 mg/m³+45 years=22.2 μg/m³.) If exposures are".

13. On page 42115, table V–6., far left column, line 5, under the heading, "Cum exposure (mg/m³-yrs)", is corrected to read, "≥5".

14. On page 42115, table V–6., middle column, under the heading "Slight proteinuria[1] No. (percent)[2]", fourth entry, the symbol "<" is deleted.

15. On page 42116, table V–8., is corrected to read,

"TABLE V–8.—PREVALENCE OF KIDNEY DYSFUNCTION BY CUMULATIVE CADMIUM EXPOSURE

Cumulative exposure [1]	Number normal [2]	Number abnormal [3]	Percent abnormal
≤500	96	5	4.9
>500–≤1000	14	0	0.0
>1000–≤1500	3	5	62.5
>1500	4	20	83.3

[1] Cumulative Exposure measured in μg/m³-year

[2] Normal measured by Retinol Binding Protein (RPB): < 40 μg RPB/mmol Cr

[3] Abnormal measured by Retinol Binding Protein (RBP): > 40 μg RPB/mmol Cr".

16. On page 42117, table V–10., right most column, third entry, under the heading "P Value", is corrected to read, "<0.0001".

17. On page 42118, first column, second paragraph, line 9 is corrected to

read, "in persons with cumulative exposure ≥".

18. On page 42119, first column, third full paragraph, line 11, is corrected to read, "μg/liter and total protein ≤135 mg/l. For".

19. On page 42129, the heading for Table V–19 is corrected to read, "Levels of Cadmium in Blood and Urine Among Workers in Pigment Production: Average Levels of Cadmium in Blood (μg/liter whole blood) and Cadmium in Urine (μg/gram creatinine)".

20. On page 42131, third column, third paragraph, line 11, is corrected to read, "The unexposed group whose".

21. On page 42132, third column, second full paragraph under the heading, "ix. Summary", line 10, is corrected to read, "were 10.3 μg/lwb and 8.78 μg/g Cr,".

22. On page 42134, first column, first paragraph, line 3, is corrected to read, "and may cause damage; there is medical".

23. On page 42149, third column, first full paragraph, lines 10 through 12 are corrected to read, "CdO-exposed rats. Neither Dr. Heinrich nor Dr. Oberdörster, however, could give an estimate of the carcinogenic".

24. On page 42168, table VI–2., column headed, "Weibull model[a]", delete the superscript "[a]".

25. On page 42170, second column, table VI–5, the entries in the column marked "Cumulative dose (μg/m³-yrs)" is corrected to read:

45
225
450
900
1800
2250
4500

26. On page 42171, second column, third full paragraph, lines 4 and 5, are corrected to read, "(Exs. 38; 19–43; L–140–23; 144–8a; 144–8b; 114–8c; 114–17). The Globe plant".

27. On page 42174, third column, line 16, is corrected to read "et al., Ex. 4–34; Levy et al., Ex. 8–117).".

28. On page 42177, Table VI–7., the "Combined" "Exp" column, the entries marked "7" on lines 2 and 10 are deleted.

29. On page 42178, first column, fourth paragraph, line 4, change the "±" symbol to a "≥" symbol.

30. On page 42178, second column, third paragraph, the equation under "Linear:" is corrected to read, "$h=\alpha+E_j(\Theta_jW_j)+\Gamma\chi+\delta Y+\beta X$".

31. On page 42178, third column, line 10, is corrected to read, "$[E_j; (\Theta_jW_j)=\Theta_j$, where j' is the particular".

32. On page 42178, third column, line 13, is corrected to read, "χ represents Hispanic ethnicity (χ=1 if".

33. On page 42179, second column below table VI–8., move the word "Where:" to below the formula and preceding the definition "RR_i is the risk ratio for lung cancer predicted by the model based on the exposure scenario assumed,".

34. On page 42179, second column, line 4 following the formula is corrected to read, "$q_1(i)$ is the background age-specific lung".

35. On page 42180, second column, table VI–9., the heading, "Relative Rate Model" should only be above the columns labeled, "Poisson regression$_a$" and "Cox regression$_b$".

36. On page 42180, second column, table VI–9., footnotes "a" and "b" are corrected to read,

"a is β=0.00061 (μg-years/m³)$^{-1}$
b is β=0.00026 (μg-years/m³)$^{-1}$".

37. On page 42181, first column, third paragraph, line 2, is corrected to read, "restriction a_{NH}=0 (corresponding to".

38. 38. On page 42181, third column, table VI–10., is corrected to read:

TABLE VI–10.—RESULTS OF APPLYING OSHA'S MODIFIED RELATIVE RISK MODEL TO THE 1984 FOLLOWUP OF THE THUN COHORT

	Case I[a] (a_{NH} = 0)	Case II[a] (a_{NH} estimated)
a_H (s.e.)	−1.4 (0.60)	−1.8 (0.91)
a_{NH}	0	−0.48 (0.77)
β^b	0.00027 (0.000098)	0.00054 (0.00057)
Deviance	10.29	9.88

[a]Case I assumes lung cancer mortality rates for U.S. white males are appropriate background rates for non-Hispanic white males in this cohort. Case II permits background rates for non-Hispanic white males to differ from rates for U.S. white males by the multiplicative constant, exp (a_{NH}).
[b]Units are (μg-years/m³)$^{-1}$.

39. On page 42181, table VI–11, is corrected to read:

TABLE VI–11.—OBSERVED AND PREDICTED LUNG CANCER DEATHS FROM THE RELATIVE RISK MODEL APPLIED TO THE 1984 UPDATE TO THE THUN COHORT

Exposure (μg-years/m³)	Number of lung cancers observed	Number of lung cancers predicted	
		Case I[a] (a_{NH}=0)	Case II[a] (a_{NH} estimated)
Non-Hispanics			
795	1	4.1	3.0
2466	7	4.4	3.8
5699	6	4.0	3.9
10836	7	9.5	10.3

TABLE VI–11.—OBSERVED AND PREDICTED LUNG CANCER DEATHS FROM THE RELATIVE RISK MODEL APPLIED TO THE 1984 UPDATE TO THE THUN COHORT—Continued

Exposure (μg-years/m³)	Number of lung cancers observed	Number of lung cancers predicted	
		Case I[a] (a_{NH}=0)	Case II[a] (a_{NH} estimated)
Hispanics			
795	1	0.71	0.50
2466	0	0.67	0.63
5699	0	0.75	0.80
10836	2	0.87	1.0
		X^2=8.5 (NS) 6 df	X^2=8.8 (NS) 5 df

NS=nonsignificant lack of fit
df=degrees of freedom
[a]Case I assumes lung cancer mortality rates for U.S. white males are appropriate background rates for non-Hispanic white males in this cohort. Case II permits background rates for non-Hispanic white males to differ from rates for U.S. white males by the multiplicative constant, exp (a_{NH}).

40. On page 42181, second column below table VI–11., line 1, the "=" symbol is corrected to read, "≡".

41. On page 42182, third column, second paragraph following the heading, "Potential for Confounding by Arsenic Exposure in Thun Cohort", line 15, is corrected to read, "That said, we can interpret the post-1940 data with".

42. On page 42187, second column, first full paragraph, line 4, is corrected to read, "exposure group (<584 mg-days/m³) of the".

43. On page 42187, second column, first full paragraph, line 20 is corrected to read, "cohort by Stayner et al. (Ex L–140–20)".

44. On page 42190, table VI–15., column under the heading "Falck (Ex. 4–28)", line 2, the word "hazing" is corrected to read "brazing".

45. On page 42191, first column, footnote number 5, line 2, the word, "thed" is corrected to read, "the".

46. On page 42191, first column, footnote number 5, line 5, the word, "multiples" is corrected to read, "multiplies".

47. On page 42192, third column, first full paragraph, line 18, is corrected to read, "test. As indicated by table VI–18, the".

48. On page 42193, table VI–18, first column, the sixth entry under the heading, "Jarup 2[c] (Ex. 8–661):", is corrected to read, ">15,000".

49. On page 42193, table VI–19, footnote c, is corrected to read, "[c] Restriction imposed of τ=1 (linear dose response)."

50. On page 42194, second column, third full paragraph, line 17, is corrected to read, "$X \geq X_O$".

51. On page 42195, third column, third paragraph, line 2, is corrected to read, "biological arguments that indicate a".

52. Beginning on page 42348, third column, second full paragraph, is corrected to read,

"MOSH also recommended that the saccharin solution aerosol protocol be corrected by deleting the reference to disposable dust respirators to reflect the fact that disposable dust respirators not equipped with high efficiency filters are not permitted by the proposed cadmium standard.".

53. On page 42351, second column, third new paragraph, line 13, is corrected to read, "guide employers and laboratories in".

54. On page 42381, first column, lines 12 and 13, are corrected to read, "cadmium; electrical grounding with cadmium welding, or electrical work using".

55. On page 42383, second column, the last line is corrected to read, "Electrical grounding with cadmium welding;".

56. On page 42385, third column, third paragraph, line 9, is corrected to read, "Electrical grounding with cadmium welding;".

57. On page 42388, second column, paragraph numbered "1.", line 8, is corrected to read, "1965, 41 U.S.C. 351 et seq.; sec. 107 Contract".

58. On page 42388, second column, paragraph numbered "1.", line 11, is corrected to read, "41, Longshoremen's and Harbor Workers' ".

59. On page 42388, second column, paragraph numbered "1.", line 12, is corrected to read, "Compensation Act, 33 U.S.C. 941; National".

PART 1910—[AMENDED]

PART 1915—[AMENDED]

60. On page 42388, second column, paragraph numbered "2.", is corrected to read,

"2. The authority citation for subpart Z of part 1910 is revised to read as follows:

Authority: Sections 4, 6, and 8, Occupational Safety and Health Act, 29 U.S.C. 653, 655, and 657; Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable; and 29 CFR part 1911.

All of subpart Z, issued under section 6(b) of the Occupational Safety and Health Act, 29 U.S.C. 655(b) except those substances listed in the Final Rule Limits columns of Table Z–1–A, which have identical limits listed in the Transitional Limits columns of Table Z–1–A, Table Z–2, or Table Z–3. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, the Transitional Limits columns of Table Z–1–A, Table Z–2, and Table Z–3 also issued under 5 U.S.C. 533. Section 1910.1000, the Transitional Limits columns of Table Z–1–A, Table Z–2, and Table Z–3 not issued under 29 CFR part 1911 except for the arsenic, benzene, cotton dust, and formaldehyde listings.

Section 1910.1001 also issued under sec. 107 of Contract Work Hours and Safety Standards Act, 40 U.S.C. 333.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

Section 1910.1025 also issued under 5 U.S.C. 553.

Section 1910.1043 also issued under 5 U.S.C. 551 et seq.

Sections 1910.1200, 1910.1499 and 1910.1500 also issued under 5 U.S.C. 553.".

61. Beginning on page 42388, third column, paragraph "6.", is corrected to read,

"6. In § 1910.1000, Table Z–2, footnotes "1" and "2" are renamed "a" and "b", respectively, and a footnote superscript "c" is added after the entries "Cadmium fume (Z37.5–1970)" and "Cadmium dust (Z37.5–1970)" and footnote "c" is added after footnote "b" to read "c. This standard applies to any operations or sectors for which § 1910.1027 is stayed or otherwise not in effect.".

62. On page 42389, first column, amendatory instruction 7. is corrected by revising the phrase "a new subpart Z" to read "subparts m through y are added and reserved and a new subpart Z—Toxic and Hazardous Substances".

63. On page 42389, first column, paragraph (b), seventh definition, lines 1 and 2, are corrected to read, "High-efficiency particulate air (HEPA) filter means a filter capable".

64. On page 42391, first column, paragraph (f)(4) is deleted.

65. On page 42391, Table 2.—Respiratory Protection for Cadmium, column under the heading "Required respirator type [b]", line 11, the phrase "unknown concentrations" is deleted.

66. On page 42391, Table 2.—Respiratory Protection for Cadmium, footnote c, is corrected to read, "HEPA means High-efficiency Particulate Air.".

67. On page 42392, second column, paragraph (i)(2)(iv), line 8, is corrected to read "paragraph (m)(3) of this section.".

68. On page 42393, third column, paragraph (l)(3)(i)(B), line 6, is corrected to read, "CdB one year after the initial".

69. On page 42395, first column, paragraph (l)(4)(iv), lines 7 through 10, are corrected to read, "specified in paragraphs (l)(3) (ii) or (iii); or, beginning on January 1, 1999, in excess of the levels specified in paragraphs (l)(3) (ii) or (iv) of this section, the".

70. On page 42395, first column, paragraph (l)(4)(v)(A), line 8, is corrected to read, "(l)(3)(i)(B) of this section one year".

71. On page 42395, second column, paragraph (l)(4)(v)(B), line 9, the word, "within" is deleted.

72. On page 42395, second column, paragraph (l)(4)(v)(B), line 12, is corrected to read, "monitoring, specified in".

73. On page 42396, first column, paragraph (l)(6)(iv), line 3, is corrected to read, "(l)(6)(i), (ii), or (iii) of this section are".

74. On page 42396, third column, paragraph (l)(11)(iv), line 5, is corrected to read, "medical removal trigger".

75. On page 42397, third column, paragraph (l)(16), lines 5 through 7, are corrected to read, "condition or disorder caused by occupational exposure to cadmium associated with employment as".

76. On page 42398, first column, paragraph (m)(4)(iii)(A), lines 4 and 5, are corrected to read, "incorporated in appendix A to this section:".

77. On page 42398, second column, paragraph (m)(4)(iii)(H), is corrected to read, "(H) The employee's rights of access to records under § 1910.20 (e) and (g).".

78. On page 42400, second column, paragraph "C. Employee Requirements", line 10, is corrected to read, "source of unnecessary cadmium exposure.".

79. On page 42402, third column, paragraph "b.", line 5, is corrected to read, "telephone: 202–219–7894.".

80. On page 42407, second column, a new paragraph "4." is to be inserted immediately preceding paragraph "C. Quantitative Fit Test (QNFT) Protocol" to read as follows.

"4. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) Threshold screening as well as fit testing subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a 3/4-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see(b)(5) below) in 100 cc of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(6) As before, the test subject shall breathe through the open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I.A. 14 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried".

81. On page 42412, first column, Appendix E, paragraph 3.5.5., is corrected to read, "Magnesium nitrate, $Mg(NO_3)_2 \bullet 6H_2O$".

82. On page 42412, second column, paragraph 3.5.8., line 3, is corrected to read, "$Mg(NO_3)_2 \bullet 6H_2O$ in approximately 200 mL deionized".

83. On page 42412, table at the top of the third column, the fifth entry in the column marked "Aliquot" is corrected to read "5".

84. On page 42412, third column, paragraph 3.10.1, line 17, is corrected to read, "method are given in Attachment 1.".

85. On page 42413, second column, line 14, is corrected to read, "Attachment 2."

86. On page 42414, first column, paragraph 4.2.1., line 12, is corrected to read, "parameters are listed in Attachment 1.".

87. On page 42414, second column, line 6, is corrected to read, "are listed in Attachment 2.".

88. On page 42414, second column, paragraph 4.3.2., line 2, is corrected to read, "$NH_4H_2PO_4$ and magnesium nitrate, $Mg(NO_3)_2\ 6H_2O$,".

89. On page 42419, first column, first full paragraph, line 10, is corrected to read, "decisions made by the" by deleting the word "discretionary".

90. On page 42419, third column, fourth full paragraph labeled, "Target Value:", lines 5 through 10 is corrected to read,

"rule. For CDB, the target values are 5, 10, and 15 μg/l. For CDU, the target values are 3, 7, and 15 μg/g CRTU. For β_2MU, the target values are 300, 750 and 1500 μg/g CRTU. (Note that target values may vary as a function of time.)".

91. On page 42420, second column, first paragraph, lines 6 through 12 are deleted.

92. On page 42420, second column, first paragraph, line 13, is corrected to read, "In determining which laboratories to employ for".

93. On page 42421, third column, sixth full paragraph, lines 13 and 14 are corrected to read "than for CTQ proficiency testing should be accompanied".

94. On page 42422, first column, line 3, delete the parenthetical notation, "(i.e., compliance samples),".

95. On page 42422, second column, fourth paragraph under paragraph 3.3.1.1., line 3, the symbol "+" is deleted.

96. On page 42422, third column, second paragraph, lines 6 and 7 are corrected to read, "compliance samples or at least one set of QC samples per analysis of compliance samples, whichever is greater. If only 2 samples".

97. On page 42422, third column, sixth paragraph, line 5, place a "^" above the "σ".

98. On page 42422, third column, sixth paragraph, line 7, is corrected to read, "(e.g., ± 1 μg or 15% of the mean, whichever is".

99. On page 42423, first column under Table 2, second paragraph, line 11, should be corrected to read, "the period; and, use of $\bar{X} \pm 2\hat{\sigma}$(as defined".

100. On page 42423, first column under table 2, third paragraph, line 7, is corrected to read, "values, $\bar{X}$, (with N being the total number of samples analyzed):".

101. On page 42423, second column under table 2, first line below the first formula, place a "^" above the "σ".

102. On page 42423, second column under table 2, third line below the first formula, place a "^" above the "σ".

103. On page 42423, second column below table 2, second formula, place a "^" above the "σ" on the left side of the equation and correct the lower case "n" in the denominator to read an upper case "N".

104. On page 42423, second column below table 2, first full paragraph under the second formula, line 2, is corrected to read, "Attachment 1) indicates that QC samples".

105. On page 42424, first column, first full paragraph, lines 2 and 3, place "^" above the "σ"s.

106. On page 42426, first column, fourth paragraph, line 16, the word "inperindividual" is corrected to read, "interindividual".

107. On page 42429, first column, first paragraph, line 6, the term, "cadmium-13" is corrected to read, "cadmium-113".

108. On page 42430, third column, first paragraph, line 4, is corrected to read, "± 10% of the true value at CDB".

109. On page 42430, in table 4, eighth column, delete the "±" so the heading is corrected to read, "Geometric mean (GSD)[e]".

110. On page 42430, in table 4, the text of footnotes a through g were omitted. The text of the footnotes should be as follows:

[a] Concentrations reported in μg Cd/l blood unless otherwise stated.
[b] NS—never smoked; S—current cigarette smoker.
[c] S.D.—Arithmetic Standard Deviation.
[d] C.I.—Confidence interval.
[e] GSD—Geometric Standard Deviation.
[f] Based on an assumed lognormal distribution.
[g] Based on an assumed normal distribution.

111. On page 42431 and page 42432, in table 5, column heading "Geometric mean (±GSD)[e]" is corrected to read "Geometric mean (GSD)[e]".

112. On page 42431 and page 42432, in Table 5, column heading,

"Lower 95th percentile of range[e] ( )[f]

should be corrected to read,

"Lower 95th percentile of range[e] ( )[f]

113. On page 42431 and page 42432, in Table 5, column heading,

"Upper 95th percentile of range[e] ( )[f]"

should be corrected to read,

"Upper 95th percentile of range[e] ( )[f]

114. On page 42431, in table 5, column headed "Mean concentration of cadmium in air (μg/m³)", first entry, is corrected to read, "≤90".

115. On page 42431, in table 5, column headed "Employment in years (mean)", tenth entry, is corrected to read "(4.2)[g]".

116. On page 42431 and page 42432, in table 5, the text of footnotes a through g was omitted. The text of the footnotes should be as follows:

[a] Concentrations reported in μg Cd/l blood unless otherwise stated.
[b] S.D.—Standard Deviation.
[c] C.I.—Confidence Interval.
[d] GSD—Geometric Standard Deviation.
[e] Based on an assumed lognormal distribution.
[f] Based on an assumed normal distribution.
[g] Years following removal.

117. On page 42432, third column, paragraph 5.1.7.3., line 12, is corrected to read, "presented in Attachment 1 is based on the".

118. On page 42434, second column, first full paragraph, lines 6 and 7, are corrected to read, "(target of ±2 μg/l or 15% of the consensus mean, whichever is greater) were achieved by only 44–52% of the 34 laboratories participating in the".

119. On page 42435 and page 42356, table 8, in the heading, the word "CONCENTRATION'S" is corrected to read, "CONCENTRATIONS".

120. On page 42435 and page 42356, table 8, column heading "Geometric mean (±GSD)[e]" is corrected to read "Geometric mean (GSD)[e]".

121. On page 42435, table 8, in the second column headed, "Work Environment", delete the space between entry 16, "(Smokers)", and entry 17, "(Nonsmokers)", so that the data in the

columns to the right correspond correctly.

122. On page 42435 and 42436, in table 8, the text of footnotes a through h was omitted. The text of the footnotes should be as follows:

[a] Concentrations are reported in µg/g Cr.
[b] S.D.—Standard Deviation.
[c] C.I.—Confidence Interval.
[d] GSD—Geometric Standard Deviation.
[e] Based on an assumed lognormal distribution.
[f] Based on an assumed normal distribution.
[g] Years following removal.
[h] Equivalent to 50 for 20–22 yrs.

123. On page 42436, second column, line 12, is corrected to read, "lower than levels of other studies reported in Table 8.".

124. On page 42437, first column, first full paragraph, line 6, is corrected to read, "µg/l, a target precision of 40% is acceptable, while".

125. On page 42438, first column, line 22, is corrected to read, "listed in Table 9 (Section 5.3.7), the average".

126. On page 42438, third column, paragraph "5.3.7.1", line 17, is corrected to read, "dysfunction (including cadmium-exposed workers with none of".

127. On page 42438, in table 9, the text of footnotes a through f, h through k, and n and p was omitted. The text of the footnotes should be as follows:

a—Based on an assumed lognormal distribution
b—m = males, f = females
c—Aged general population from non-polluted area; 47.9% population aged 50–69; 52.1% ≥ 70 years of age; values reported in study
d—Exposed workers without proteinuria
e—492 females, 484 males
f—Creatinine-adjusted; males = 68.1 µg/g Cr, females = 64.3 µg/g Cr
h—Reported in the study
i—Arithmetic mean
j—Geometric standard error
k—Upper 95% tolerance limits: for Falck this is based on the 24 hour urine sample
n—Controls
p—Exposed synthetic resin and pigment workers without proteinuria; Cadmium in urine levels up to 10 µg/g Cr

128. On page 42440, first column, paragraph 5.3.8.3, line 5, the word, "Delphiad" is corrected to read, "Delphia".

129. On page 42440, second column, second paragraph under paragraph 5.4.3., line 4, the word, "chromofore", is corrected to read, "chromophore".

130. On page 42442, third column, first paragraph under the heading "Attachment 1—Nonmandatory Protocol for an Internal Quality Assurance/Quality Control Program" line 4, is corrected to read "satisfy OSHA requirements under".

131. On page 42442, third column, second paragraph under the heading "Attachment 1—Nonmandatory Protocol for an Internal Quality Assurance/Quality Control Program" line 2, is corrected to read "protocol, the QA/QC program for".

132. On page 42443, first column, first full paragraph is corrected to read, "All standards should be kept fresh, and as they get old, they should be compared with new standards and replaced if they exceed the new standards by ± 15%."

133. On page 42443, first column, first full paragraph under the heading "Initial Characterization Runs and Establishing Control" lines 3 and 4, are corrected to read, "of the analytes for which determinations will be made. The concentrations of quality".

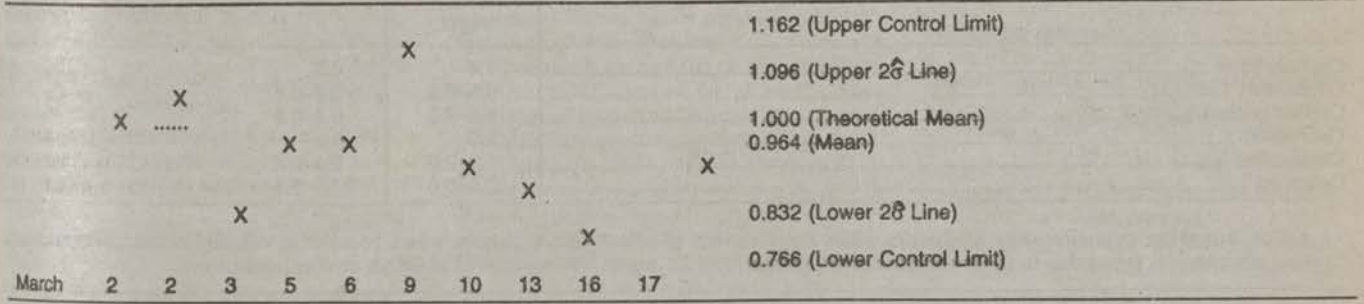
134. On page 42443, first column, last two lines above Figure 1, are corrected to read, "pool of each analyte for which determinations will be made and control charts".

135. On page 42443, second column, first paragraph following the second formula, lines 2 and 3 are corrected to read, "then given by the mean plus or minus 2 standard deviations ($X \pm 2\hat{\sigma}$). The control".

136. On page 42443, third column, third paragraph, line 10, insert "^" above the "σ".

137. On page 42443, Figure 1, is corrected to read,

"FIGURE 1.—THEORETICAL EXAMPLE OF A CONTROL CHART FOR A POOL OF AN ANALYTE



138. On page 42444, first column, first paragraph, lines 9 through 11, are corrected to read, "updated every 2 months.".

139. On page 42444, first column, in the fifth paragraph (numbered "2."), the statistical terms "2δ" are corrected to read "2σ̂".

140. On page 42444, second column, first paragraph under the heading "Corrective Actions", lines 14 and 15, are corrected to read, "(CAR) must be completed. CARs should be kept on file by the laboratory.".

141. On page 42444, second and third column, the second paragraph under the heading "Corrective Actions" is deleted.

142. Beginning on page 42444 and continuing through page 42446, "Attachment 2" is corrected to read,

Attachment 2

Creatinine in Urine (Jaffe Procedure)

Intended Use: The CREA pack is used in the Du Pont ACA® discrete clinical analyzer to quantitatively measure creatinine in serum and urine.

Summary: The CREA method employs a modification of the kinetic Jaffe reaction reported by Larsen. This method has been reported to be less susceptible than conventional methods to interference from noncreatinine, Jaffe-positive compounds.[1]

A split sample comparison between the CREA method and a conventional Jaffe procedure on Autoanalyzer® showed a good correlation. (See Specific Performance Characteristics).

* Note: Numbered subscripts refer to the bibliography and lettered subscripts refer to footnotes.

Autoanalyzer,® is a registered trademark of Technicon Corp., Tarrytown, NY.

Principles of Procedure: In the presence of a strong base such as NaOH, picrate reacts with creatinine to form a red chromophore. The rate of increasing absorbance at 510 nm

due to the formation of this chromophore during a 17.07-second measurement period is directly proportional to the creatinine concentration in the sample.

$$\text{Creatinine} + \text{Picrate} \xrightarrow{\text{NaOH}} \text{Red chromophore (absorbs at 510 nm)}$$

Reagents:

Compartment[a]	Form	Ingredient–Quantity[b]
No. 2, 3, & 4	Liquid Picrate ..	0.11 mmol.
No. 6	Liquid	NaOH (for pH adjustment)[c].

a. Compartments are numbered 1–7, with compartment #7 located closest to pack fill position #2.
b. Nominal value at manufacture.
c. See Precautions.

Precautions: Compartment #6 Contains 75µL of 10 N NaOH; Avoid Contact; Skin Irritant; Rinse Contacted Area With Water. Comply With OSHA's Bloodborne Pathogens Standard While Handling Biological Samples (29 CFR 1910.1039).

Used Packs Contain Human Body Fluids; Handle With Appropriate Care.

For In Vitro Diagnostic Use

Mixing and Diluting: Mixing and diluting are automatically performed by the ACA® discrete clinical analyzer. The sample cup must contain sufficient quantity to accommodate the sample volume plus the "dead volume"; precise cup filling is not required.

SAMPLE CUP VOLUMES (µL)

Analyzer	Standard		Microsystem	
	Dead	Total	Dead	Total
II, III	120	3000	10	500
IV, SX	120	3000	30	500
V	90	3000	10	500

Storage of Unprocessed Packs: Store at 2–8°C. Do not freeze. Do not expose to temperatures above 35° C or to direct sunlight.

Expiration: Refer to EXPIRATION DATE on the tray label.

Specimen Collection: Serum or urine can be collected and stored by normal procedures.[2]

Known Interfering Substances:[3]

• Serum Protein Influence—Serum protein levels exert a direct influence on the CREA assay. The following should be taken into account when this method is used for urine samples and when it is calibrated:

Aqueous creatinine standards or urine specimens will give CREA results depressed by approximately 0.7 mg/dL [62 µmol/L][d] and will be less precise than samples containing more than 3 g/dL [30 g/L] protein.

All urine specimens should be diluted with an albumin solution to give a final protein concentration of at least 3 g/dL [30 g/L]. Du Pont Enzyme Diluent (Cat. #790035-901) may be used for this purpose.

• High concentration of endrogenous bilirubin (>20 mg/dL [>342 µmol/L]) will give depressed CREA results (average depression 0.8 mg/dL [71 µmol/L]).[4]

• Grossly hemolyzed (hemoglobin >100 mg/dL [>62 µmol/L]) or visibly lipemic specimens may cause falsely elevated CREA results.[5,6]

• The following cephalosporin antibiotics do not interfere with the CREA method when present at the concentrations indicated. Systematic inaccuracies (bias) due to these substances are less than or equal to 0.1 mg/dL [8.84 µmol/L] at CREA concentrations of approximately 1 mg/dL [88 µmol/L].

Antibiotic	Peak serum level[7,8,9]	Drug concentration		
	mg/dL	[mmol/L]mg/dL		[mmol/L]
Cephaloridine	1.4	0.3	25	6.0
Cephalexin	0.6–2.0	0.2–0.6	25	7.2
Cephamandole	1.3–2.5	0.3–0.5	25	4.9
Cephapirin	2.0	0.4	25	5.6
Cephradine	1.5–2.0	0.4–0.6	25	7.1
Cefazolin	2.5–5.0	0.55–1.1	50	11.0

• The following cephalosporin antibiotics have been shown to affect CREA results when present at the indicated concentrations. System inaccuracies (bias) due to these substances are greater that 0.1 mg/dL [8.84 µmol/L] at CREA concentrations of:

Antibiotic	Peak serum level[8,10]	Drug concentration		
	mg/dL	[mmol/L]mg/dL		[mmol/L] effect (percent)
Cephalothin	1–6	0.2–1.5	10025.2	↓20–25
Cephoxitin	2.0	0.5	5.01.2	↑35–40

• The single wavelength measurement used in this method eliminates interference from chromophores whose 510 nm absorbance is constant throughout the measurement period.

• Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot to lot

Procedure:

d. Systeme International d'unites (S.I. Units) are in brackets.

TEST MATERIALS

Item	II, III Du Pont cat. No.	IV, SX Du Pont cat. No.	V Du Pont cat. No.
ACA® CREA Analytical Test Pack	701976901	701976901	701976901
Sample System Kit	710642901	710642901	713697901
or			
Micro Sample System Kit	702694901	710356901	NA
and			
Micro Sample System Holders	702785000	NA	NA
DYLUX® Photosensitive Printer Paper	700036000	NA	NA
Thermal Printer Paper	NA	710639901	713645901
Du Pont Purified Water	704209901	710615901	710815901
Cell Wash Solution	701864901	710664901	710864901

Test Steps: The operator need only load the sample kit and appropriate test pack(s) into a properly prepared ACA® discrete clinical analyzer. It automatically advances the pack(s) through the test steps and prints a result(s). See the Instrument Manual of the ACA® analyzer for details of mechanical travel of the test pack(s).

Preset Creatinine (CREA) Test Conditions

- Sample Volume: 200 µL
- Diluent: Purified Water
- Temperature: 37.0±0.1°C
- Reaction Period: 29 seconds
- Type of Measurement: Rate
- Measurement Period: 17.07 seconds
- Wavelength: 510 nm
- Units: mg/dL [µmol/L]

Calibration: The general calibration procedure is described in the Calibration/Verification chapter of the Manuals.

The following information should be considered when calibrating the CREA method.

- Assay Range: 0–20 mg/mL [0–1768 µmol/L][e]
- Reference Material: Protein containing primary standards[f] or secondary calibrators such as Du Pont Elevated Chemistry Control (Cat. #790035903) and Normal Chemistry Control (Cat.# 790035905)[g]
- Suggested Calibration Levels: 1,5,20, mg/mL [88, 442, 1768 µmol/L]
- Calibration Scheme: 3 levels, 3 packs per level
- Frequency: Each new pack lot. Every 3 months for any one pack lot.

PRESET CREATININE (CREA) TEST CONDITIONS

Item	ACA®II analyzer	ACA® III, IV, SX, V analyzer
Count by	One(1) [Five (5)].	NA

PRESET CREATININE (CREA) TEST CONDITIONS—Continued

Item	ACA®II analyzer	ACA® III, IV, SX, V analyzer
Decimal Point.	0.0 mg/dL	000.0 mg/dL
Location	[000. µmol/L]	[000 µmol/L]
Assigned Starting.	999.8	−1.000 E1
Point or Offset C_0.	[9823.]	[−8.840 E2]
Scale Factor or.	0.2000	2.004 E−1[h]
Assigned	mg/dL/count[h].	
Linear Term C_1[h].	[0.3536 µmol/L/count].	[1.772E1]

Quality Control: Two types of quality control procedures are recommended:

- General Instrument Check. Refer to the Filter Balance Procedure and the Absorbance Test Method described in the ACA Analyzer Instrument Manual. Refer also to the ABS Test Methodology literature.
- Creatinine Method Check. At least once daily run a CREA test on a solution of known creatinine activity such as an assayed control or calibration standard other than that used to calibrate the CREA method. For further details review the Quality Assurance Section of the Chemistry Manual. The result obtained should fall within acceptable limits defined by the day-to-day variability of the system as measured in the user's laboratory. (See SPECIFIC PERFORMANCE CHARACTERISTICS for guidance.) If the result falls outside the laboratory's acceptable limits, follow the procedure outlined in the Chemistry Troubleshooting Section of the Chemistry Manual.

A possible system malfunction is indicated when analysis of a sample with five consecutive test packs gives the following results:

Level	SD
1 mg/dL	>0.15 mg/dL
[88 µmol/L]	[>13 µmol/L]
20 mg/dL	>0.68 mg/dL
[1768 µmol/L]	[>60 µmol/L]

Refer to the procedure outlined in the Trouble Shooting Section of the Manual.

Results: The ACAR® analyzer automatically calculates and prints the CREA result in mg/dL [µmol/L].

Limitation of Procedure: Results >20 mg/dL [1768 µmol/L]:

- Dilute with suitable protein base diluent. Reassay. Correct for diluting before reporting.

The reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing a letter code or word immediately following the numerical value should not be reported. Refer to the Manual for the definition of error codes.

Reference Interval

Serum:[11,i]

Males	0.8–1.3 md/dL	[71–115 µmol/L]
Females	0.6–1.0 md/dL	[53–88 µmol/L]

Urine:[12]

Males	0.6–2.5 g/24 hr	[53–221 mmol/24 hr]
Females	0.6–1.5 g/24 hr	[53–133 mmol/24 hr]

i. Reference interval data obtained from 200 apparently healthy individuals (71 males, 129 females) between the ages of 19 and 72.

Each laboratory should establish its own reference intervals for CREA as performed on the analyzer.

Specific Performance Characteristics:[j]

e. For the results in S.I. units [µmol/L] the conversion factory is 88.4.

f. Refer to the Creatinine Standard Preparation and Calibration Procedure available on request from a Du Pont Representative.

g. If the Du Pont Chemistry Controls are being used, prepare them according to the instructions on the product insert sheets.

h. The preset scale factor (linear term) was derived from the molar absorptivity of the indicator and is based on an absorbance to activity relationship (sensitivity) of 0.596 (mA/min)/(U/L). Due to small differences in filters and electronic components between instruments, the actual scale factor (linear term) may differ slightly from that given above.

REPRODUCIBILITY[k]

Material	Mean	Standard deviation (percent CV)	
		Within-run	Between-day
Lyophilized	1.3	0.05 (3.7)	0.05 (3.7)
Control	[115]	[4.4]	[4.4]
Lyophilized	20.6	0.12 (0.6)	0.37 (1.8)
Control	[1821]	[10.6]	[32.7]

CORRELATION

[Regression statistics][l]

Comparative method	Slope	Intercept	Correlation coefficient	n
Autoanalyzer®	1.03	0.03 [2.7]	0.997	260

j. All specific performance characteristics tests were run after normal recommended equipment quality control checks were performed (see Instrument Manual).

k. Specimens at each level were analyzed in duplicate for twenty days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

l. Model equation for regression statistics is:

$$\text{Result of ACA}^{®}\text{ Analyzer} = \text{Slope (Comparative method result)} + \text{intercept}$$

Assay Range:[m] 0.0–20.0 mg/dl [0–1768 µmol]

m. See REPRODUCIBILITY for method performance within the assay range.

Analytical Specificity: See KNOWN INTERFERING SUBSTANCES section for details.

Bibliography:

[1] Larsen, K, Clin Chem Acta 41, 209 (1972).

[2] Tietz, NW, Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia, PA, 1976, pp 47–52, 1211.

[3] Supplementary information pertaining to the effects of various drugs and patient conditions on in vivo or in vitro diagnostic levels can be found in "Drug Interferences with Clinical Laboratory Tests," Clin. Chem 21 (5) (1975), and "Effects of Disease on Clinical Laboratory Tests," Clin Chem, 26 (4) 1D–476D (1980).

[4] Watkins, R. Fieldkamp, SC, Thibert, RJ, and Zak, B, Clin Chem, 21, 1002 (1975).

[5] Kawas, EE, Richards, AH, and Bigger, R, An Evaluation of a Kinetic Creatinine Test for the DuPont ACA, Du Pont Company, Wilmington, DE (February 1973). (Reprints available from Du Pont Company, Diagnostic Systems)

[6] Westgard, JO, Effects of Hemolysis and Lipemia on ACA Creatinine Method,0.200 µL, Sample Size, DuPont Company, Wilmington, DE (October 1972).

[7] Physicians' Desk Reference, Medical Economics Company, 33 Edition, 1979.

[8] Henry, JB, Clinical Diagnosis and Management by Laboratory Methods, W.B. Saunders Co., Philadelphia, PA 1979, Vol. III.

[9] Krupp, MA, Tierney, LM Jr., Jawetz, E, Roe, RI, Camargo, CA, Physicians Handbook, Lange Medical Publications, Los Altos, CA, 1982 pp 635–636.

[10] Sarah, AJ, Koch, TR, Drusano, GL, Celoxitin Falsely Elevates Creatinine Levels, JAMA 247, 205–206 (1982).

[11] Gadsden, RH, and Phelps, CA, A Normal Range Study of Amylase in Urine and Serum on the Du Pont ACA, DuPont Company, Wilmington, DE (March 1978). (Reprints available from DuPont Company, Diagnostic Systems).

[12] Dicht, JJ, Reference Intervals for Serum Amylase and Urinary Creatinine on the Du Pont ACA® Discrete Clinical Analyzer, DuPont Company, Wilmington, DE (November 1984).

143. On page 42446, third column, the heading "Attachment 3" is corrected to read, "**Attachment 3** Analysis of Creatinine for the Normalization of Cadmium and Beta-2-Microglobulin Concentrations in Urine (OSLTC Procedure)".

144. On page 42446, third column, lines 1, 2 and 3 under the heading "Attachment 3" are deleted.

145. On page 42447, first column, line 34, is corrected to read, "methylhydantoin-2-imide".

146. On page 42447 and page 42448, the Storage Data Table, is corrrected to read,

STORAGE DATA

Sample	4 days		54 days	
	W/o SEP–PAK g/L creatinine	With SEP–PAK g/L creatinine	W/o SEP–PAK g/L creatinine	With SEP–PAK g/L creatinine
Acid	1.09	1.09	1.08	1.09
Acid	1.10	1.10	1.09	1.10
Acid			1.09	1.09
Untreated	1.13	1.14	1.09	1.11
Untreated	1.15	1.14	1.10	1.10
Untreated			1.09	1.10
pH 7	1.14	1.13	1.12	1.12
pH 7	1.14	1.13	1.12	1.12
pH 7			1.12	1.12

147. On page 42448, first column, paragraph 2.7.2, line 6, is corrected to read, "(CDC) (Ref. 5.8.) and OSHA's Bloodborne Pathogens standard (29 CFR 1910.1039).".

148. On page 42448, second column, first paragraph under paragraph 3.3., line 1, is corrected to read, "3.3.1 Stock standards are prepared by".

149. On page 42452, first column, first formula, the result on the far right side of the equation reading "mg/L" is corrected by lowering it and made parallel to the middle column reading, "µg/mL".

150. On page 42452, first column, the far right side of the equation following paragraph "3.7.4.", is corrected to read, "µg A/g creatinine".

151. On page 42452, first column, heading "XI. Final Standard (Construction)" is corrected to read, "XII. Final Standard (Construction)".

PART 1926—[AMENDED]

152. On page 42452, second column, paragraph numbered, "10", line 6, is corrected to read, "C, D, E, and F of § 1910.1027 of subpart Z".

153. On page 42452, second column, paragraph (a)(6) is corrected to read,

"(6) Electrical grounding with cadmium welding, or electrical work using cadmium-coated conduit;".

154. On page 42453, first column, second full paragraph, lines 1 and 2, are corrected to read, "High-efficiency Particulate Air (HEPA) filter means a filter capable".

155. On page 42454, second column, paragraph (f)(5)(i), lines 1 through 8, are corrected to read,

(5) *Compliance program.* Where employee exposure to cadmium exceeds the PEL and the employer is required under paragraph (f)(1) of this section to implement controls to comply with the PEL, prior to the commencement of the job the employer shall establish and implement a written compliance program to reduce employee exposure to or below the PEL. To the extent that.

156. On page 42455, table 1.—Respiratory Protection for Cadmium, right column, line 2 under the heading, "Required respirator type b", is corrected by inserting a closed parenthesis after the abbreviation, "("PAPR" ".

157. On page 42455, table 1.—Respiratory Protection for Cadmium, right column, line 11 under heading "Required respirator type [b]", is corrected to read, "A self-contained breathing apparatus with a full facepiece operated in the pressure".

158. On page 42455, table 1.—Respiratory Protection for Cadmium, footnote c, is corrected to read, "HEPA means High-efficiency Particulate Air.".

159. On page 42456, third column, paragraph (l)(1)(i)(A), line 9, is corrected to read, "grounding with cadmium welding; cutting,".

160. On page 42456, third column, paragraph (l)(1)(i)(A), line 17, the word "reinforcing" is corrected to read, "reinforced".

161. On page 42457, third column, paragraph (l)(3)(i)(B), line 1, is corrected to read "one year after the initial".

162. On page 42458, third column, paragraph (l)(4)(iv), lines 7 through 13 are corrected to read,

"specified in paragraphs (l)(3)(ii) or (iii) of this section; or beginning on January 1, 1999, in excess of the levels specified in paragraphs (l)(3)(ii) or (iv), the employer shall take the appropriate actions specified in paragraphs (l)(3)(ii)–(iv) of this section, respectively.".

163. On page 42458, third column, paragraph (l)(4)(v)(A), line 8, is corrected to read, "(l)(3)(i)(B) of this section one year".

164. On page 42459, first column, paragraph (l)(4)(v)(B), line 10, the word "within" is deleted.

165. On page 42459, first column, paragraph (l)(4)(v)(B), line 13, is corrected to read, "monitoring specified in".

166. On page 42459, second column, paragraph (l)(6)(iv), lines 1 through 5 are corrected to read,

" (iv) Where the results of the examination required under paragraphs (l)(6)(i), (ii) or (iii) of this section are abnormal, medical limitation or prohibition of respirator use shall be".

167. On page 42459, third column, paragraph (l)(8)(ii), line 3, is corrected to read, "surveillance under paragraph (l)(4)(v) of".

168. On page 42462, first column, paragraph (m)(4)(iii)(H), line 2, is corrected to read, "records under § 1910.20(e) and (g)."

In addition to the corrections above, Part 1928 is being amended as set forth below:

PART 1928—[AMENDED]

1. The authority citation for 29 CFR part 1928, Subpart M is revised to read as follows:

Authority: Secs. 4, 6, and 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable; and 29 CFR part 1911.

Section 1928.21 also issued under 5 U.S.C. 553.

2. Part 1928 is amended by adding and reserving subparts J through L and adding a new subpart M—Occupational Health, consisting of a new section 1928.1027, as set forth below.

Subpart M—Occupational Health

§ 1928.1027 Cadmium

(a) Scope. This standard applies to all occupational exposures to cadmium and cadmium compounds, in all forms, and in all industries covered by the Occupational Safety and Health Act, except the construction-related industries, which are covered under 29 CFR 1926.63.

(b) Definitions. *Action level* (AL) is defined as an airborne concentration of cadmium of 2.5 micrograms per cubic meter of air (2.5 $\mu g/m^3$), calculated as an 8-hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person authorized by the employer and required by work duties to be present in regulated areas or any person authorized by the OSH Act or regulations issued under it to be in regulated areas.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Employee exposure and similar language referring to the air cadmium level to which an employee is exposed means the exposure to airborne cadmium that would occur if the employee were not using respiratory protective equipment.

Final medical determination is the written medical opinion of the employee's health status by the examining physician under paragraphs (l)(3)–(12) or, if multiple physician review under paragraph (l)(13) or the alternative physician determination under paragraph (l)(14) is invoked, it is the final, written medical finding, recommendation or determination that emerges from that process.

High-efficiency particulate air [HEPA] filter means a filter capable of trapping and retaining at least 99.97 percent of mono-dispersed particles of 0.3 micrometers in diameter.

Regulated area means an area demarcated by the employer where an employee's exposure to airborne concentrations of cadmium exceeds, or can reasonably be expected to exceed the permissible exposure limit (PEL).

This section means this cadmium standard.

(c) Permissible Exposure Limit (PEL).

The employer shall assure that no employee is exposed to an airborne concentration of cadmium in excess of

five micrograms per cubic meter of air (5 μg/m³), calculated as an eight-hour time-weighted average exposure (TWA).

(d) Exposure monitoring.

(1) *General.*

(i) Each employer who has a workplace or work operation covered by this section shall determine if any employee may be exposed to cadmium at or above the action level.

(ii) Determinations of employee exposure shall be made from breathing zone air samples that reflect the monitored employee's regular, daily 8-hour TWA exposure to cadmium.

(iii) Eight-hour TWA exposures shall be determined for each employee on the basis of one or more personal breathing zone air samples reflecting full shift exposure on each shift, for each job classification, in each work area. Where several employees perform the same job tasks, in the same job classification, on the same shift, in the same work area, and the length, duration, and level of cadmium exposures are similar, an employer may sample a representative fraction of the employees instead of all employees in order to meet this requirement. In representative sampling, the employer shall sample the employee(s) expected to have the highest cadmium exposures.

(2) *Specific.*

(i) *Initial monitoring.* Except as provided for in paragraphs (d)(2)(ii) and (d)(2)(iii) of this section, the employer shall monitor employee exposures and shall base initial determinations on the monitoring results.

(ii) Where the employer has monitored after September 14, 1991, under conditions that in all important aspects closely resemble those currently prevailing and where that monitoring satisfies all other requirements of this section, including the accuracy and confidence levels of paragraph (d)(6), the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(iii) Where the employer has objective data, as defined in paragraph (n)(2) of this section, demonstrating that employee exposure to cadmium will not exceed the action level under the expected conditions of processing, use, or handling, the employer may rely upon such data instead of implementing initial monitoring.

(3) *Monitoring frequency (periodic monitoring).*

(i) If the initial monitoring or periodic monitoring reveals employee exposures to be at or above the action level, the employer shall monitor at a frequency and pattern needed to represent the levels of exposure of employees and where exposures are above the PEL to assure the adequacy of respiratory selection and the effectiveness of engineering and work practice controls. However, such exposure monitoring shall be performed at least every six months. The employer, at a minimum, shall continue these semi-annual measurements unless and until the conditions set out in paragraph (d)(3)(ii) are met.

(ii) If the initial monitoring or the periodic monitoring indicates that employee exposures are below the action level and that result is confirmed by the results of another monitoring taken at least seven days later, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(4) *Additional monitoring.*

The employer also shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change in the raw materials, equipment, personnel, work practices, or finished products that may result in additional employees being exposed to cadmium at or above the action level or in employees already exposed to cadmium at or above the action level being exposed above the PEL, or whenever the employer has any reason to suspect that any other change might result in such further exposure.

(5) *Employee notification of monitoring results.*

(i) Within 15 working days after the receipt of the results of any monitoring performed under this section, the employer shall notify each affected employee individually in writing of the results. In addition, within the same time period the employer shall post the results of the exposure monitoring in an appropriate location that is accessible to all affected employees.

(ii) Wherever monitoring results indicate that employee exposure exceeds the PEL, the employer shall include in the written notice a statement that the PEL has been exceeded and a description of the corrective action being taken by the employer to reduce employee exposure to or below the PEL.

(6) *Accuracy of measurement.*

The employer shall use a method of monitoring and analysis that has an accuracy of not less than plus or minus 25 percent (±25%), with a confidence level of 95 percent, for airborne concentrations of cadmium at or above the action level, the permissible exposure limit (PEL), and the separate engineering control air limit (SECAL).

(e) Regulated areas.

(1) *Establishment.* The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of cadmium is, or can reasonably be expected to be in excess of the permissible exposure limit (PEL).

(2) *Demarcation.* Regulated areas shall be demarcated from the rest of the workplace in any manner that adequately establishes and alerts employees of the boundaries of the regulated area.

(3) *Access.* Access to regulated areas shall be limited to authorized persons.

(4) *Provision of respirators.* Each person entering a regulated area shall be supplied with and required to use a respirator, selected in accordance with paragraph (g)(2) of this section.

(5) *Prohibited activities.* The employer shall assure that employees do not eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas, carry the products associated with these activities into regulated areas, or store such products in those areas.

(f) Methods of compliance.

(1) *Compliance hierarchy.*

(i) Except as specified in paragraphs (f)(1) (ii), (iii) and (iv) of this section the employer shall implement engineering and work practice controls to reduce and maintain employee exposure to cadmium at or below the PEL, except to the extent that the employer can demonstrate that such controls are not feasible.

(ii) Except as specified in paragraphs (f)(1) (iii) and (iv) of this section, in industries where a separate engineering control air limit (SECAL) has been specified for particular processes (See Table 1), the employer shall implement engineering and work practice controls to reduce and maintain employee exposure at or below the SECAL, except to the extent that the employer can demonstrate that such controls are not feasible.

TABLE I.—SEPARATE ENGINEERING CONTROL AIRBORNE LIMITS (SECALS) FOR PROCESSES IN SELECTED INDUSTRIES

Industry	Process	SECAL (μg/m³)
Nickel Cadmium Battery ..	Plate making, plate preparation	50

TABLE I.—SEPARATE ENGINEERING CONTROL AIRBORNE LIMITS (SECALS) FOR PROCESSES IN SELECTED INDUSTRIES—Continued

Industry	Process	SECAL (μg/m³)
	All other processes	15
Zinc/Cadmium Refining [1]	Cadmium refining, casting, melting, oxide production, sinter plant	50
Pigment Manufacture	Calcine, crushing, milling, blending	50
	All other processes	15
Stabilizers [1]	Cadmium oxide charging, crushing, drying, blending	50
Lead Smelting [1]	Sinter plant, blast furnace, baghouse, yard area	50
Plating [1]	Mechanical plating	15

[1] Processes in these industries that are not specified in this table must achieve the PEL using engineering controls and work practices as required in f(1)(i).

(iii) The requirement to implement engineering and work practice controls to achieve the PEL or, where applicable, the SECAL does not apply where the employer demonstrates the following:

(A) The employee is only intermittently exposed; and

(B) The employee is not exposed above the PEL on 30 or more days per year (12 consecutive months).

(iv) Wherever engineering and work practice controls are required and are not sufficient to reduce employee exposure to or below the PEL or, where applicable, the SECAL, the employer nonetheless shall implement such controls to reduce exposures to the lowest levels achievable. The employer shall supplement such controls with respiratory protection that complies with the requirements of paragraph (g) of this section and the PEL.

(v) The employer shall not use employee rotation as a method of compliance.

(2) *Compliance program.*

(i) Where the PEL is exceeded, the employer shall establish and implement a written compliance program to reduce employee exposure to or below the PEL by means of engineering and work practice controls, as required by paragraph (f)(1) of this section. To the extent that engineering and work practice controls cannot reduce exposures to or below the PEL, the employer shall include in the written compliance program the use of appropriate respiratory protection to achieve compliance with the PEL.

(ii) Written compliance programs shall include at least the following:

(A) A description of each operation in which cadmium is emitted; e.g., machinery used, material processed, controls in place, crew size, employee job responsibilities, operating procedures, and maintenance practices;

(B) A description of the specific means that will be employed to achieve compliance, including engineering plans and studies used to determine methods selected for controlling exposure to cadmium, as well as, where necessary, the use of appropriate respiratory protection to achieve the PEL;

(C) A report of the technology considered in meeting the PEL;

(D) Air monitoring data that document the sources of cadmium emissions;

(E) A detailed schedule for implementation of the program, including documentation such as copies of purchase orders for equipment, construction contracts, etc.;

(F) A work practice program that includes items required under paragraphs (h),(i), and (j) of this section;

(G) A written plan for emergency situations, as specified in paragraph (h) of this section; and

(H) Other relevant information.

(iii) The written compliance programs shall be reviewed and updated at least annually, or more often if necessary, to reflect significant changes in the employer's compliance status.

(iv) Written compliance programs shall be provided upon request for examination and copying to affected employees, designated employee representatives as well as to the Assistant Secretary, and the Director.

(3) *Mechanical ventilation.*

(i) When ventilation is used to control exposure, measurements that demonstrate the effectiveness of the system in controlling exposure, such as capture velocity, duct velocity, or static pressure shall be made as necessary to maintain its effectiveness.

(ii) Measurements of the system's effectiveness in controlling exposure shall be made as necessary within five working days of any change in production, process, or control that might result in a significant increase in employee exposure to cadmium.

(iii) *Recirculation of air.* If air from exhaust ventilation is recirculated into the workplace, the system shall have a high efficiency filter and be monitored to assure effectiveness.

(iv) Procedures shall be developed and implemented to minimize employee exposure to cadmium when maintenance of ventilation systems and changing of filters is being conducted.

(g) Respirator protection.

(1) *General.*

Where respirators are required by this section, the employer shall provide them at no cost to the employee and shall assure that they are used in compliance with the requirements of this section. Respirators shall be used in the following circumstances:

(i) Where exposure levels exceed the PEL, during the time period necessary to install or implement feasible engineering and work practice controls;

(ii) In those maintenance and repair activities and during those brief or intermittent operations where exposures exceed the PEL and engineering and work practice controls are not feasible or are not required;

(iii) In regulated areas, as prescribed in paragraph (e) of this section;

(iv) Where the employer has implemented all feasible engineering and work practice controls and such controls are not sufficient to reduce exposures to or below the PEL;

(v) In emergencies;

(vi) Wherever an employee who is exposed to cadmium at or above the action level requests a respirator;

(vii) Wherever an employee is exposed above the PEL in an industry to which a SECAL is applicable; and

(viii) Wherever an employee is exposed to cadmium above the PEL and engineering controls are not required under paragraph (f)(1)(iii) of this section.

(2) *Respirator selection.*

(i) Where respirators are required under this section, the employer shall select and provide the appropriate respirator as specified in Table 2. The employer shall select respirators from among those jointly approved as acceptable protection against cadmium dust, fume, and mist by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11.

TABLE 2.—RESPIRATORY PROTECTION FOR CADMIUM

Airborne concentration or condition of use [a]	Required respirator type [b]
10 × or less	A half mask, air-purifying respirator equipped with a HEPA [c] filter [d].
25 × or less	A powered air-purifying respirator ("PAPR") with a loose-fitting hood or helmet equipped with a HEPA filter, or a supplied-air respirator with a loose-fitting hood or helmet facepiece operated in the continuous flow mode.
50 × or less	A full facepiece air-purifying respirator equipped with a HEPA filter, or a powered air-purifying respirator with a tight-fitting half mask equipped with a HEPA filter, or a supplied air respirator with a tight-fitting half mask operated in the continuous flow mode.
250 × or less	A powered air-purifying respirator with a tight-fitting full facepiece equipped with a HEPA filter, or a supplied-air respirator with a tight-fitting full facepiece operated in the continuous flow mode.
1000 × or less	A supplied-air respirator with half mask or full facepiece operated in the pressure demand or other positive pressure mode.
>1000 × or unknown concentrations	A self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode, or a supplied-air respirator with a full facepiece operated in the pressure demand or other positive pressure mode and equipped with an auxiliary escape type self contained breathing apparatus operated in the pressure demand mode.
Fire fighting	A self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

[a] Concentrations expressed as multiple of the PEL.
[b] Respirators assigned for higher environmental concentrations may be used at lower exposure levels. Quantitative fit testing is required for all tight-fitting air purifying respirators where airborne concentration of cadmium exceeds 10 times the TWA PEL ($10 \times 5\ \mu g/m^3 = 50\ \mu g/m^3$). A full facepiece respirator is required when eye irritation is experienced.
[c] HEPA means High Efficiency Particulate Air.
[d] Fit testing, qualitative or quantitative, is required.
Source: *Respiratory Decision Logic*, NIOSH, 1987.

(ii) The employer shall provide a powered, air-purifying respirator (PAPR) in lieu of a negative pressure respirator wherever:

(A) An employee entitled to a respirator chooses to use this type of respirator; and

(B) This respirator will provide adequate protection to the employee.

(3) *Respirator program.*

(i) Where respiratory protection is required, the employer shall institute a respirator protection program in accordance with 29 CFR 1910.134.

(ii) The employer shall permit each employee who is required to use an air purifying respirator to leave the regulated area to change the filter elements or replace the respirator whenever an increase in breathing resistance is detected and shall maintain an adequate supply of filter elements for this purpose.

(iii) The employer shall also permit each employee who is required to wear a respirator to leave the regulated area to wash his or her face and the respirator facepiece whenever necessary to prevent skin irritation associated with respirator use.

(iv) If an employee exhibits difficulty in breathing while wearing a respirator during a fit test or during use, the employer shall make available to the employee a medical examination in accordance with paragraph (l)(6)(ii) of this section to determine if the employee can wear a respirator while performing the required duties.

(v) No employee shall be assigned a task requiring the use of a respirator if, based upon his or her most recent examination, an examining physician determines that the employee will be unable to continue to function normally while wearing a respirator. If the physician determines the employee must be limited in, or removed from his or her current job because of the employee's inability to wear a respirator, the limitation or removal shall be in accordance with paragraphs (l)(11) and (12) of this section.

(4) *Respirator fit testing.*

(i) The employer shall assure that the respirator issued to the employee is fitted properly and exhibits the least possible facepiece leakage.

(ii) For each employee wearing a tight-fitting, air purifying respirator (either negative or positive pressure) who is exposed to airborne concentrations of cadmium that do not exceed 10 times the PEL ($10 \times 5\ \mu g/m^3 = 50\ \mu g/m^3$), the employer shall perform either quantitative or qualitative fit testing at the time of initial fitting and at least annually thereafter. If quantitative fit testing is used for a negative pressure respirator, a fit factor that is at least 10 times the protection factor for that class of respirators (Table 2) shall be achieved at testing.

(iii) For each employee wearing a tight-fitting air purifying respirator (either negative or positive pressure) who is exposed to airborne concentrations of cadmium that exceed 10 times the PEL ($10 \times 5\ \mu g/m^3 = 50\ \mu g/m^3$), the employer shall perform quantitative fit testing at the time of initial fitting and at least annually thereafter. For negative-pressure respirators, a fit factor that is at least 10 times the protection factor for that class of respirators (Table 2) shall be achieved during quantitative fit testing.

(iv) For each employee wearing a tight-fitting, supplied-air respirator or self-contained breathing apparatus, the employer shall perform quantitative fit testing at the time of initial fitting and at least annually thereafter. This shall be accomplished by fit testing an air purifying respirator of identical type facepiece, make, model, and size as the supplied air respirator or self-contained breathing apparatus that is equipped with HEPA filters and tested as a surrogate (substitute) in the negative pressure mode. A fit factor that is at least 10 times the protection factor for that class of respirators (Table 2) shall be achieved during quantitative fit testing. A supplied-air respirator or self-contained breathing apparatus with the same type facepiece, make, model, and size as the air purifying respirator with which the employee passed the quantitative fit test may then be used by that employee up to the protection factor listed in Table 2 for that class of respirators.

(v) Fit testing shall be conducted in accordance with Appendix C of this section.

(h) Emergency situations.

The employer shall develop and implement a written plan for dealing with emergency situations involving substantial releases of airborne cadmium. The plan shall include provisions for the use of appropriate respirators and personal protective equipment. In addition, employees not essential to correcting the emergency situation shall be restricted from the area and normal operations halted in that area until the emergency is abated.

(i) Protective work clothing and equipment.

(1) *Provision and use.*

If an employee is exposed to airborne cadmium above the PEL or where skin or eye irritation is associated with cadmium exposure at any level, the employer shall provide at no cost to the employee, and assure that the employee uses, appropriate protective work clothing and equipment that prevents contamination of the employee and the employee's garments. Protective work clothing and equipment includes, but is not limited to:

(i) Coveralls or similar full-body work clothing;

(ii) Gloves, head coverings, and boots or foot coverings; and

(iii) Face shields, vented goggles, or other appropriate protective equipment that complies with 29 CFR 1910.133.

(2) *Removal and storage.*

(i) The employer shall assure that employees remove all protective clothing and equipment contaminated with cadmium at the completion of the work shift and do so only in change rooms provided in accordance with paragraph (j)(1) of this section.

(ii) The employer shall assure that no employee takes cadmium-contaminated protective clothing or equipment from the workplace, except for employees authorized to do so for purposes of laundering, cleaning, maintaining, or disposing of cadmium contaminated protective clothing and equipment at an appropriate location or facility away from the workplace.

(iii) The employer shall assure that contaminated protective clothing and equipment, when removed for laundering, cleaning, maintenance, or disposal, is placed and stored in sealed, impermeable bags or other closed, impermeable containers that are designed to prevent dispersion of cadmium dust.

(iv) The employer shall assure that bags or containers of contaminated protective clothing and equipment that are to be taken out of the change rooms or the workplace for laundering, cleaning, maintenance or disposal shall bear labels in accordance with paragraph (m)(3) of this section.

(3) *Cleaning, replacement, and disposal.*

(i) The employer shall provide the protective clothing and equipment required by paragraph (i)(1) of this section in a clean and dry condition as often as necessary to maintain its effectiveness, but in any event at least weekly. The employer is responsible for cleaning and laundering the protective clothing and equipment required by this paragraph to maintain its effectiveness and is also responsible for disposing of such clothing and equipment.

(ii) The employer also is responsible for repairing or replacing required protective clothing and equipment as needed to maintain its effectiveness. When rips or tears are detected while an employee is working they shall be immediately mended, or the worksuit shall be immediately replaced.

(iii) The employer shall prohibit the removal of cadmium from protective clothing and equipment by blowing, shaking, or any other means that disperses cadmium into the air.

(iv) The employer shall assure that any laundering of contaminated clothing or cleaning of contaminated equipment in the workplace is done in a manner that prevents the release of airborne cadmium in excess of the permissible exposure limit prescribed in paragraph (c) of this section.

(v) The employer shall inform any person who launders or cleans protective clothing or equipment contaminated with cadmium of the potentially harmful effects of exposure to cadmium and that the clothing and equipment should be laundered or cleaned in a manner to effectively prevent the release of airborne cadmium in excess of the PEL.

(j) Hygiene areas and practices.

(1) *General.*

For employees whose airborne exposure to cadmium is above the PEL, the employer shall provide clean change rooms, handwashing facilities, showers, and lunchroom facilities that comply with 29 CFR 1910.141.

(2) *Change rooms.*

The employer shall assure that change rooms are equipped with separate storage facilities for street clothes and for protective clothing and equipment, which are designed to prevent dispersion of cadmium and contamination of the employee's street clothes.

(3) *Showers and handwashing facilities.*

(i) The employer shall assure that employees who are exposed to cadmium above the PEL shower during the end of the work shift.

(ii) The employer shall assure that employees whose airborne exposure to cadmium is above the PEL wash their hands and faces prior to eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics.

(4) *Lunchroom facilities.*

(i) The employer shall assure that the lunchroom facilities are readily accessible to employees, that tables for eating are maintained free of cadmium, and that no employee in a lunchroom facility is exposed at any time to cadmium at or above a concentration of 2.5 $\mu g/m^3$.

(ii) The employer shall assure that employees do not enter lunchroom facilities with protective work clothing or equipment unless surface cadmium has been removed from the clothing and equipment by HEPA vacuuming or some other method that removes cadmium dust without dispersing it.

(k) Housekeeping.

(1) All surfaces shall be maintained as free as practicable of accumulations of cadmium.

(2) All spills and sudden releases of material containing cadmium shall be cleaned up as soon as possible.

(3) Surfaces contaminated with cadmium shall, wherever possible, be cleaned by vacuuming or other methods that minimize the likelihood of cadmium becoming airborne.

(4) HEPA-filtered vacuuming equipment or equally effective filtration methods shall be used for vacuuming. The equipment shall be used and emptied in a manner that minimizes the reentry of cadmium into the workplace.

(5) Shoveling, dry or wet sweeping, and brushing may be used only where vacuuming or other methods that minimize the likelihood of cadmium becoming airborne have been tried and found not to be effective.

(6) Compressed air shall not be used to remove cadmium from any surface unless the compressed air is used in conjunction with a ventilation system designed to capture the dust cloud created by the compressed air.

(7) Waste, scrap, debris, bags, containers, personal protective equipment, and clothing contaminated with cadmium and consigned for disposal shall be collected and disposed of in sealed impermeable bags or other closed, impermeable containers. These bags and containers shall be labeled in accordance with paragraph (m)(2) of this section.

(l) Medical surveillance.

(1) *General.*

(i) *Scope.*

(A) Currently exposed—The employer shall institute a medical surveillance program for all employees who are or

may be exposed to cadmium at or above the action level unless the employer demonstrates that the employee is not, and will not be, exposed at or above the action level on 30 or more days per year (twelve consecutive months); and,

(B) Previously exposed—The employer shall also institute a medical surveillance program for all employees who prior to the effective date of this section might previously have been exposed to cadmium at or above the action level by the employer, unless the employer demonstrates that the employee did not prior to the effective date of this section work for the employer in jobs with exposure to cadmium for an aggregated total of more than 60 months.

(ii) To determine an employee's fitness for using a respirator, the employer shall provide the limited medical examination specified in paragraph (l)(6) of this section.

(iii) The employer shall assure that all medical examinations and procedures required by this standard are performed by or under the supervision of a licensed physician, who has read and is familiar with the health effects section of Appendix A, the regulatory text of this section, the protocol for sample handling and laboratory selection in Appendix F, and the questionnaire of Appendix D. These examinations and procedures shall be provided without cost to the employee and at a time and place that is reasonable and convenient to employees.

(iv) The employer shall assure that the collecting and handling of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (β_2-M) taken from employees under this section is done in a manner that assures their reliability and that analysis of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (β_2-M) taken from employees under this section is performed in laboratories with demonstrated proficiency for that particular analyte. (See Appendix F.)

(2) *Initial examination.*

(i) The employer shall provide an initial (preplacement) examination to all employees covered by the medical surveillance program required in paragraph (l)(1)(i) of this section. The examination shall be provided to those employees within 30 days after initial assignment to a job with exposure to cadmium or no later than 90 days after the effective date of this section, whichever date is later.

(ii) The initial (preplacement) medical examination shall include:

(A) A detailed medical and work history, with emphasis on: past, present, and anticipated future exposure to cadmium; any history of renal, cardiovascular, respiratory, hematopoietic, reproductive, and/or musculo-skeletal system dysfunction; current usage of medication with potential nephrotoxic side-effects; and smoking history and current status; and

(B) Biological monitoring that includes the following tests:

(*1*) Cadmium in urine (CdU), standardized to grams of creatinine (g/Cr);

(*2*) Beta-2 microglobulin in urine (β_2-M), standardized to grams of creatinine (g/Cr), with pH specified, as described in Appendix F; and

(*3*) Cadmium in blood (CdB), standardized to liters of whole blood (lwb).

(iii) *Recent examination:* An initial examination is not required to be provided if adequate records show that the employee has been examined in accordance with the requirements of paragraph (l)(2)(ii) of this section within the past 12 months. In that case, such records shall be maintained as part of the employee's medical record and the prior exam shall be treated as if it were an initial examination for the purposes of paragraphs (l) (3) and (4) of this section.

(3) *Actions triggered by initial biological monitoring:*

(i) If the results of the initial biological monitoring tests show the employee's CdU level to be at or below 3 μg/g Cr, β_2-M level to be at or below 300 μg/g Cr and CdB level to be at or below 5 μg/lwb, then:

(A) For currently exposed employees, who are subject to medical surveillance under paragraph (l)(1)(i)(A) of this section, the employer shall provide the minimum level of periodic medical surveillance in accordance with the requirements in paragraph (l)(4)(i) of this section; and

(B) For previously exposed employees, who are subject to medical surveillance under paragraph (l)(1)(i)(B) of this section, the employer shall provide biological monitoring for CdU, β_2-M, and CdB one year after the initial biological monitoring and then the employer shall comply with the requirements of paragraph (l)(4)(v).

(ii) For all employees who are subject to medical surveillance under paragraph (l)(1)(i), if the results of the initial biological monitoring tests show the level of CdU to exceed 3 μg/g Cr, the level of $\beta_2$2-M to exceed 300 μg/g Cr, or the level of CdB to exceed 5 μg/lwb, the employer shall:

(A) Within two weeks after receipt of biological monitoring results, reassess the employee's occupational exposure to cadmium as follows:

(*1*) reassess the employee's work practices and personal hygiene;

(*2*) reevaluate the employee's respirator use, if any, and the respirator program;

(*3*) review the hygiene facilities;

(*4*) reevaluate the maintenance and effectiveness of the relevant engineering controls;

(*5*) assess the employee's smoking history and status;

(B) Within 30 days after the exposure reassessment, specified in (l)(3)(ii)(A), take reasonable steps to correct any deficiencies found in the reassessment that may be responsible for the employee's excess exposure to cadmium; and,

(C) Within 90 days after receipt of biological monitoring results, provide a full medical examination to the employee in accordance with the requirements of paragraph (l)(4)(ii) of this section. After completing the medical examination, the examining physician shall determine in a written medical opinion whether to medically remove the employee. If the physician determines that medical removal is not necessary, then until the employee's CdU level falls to or below 3 μg/g Cr, $\beta_2$2-M level falls to or below 300 μg/g Cr and CdB level falls to or below 5 μg/lwb, the employer shall:

(*1*) Provide biological monitoring in accordance with paragraph (l)(2)(ii)(B) of this section on a semiannual basis; and

(*2*) Provide annual medical examinations in accordance with paragraph (l)(4)(ii) of this section.

(iii) For all employees who are subject to medical surveillance under paragraph (l)(1)(i), if the results of the initial biological monitoring tests show the level of CdU to be in excess of 15 μg/g Cr, or the level of CdB to be in excess of 15 μg/lwb, or the level of $\beta_2$2-M to be in excess of 1,500 μg/g Cr, the employer shall comply with the requirements of paragraphs (l)(3)(ii)(A)–(B) of this section. Within 90 days after receipt of biological monitoring results, the employer shall provide a full medical examination to the employee in accordance with the requirements of paragraph (l)(4)(ii) of this section. After completing the medical examination, the examining physician shall determine in a written medical opinion whether to medically remove the employee. However, if the initial biological monitoring results and the biological monitoring results obtained during the medical examination both

show that: CdU exceeds 15 μg/g Cr; or CdB exceeds 15 μg/lwb; or $\beta_2$2-M exceeds 1500 μg/g Cr, and in addition CdU exceeds 3 μg/g Cr or CdB exceeds 5 μg/liter of whole blood, then the physician shall medically remove the employee from exposure to cadmium at or above the action level. If the second set of biological monitoring results obtained during the medical examination does not show that a mandatory removal trigger level has been exceeded, then the employee is not required to be removed by the mandatory provisions of this paragraph. If the employee is not required to be removed by the mandatory provisions of this paragraph or by the physician's determination, then until the employee's CdU level falls to or below 3 μg/g Cr, $\beta_2$2-M level falls to or below 300 μg/g Cr and CdB level falls to or below 5 μg/lwb, the employer shall:

(A) Periodically reassess the employee's occupational exposure to cadmium;

(B) Provide biological monitoring in accordance with paragraph (l)(2)(ii)(B) of this section on a quarterly basis; and

(C) Provide semiannual medical examinations in accordance with paragraph (l)(4)(ii) of this section.

(iv) For all employees to whom medical surveillance is provided, beginning on January 1, 1999, and in lieu of paragraphs (l)(3)(i)–(iii):

(A) If the results of the initial biological monitoring tests show the employee's CdU level to be at or below 3 μg/g Cr, β_2-M level to be at or below 300 μg/g Cr and CdB level to be at or below 5 μg/lwb, then for currently exposed employees, the employer shall comply with the requirements of paragraph (l)(3)(i)(A), and for previously exposed employees, the employer shall comply with the requirements of paragraph (l)(3)(i)(B);

(B) If the results of the initial biological monitoring tests show the level of CdU to exceed 3 μg/g Cr, the level of β_2-M to exceed 300 μg/g Cr, or the level of CdB to exceed 5 μg/lwb, the employer shall comply with the requirements of paragraphs (l)(3)(ii)(A)–(C); and,

(C) If the results of the initial biological monitoring tests show the level of CdU to be in excess of 7 μg/g Cr, or the level of CdB to be in excess of 10 μg/lwb, or the level of β_2-M to be in excess of 750 μg/g Cr, the employer shall: comply with the requirements of paragraphs (l)(3)(ii)(A)–(B); and, within 90 days after receipt of biological monitoring results, provide a full medical examination to the employee in accordance with the requirements of paragraph (l)(4)(ii) of this section. After completing the medical examination, the examining physician shall determine in a written medical opinion whether to medically remove the employee. However, if the initial biological monitoring results and the biological monitoring results obtained during the medical examination both show that: CdU exceeds 7 μg/g Cr; or CdB exceeds 10 μg/lwb; or β_2-M exceeds 750 μg/g Cr, and in addition CdU exceeds 3 μg/g Cr or CdB exceeds 5 μg/liter of whole blood, then the physician shall medically remove the employee from exposure to cadmium at or above the action level. If the second set of biological monitoring results obtained during the medical examination does not show that a mandatory removal trigger level has been exceeded, then the employee is not required to be removed by the mandatory provisions of this paragraph. If the employee is not required to be removed by the mandatory provisions of this paragraph or by the physician's determination, then until the employee's CdU level falls to or below 3 μg/g Cr, β_2-M level falls to or below 300 μg/g Cr and CdB level falls to or below 5 μg/lwb, the employer shall: periodically reassess the employee's occupational exposure to cadmium; provide biological monitoring in accordance with paragraph (l)(2)(ii)(B) of this section on a quarterly basis; and provide semiannual medical examinations in accordance with paragraph (l)(4)(ii) of this section.

(4) *Periodic medical surveillance.*

(i) For each employee who is covered under paragraph (l)(1)(i)(A), the employer shall provide at least the minimum level of periodic medical surveillance, which consists of periodic medical examinations and periodic biological monitoring. A periodic medical examination shall be provided within one year after the initial examination required by paragraph (l)(2) and thereafter at least biennially. Biological sampling shall be provided at least annually, either as part of a periodic medical examination or separately as periodic biological monitoring.

(ii) The periodic medical examination shall include:

(A) A detailed medical and work history, or update thereof, with emphasis on: past, present and anticipated future exposure to cadmium; smoking history and current status; reproductive history; current use of medications with potential nephrotoxic side-effects; any history of renal, cardiovascular, respiratory, hematopoietic, and/or musculo-skeletal system dysfunction; and as part of the medical and work history, for employees who wear respirators, questions 3–11 and 25–32 in Appendix D;

(B) A complete physical examination with emphasis on: blood pressure, the respiratory system, and the urinary system;

(C) A 14 inch by 17 inch, or a reasonably standard sized posterior-anterior chest X-ray (after the initial X-ray, the frequency of chest X-rays is to be determined by the examining physician);

(D) Pulmonary function tests, including forced vital capacity (FVC) and forced expiratory volume at 1 second (FEV1);

(E) Biological monitoring, as required in paragraph (l)(2)(ii)(B);

(F) Blood analysis, in addition to the analysis required under paragraph (l)(2)(ii)(B), including blood urea nitrogen, complete blood count, and serum creatinine;

(G) Urinalysis, in addition to the analysis required under paragraph (l)(2)(ii)(B), including the determination of albumin, glucose, and total and low molecular weight proteins;

(H) For males over 40 years old, prostate palpation, or other at least as effective diagnostic test(s); and

(I) Any additional tests deemed appropriate by the examining physician.

(iii) Periodic biological monitoring shall be provided in accordance with paragraph (l)(2)(ii)(B).

(iv) If the results of periodic biological monitoring or the results of biological monitoring performed as part of the periodic medical examination show the level of the employee's CdU, β_2–M, or CdB to be in excess of the levels specified in paragraphs (l)(3) (ii) or (iii); or, beginning on January 1, 1999, in excess of the levels specified in paragraphs (l)(3) (ii) or (iv) of this section, the employer shall take the appropriate actions specified in paragraphs (l)(3)(ii)–(iv) of this section.

(v) For previously exposed employees under paragraph (l)(1)(i)(B):

(A) If the employee's levels of CdU did not exceed 3 μg/g Cr, CdB did not exceed 5 μg/lwb, and β_2-M did not exceed 300 μg/g Cr in the initial biological monitoring tests, and if the results of the followup biological monitoring required by paragraph (l)(3)(i)(B) one year after the initial examination confirm the previous results, the employer may discontinue all periodic medical surveillance for that employee.

(B) If the initial biological monitoring results for CdU, CdB, or β_2-M were in excess of the levels specified in (l)(3)(i), but subsequent biological monitoring results required by (l)(3)(ii)–(iv) show

that the employee's CdU levels no longer exceed 3 μg/g Cr, CdB levels no longer exceed 5 μg/lwb, and β_2-M levels no longer exceed 300 μg/g Cr, the employer shall provide biological monitoring for CdU, CdB, and β_2-M one year after these most recent biological monitoring results. If the results of the followup biological monitoring, specified in this paragraph, confirm the previous results, the employer may discontinue all periodic medical surveillance for that employee.

(C) However, if the results of the follow-up tests specified in (l)(4)(v) (A) or (B) indicate that the level of the employee's CdU, β_2-M, or CdB exceeds these same levels, the employer is required to provide annual medical examinations in accordance with the provisions of paragraph (l)(4)(ii) until the results of biological monitoring are consistently below these levels or the examining physician determines in a written medical opinion that further medical surveillance is not required to protect the employee's health.

(vi) A routine, biennial medical examination is not required to be provided in accordance with paragraphs (l)(3)(i) and (l)(4) if adequate medical records show that the employee has been examined in accordance with the requirements of paragraph (l)(4)(ii) within the past 12 months. In that case, such records shall be maintained by the employer as part of the employee's medical record, and the next routine, periodic medical examination shall be made available to the employee within two years of the previous examination.

(5) *Actions triggered by medical examinations:*

(i) If the results of a medical examination carried out in accordance with this section indicate any laboratory or clinical finding consistent with cadmium toxicity that does not require employer action under paragraphs (1) (2), (3) or (4) of this section, the employer, within 30 days, shall reassess the employee's occupational exposure to cadmium and take the following corrective action until the physician determines they are no longer necessary:

(A) Periodically reassess: The employee's work practices and personal hygiene; the employee's respirator use, if any; the employee's smoking history and status; the respiratory protection program; the hygiene facilities; and the maintenance and effectiveness of the relevant engineering controls;

(B) Within 30 days after the reassessment, take all reasonable steps to correct the deficiencies found in the reassessment that may be responsible for the employee's excess exposure to cadmium;

(C) Provide semiannual medical reexaminations to evaluate the abnormal clinical sign(s) of cadmium toxicity until the results are normal or the employee is medically removed; and

(D) Where the results of tests for total proteins in urine are abnormal, provide a more detailed medical evaluation of the toxic effects of cadmium on the employee's renal system.

(6) *Examination for respirator use:*

(i) To determine an employee's fitness for respirator use, the employer shall provide a medical examination that includes the elements specified in (l)(6)(A)-(D). This examination shall be provided prior to the employee's being assigned to a job that requires the use of a respirator or no later than 90 days after this section goes into effect, whichever date is later, to any employee without a medical examination within the preceding 12 months that satisfies the requirements of this paragraph.

(A) A detailed medical and work history, or update thereof, with emphasis on: past exposure to cadmium; smoking history and current status; any history of renal, cardiovascular, respiratory, hematopoietic, and/or musculo-skeletal system dysfunction; a description of the job for which the respirator is required; and questions 3–11 and 25–32 in Appendix D;

(B) A blood pressure test;

(C) Biological monitoring of the employee's levels of CdU, CdB and β_2-M in accordance with the requirements of paragraph (l)(2)(ii)(B), unless such results already have been obtained within the previous 12 months; and

(D) Any other test or procedure that the examining physician deems appropriate.

(ii) After reviewing all the information obtained from the medical examination required in paragraph (l)(6)(i) of this section, the physician shall determine whether the employee is fit to wear a respirator.

(iii) Whenever an employee has exhibited difficulty in breathing during a respirator fit test or during use of a respirator, the employer, as soon as possible, shall provide the employee with a periodic medical examination in accordance with paragraph (l)(4)(ii) to determine the employee's fitness to wear a respirator.

(iv) Where the results of the examination required under paragraph (l)(6)(i), (ii) or (iii) of this section are abnormal, medical limitation or prohibition of respirator use shall be considered. If the employee is allowed to wear a respirator, the employee's ability to continue to do so shall be periodically evaluated by a physician.

(7) *Emergency examinations:*

(i) In addition to the medical surveillance required in paragraphs (l)(2)–(6) of this section, the employer shall provide a medical examination as soon as possible to any employee who may have been acutely exposed to cadmium because of an emergency.

(ii) The examination shall include the requirements of paragraph (l)(4)(ii), with emphasis on the respiratory system, other organ systems considered appropriate by the examining physician, and symptoms of acute overexposure, as identified in Appendix A of this section in paragraphs II(B)(1)-(2) and IV.

(8) *Termination of employment examination:*

(i) At termination of employment, the employer shall provide a medical examination in accordance with paragraph (l)(4)(ii) of this section, including a chest X-ray, to any employee to whom at any prior time the employer was required to provide medical surveillance under paragraphs (l)(1)(i) or (l)(7) of this section. However, if the last examination satisfied the requirements of paragraph (l)(4)(ii) of this standard and was less than six months prior to the date of termination, no further examination is required unless otherwise specified in paragraphs (l)(3) or (l)(5);

(ii) However, for employees covered by paragraph (l)(1)(i)(B), if the employer has discontinued all periodic medical surveillance under (l)(4)(v), no termination of employment medical examination is required.

(9) *Information provided to the physician:*

The employer shall provide the following information to the examining physician:

(i) A copy of this standard and appendices;

(ii) A description of the affected employee's former, current, and anticipated duties as they relate to the employee's occupational exposure to cadmium;

(iii) The employee's former, current, and anticipated future levels of occupational exposure to cadmium;

(iv) A description of any personal protective equipment, including respirators, used or to be used by the employee, including when and for how long the employee has used that equipment; and

(v) Relevant results of previous biological monitoring and medical examinations.

(10) *Physician's written medical opinion:*

(i) The employer shall promptly obtain a written, signed medical opinion from the examining physician for each

medical examination performed on each employee. This written opinion shall contain:

(A) The physician's diagnosis for the employee;

(B) The physician's opinion as to whether the employee has any detected medical condition(s) that would place the employee at increased risk of material impairment to health from further exposure to cadmium, including any indications of potential cadmium toxicity;

(C) The results of any biological or other testing or related evaluations that directly assess the employee's absorption of cadmium;

(D) Any recommended removal from, or limitation on the activities or duties of the employee or on the employee's use of personal protective equipment, such as respirators;

(E) A statement that the physician has clearly and carefully explained to the employee the results of the medical examination, including all biological monitoring results and any medical conditions related to cadmium exposure that require further evaluation or treatment, and any limitation on the employee's diet or use of medications.

(ii) The employer promptly shall obtain a copy of the results of any biological monitoring provided by an employer to an employee independently of a medical examination under paragraphs (l)(2) and (l)(4), and, in lieu of a written medical opinion, an explanation sheet explaining those results.

(iii) The employer shall instruct the physician not to reveal orally or in the written medical opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to cadmium.

(11) *Medical Removal Protection (MRP):*

(i) *General.*

(A) The employer shall temporarily remove an employee from work where there is excess exposure to cadmium on each occasion that medical removal is required under paragraphs (l)(3), (l)(4), or (l)(6) of this section and on each occasion that a physician determines in a written medical opinion that the employee should be removed from such exposure. The physician's determination may be based on biological monitoring results, inability to wear a respirator, evidence of illness, other signs or symptoms of cadmium-related dysfunction or disease, or any other reason deemed medically sufficient by the physician.

(B) The employer shall medically remove an employee in accordance with paragraph (l)(11) of this section regardless of whether at the time of removal a job is available into which the removed employee may be transferred.

(C) Whenever an employee is medically removed under paragraph (l)(11) of this section, the employer shall transfer the removed employee to a job where the exposure to cadmium is within the permissible levels specified in that paragraph as soon as one becomes available.

(D) For any employee who is medically removed under the provisions of paragraph (l)(11)(i) of this section, the employer shall provide follow-up biological monitoring in accordance with (l)(2)(ii)(B) at least every three months and follow-up medical examinations semi-annually at least every six months until in a written medical opinion the examining physician determines that either the employee may be returned to his/her former job status as specified under (l)(11)(iv)–(v) or the employee must be permanently removed from excess cadmium exposure.

(E) The employer may not return an employee who has been medically removed for any reason to his/her former job status until a physician determines in a written medical opinion that continued medical removal is no longer necessary to protect the employee's health.

(ii) Where an employee is found unfit to wear a respirator under paragraph (l)(6)(ii), the employer shall remove the employee from work where exposure to cadmium is above the PEL.

(iii) Where removal is based on any reason other than the employee's inability to wear a respirator, the employer shall remove the employee from work where exposure to cadmium is at or above the action level.

(iv) Except as specified in paragraph (l)(11)(v), no employee who was removed because his/her level of CdU, CdB and/or β_2-M exceeded the medical removal trigger levels in paragraph (l)(3) or (l)(4) may be returned to work with exposure to cadmium at or above the action level until the employee's levels of CdU fall to or below 3 μg/g Cr, CdB falls to or below 5 μg/lwb, and β_2-M falls to or below 300 μg/g Cr.

(v) However, when in the examining physician's opinion continued exposure to cadmium will not pose an increased risk to the employee's health and there are special circumstances that make continued medical removal an inappropriate remedy, the physician shall fully discuss these matters with the employee, and then in a written determination may return a worker to his/her former job status despite what would otherwise be unacceptably high biological monitoring results. Thereafter, the returned employee shall continue to be provided with medical surveillance as if he/she were still on medical removal until the employee's levels of CdU fall to or below 3 μg/g Cr, CdB falls to or below 5 μg/lwb, and β_2-M falls to or below 300 μg/g Cr.

(vi) Where an employer, although not required by (l)(11)(i)–(iii) of this section to do so, removes an employee from exposure to cadmium or otherwise places limitations on an employee due to the effects of cadmium exposure on the employee's medical condition, the employer shall provide the same medical removal protection benefits to that employee under paragraph (l)(12) as would have been provided had the removal been required under paragraph (l)(11)(i)–(iii) of this section.

(12) *Medical Removal Protection Benefits (MRPB).*

(i) The employer shall provide MRPB for up to a maximum of 18 months to an employee each time and while the employee is temporarily medically removed under paragraph (l)(11) of this section.

(ii) For purposes of this section, the requirement that the employer provide MRPB means that the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits of the removed employee, including the employee's right to his/her former job status, as if the employee had not been removed from the employee's job or otherwise medically limited.

(iii) Where, after 18 months on medical removal because of elevated biological monitoring results, the employee's monitoring results have not declined to a low enough level to permit the employee to be returned to his/her former job status:

(A) The employer shall make available to the employee a medical examination pursuant to this section in order to obtain a final medical determination as to whether the employee may be returned to his/her former job status or must be permanently removed from excess cadmium exposure; and

(B) The employer shall assure that the final medical determination indicates whether the employee may be returned to his/her former job status and what steps, if any, should be taken to protect the employee's health.

(iv) The employer may condition the provision of MRPB upon the employee's participation in medical surveillance provided in accordance with this section.

(13) *Multiple physician review.*

(i) If the employer selects the initial physician to conduct any medical examination or consultation provided to an employee under this section, the employee may designate a second physician to:

(A) Review any findings, determinations, or recommendations of the initial physician; and

(B) Conduct such examinations, consultations, and laboratory tests as the second physician deems necessary to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician provided by the employer conducts a medical examination or consultation pursuant to this section. The employer may condition its participation in, and payment for, multiple physician review upon the employee doing the following within fifteen (15) days after receipt of this notice, or receipt of the initial physician's written opinion, whichever is later:

(A) Informing the employer that he or she intends to seek a medical opinion; and

(B) Initiating steps to make an appointment with a second physician.

(iii) If the findings, determinations, or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve any disagreement.

(iv) If the two physicians have been unable to quickly resolve their disagreement, then the employer and the employee, through their respective physicians, shall designate a third physician to:

(A) Review any findings, determinations, or recommendations of the other two physicians; and

(B) Conduct such examinations, consultations, laboratory tests, and discussions with the other two physicians as the third physician deems necessary to resolve the disagreement among them.

(v) The employer shall act consistently with the findings, determinations, and recommendations of the third physician, unless the employer and the employee reach an agreement that is consistent with the recommendations of at least one of the other two physicians.

(14) *Alternate physician determination.*

The employer and an employee or designated employee representative may agree upon the use of any alternate form of physician determination in lieu of the multiple physician review provided by paragraph (l)(13) of this section, so long as the alternative is expeditious and at least as protective of the employee.

(15) *Information the employer must provide the employee.*

(i) The employer shall provide a copy of the physician's written medical opinion to the examined employee within two weeks after receipt thereof.

(ii) The employer shall provide the employee with a copy of the employee's biological monitoring results and an explanation sheet explaining the results within two weeks after receipt thereof.

(iii) Within 30 days after a request by an employee, the employer shall provide the employee with the information the employer is required to provide the examining physician under paragraph (l)(9) of this section.

(16) Reporting.

In addition to other medical events that are required to be reported on the OSHA Form No. 200, the employer shall report any abnormal condition or disorder caused by occupational exposure to cadmium associated with employment as specified in Chapter (V)(E) of the *Reporting Guidelines for Occupational Injuries and Illnesses.*

(m) Communication of cadmium hazards to employees.

(1) *General.*

In communications concerning cadmium hazards, employers shall comply with the requirements of OSHA's Hazard Communication Standard, 29 CFR 1910.1200, including but not limited to the requirements concerning warning signs and labels, material safety data sheets (MSDS), and employee information and training. In addition, employers shall comply with the following requirements:

(2) *Warning signs.*

(i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) Warning signs required by paragraph (m)(2)(i) of this section shall bear the following information:

DANGER
CADMIUM
CANCER HAZARD
CAN CAUSE LUNG AND KIDNEY DISEASE
AUTHORIZED PERSONNEL ONLY
RESPIRATORS REQUIRED IN THIS AREA

(iii) The employer shall assure that signs required by this paragraph are illuminated, cleaned, and maintained as necessary so that the legend is readily visible.

(3) *Warning labels.*

(i) Shipping and storage containers containing cadmium, cadmium compounds, or cadmium contaminated clothing, equipment, waste, scrap, or debris shall bear appropriate warning labels, as specified in paragraph (m)(3)(ii) of this section.

(ii) The warning labels shall include at least the following information:

DANGER
CONTAINS CADMIUM
CANCER HAZARD
AVOID CREATING DUST
CAN CAUSE LUNG AND KIDNEY DISEASE

(iii) Where feasible, installed cadmium products shall have a visible label or other indication that cadmium is present.

(4) *Employee information and training.*

(i) The employer shall institute a training program for all employees who are potentially exposed to cadmium, assure employee participation in the program, and maintain a record of the contents of such program.

(ii) Training shall be provided prior to or at the time of initial assignment to a job involving potential exposure to cadmium and at least annually thereafter.

(iii) The employer shall make the training program understandable to the employee and shall assure that each employee is informed of the following:

(A) The health hazards associated with cadmium exposure, with special attention to the information incorporated in Appendix A to this section;

(B) The quantity, location, manner of use, release, and storage of cadmium in the workplace and the specific nature of operations that could result in exposure to cadmium, especially exposures above the PEL;

(C) The engineering controls and work practices associated with the employee's job assignment;

(D) The measures employees can take to protect themselves from exposure to cadmium, including modification of such habits as smoking and personal hygiene, and specific procedures the employer has implemented to protect employees from exposure to cadmium such as appropriate work practices, emergency procedures, and the provision of personal protective equipment;

(E) The purpose, proper selection, fitting, proper use, and limitations of respirators and protective clothing;

(F) The purpose and a description of the medical surveillance program required by paragraph (l) of this standard;

(G) The contents of this section and its appendices, and,

(H) The employee's rights of access to records under § 1910.20 (e) and (g).

(iv) Additional access to information and training program and materials.

(A) The employer shall make a copy of this section and its appendices readily available without cost to all affected employees and shall provide a copy if requested.

(B) The employer shall provide to the Assistant Secretary or the Director, upon request, all materials relating to the employee information and the training program.

(n) Recordkeeping.

(1) *Exposure Monitoring.*

(i) The employer shall establish and keep an accurate record of all air monitoring for cadmium in the workplace.

(ii) This record shall include at least the following information:

(A) The monitoring date, duration, and results in terms of an 8-hour TWA of each sample taken;

(B) The name, social security number, and job classification of the employees monitored and of all other employees whose exposures the monitoring is intended to represent;

(C) A description of the sampling and analytical methods used and evidence of their accuracy;

(D) The type of respiratory protective device, if any, worn by the monitored employee;

(E) A notation of any other conditions that might have affected the monitoring results.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.20.

(2) *Objective data for exemption from requirement for initial monitoring.*

(i) For purposes of this section, objective data are information demonstrating that a particular product or material containing cadmium or a specific process, operation, or activity involving cadmium cannot release dust or fumes in concentrations at or above the action level even under the worst-case release conditions. Objective data can be obtained from an industry-wide study or from laboratory product test results from manufacturers of cadmium-containing products or materials. The data the employer uses from an industry-wide survey must be obtained under workplace conditions closely resembling the processes, types of material, control methods, work practices and environmental conditions in the employer's current operations.

(ii) The employer shall establish and maintain a record of the objective data for at least 30 years.

(3) *Medical surveillance.*

(i) The employer shall establish and maintain an accurate record for each employee covered by medical surveillance under paragraph (l)(1)(i) of this section.

(ii) The record shall include at least the following information about the employee:

(A) Name, social security number, and description of the duties;

(B) A copy of the physician's written opinions and an explanation sheet for biological monitoring results;

(C) A copy of the medical history, and the results of any physical examination and all test results that are required to be provided by this section, including biological tests, X-rays, pulmonary function tests, etc., or that have been obtained to further evaluate any condition that might be related to cadmium exposure;

(D) The employee's medical symptoms that might be related to exposure to cadmium; and

(E) A copy of the information provided to the physician as required by paragraph (l)(9)(ii)-(v) of this section.

(iii) The employer shall assure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.20.

(4) *Training.*

The employer shall certify that employees have been trained by preparing a certification record which includes the identity of the person trained, the signature of the employer or the person who conducted the training, and the date the training was completed. The certification records shall be prepared at the completion of training and shall be maintained on file for one (1) year beyond the date of training of that employee.

(5) *Availability.*

(i) Except as otherwise provided for in this section, access to all records required to be maintained by paragraphs (n)(1)–(4) of this section shall be in accordance with the provisions of 29 CFR 1910.20.

(ii) Within 15 days after a request, the employer shall make an employee's medical records required to be kept by paragraph (n)(3) of this section available for examination and copying to the subject employee, to designated representatives, to anyone having the specific written consent of the subject employee, and after the employee's death or incapacitation, to the employee's family members.

(6) *Transfer of records.*

Whenever an employer ceases to do business and there is no successor employer to receive and retain records for the prescribed period or the employer intends to dispose of any records required to be preserved for at least 30 years, the employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.20 (h).

(o) Observation of monitoring.

(1) *Employee observation.*

The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to cadmium.

(2) *Observation procedures.*

When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with that clothing and equipment and shall assure that the observer uses such clothing and equipment and complies with all other applicable safety and health procedures.

(p) Dates.

(1) *Effective date.*

This section became effective December 14, 1992.

(2) *Start-up dates.*

All obligations of this section commence on the effective date except as follows:

(i) *Exposure monitoring.* Except for small businesses [nineteen (19) or fewer employees], initial monitoring required by paragraph (d)(2) of this section shall be completed as soon as possible and in any event no later than 60 days after the effective date of this standard. For small businesses, initial monitoring required by paragraph (d)(2) of this section shall be completed as soon as possible and in any event no later than 120 days after the effective date of this standard.

(ii) *Regulated areas.* Except for small business, defined under paragraph (p)(2)(i) of this section, regulated areas required to be established by paragraph (e) of this section shall be set up as soon as possible after the results of exposure monitoring are known and in any event no later than 90 days after the effective date of this section. For small businesses, regulated areas required to be established by paragraph (e) of this section shall be set up as soon as possible after the results of exposure monitoring are known and in any event no later than 150 days after the effective date of this section.

(iii) *Respiratory protection.* Except for small businesses, defined under paragraph (p)(2)(i) of this section, respiratory protection required by paragraph (g) of this section shall be provided as soon as possible and in any event no later than 90 days after the effective date of this section. For small businesses, respiratory protection required by paragraph (g) of this section shall be provided as soon as possible and in any event no later than 150 days after the effective date of this section.

(iv) *Compliance program.* Written compliance programs required by paragraph (f)(2) of this section shall be completed and available for inspection and copying as soon as possible and in any event no later than 1 year after the effective date of this section.

(v) *Methods of compliance.* The engineering controls required by paragraph (f)(1) of this section shall be implemented as soon as possible and in any event no later than two (2) years after the effective date of this section. Work practice controls shall be implemented as soon as possible. Work practice controls that are directly related to engineering controls to be implemented in accordance with the compliance plan shall be implemented as soon as possible after such engineering controls are implemented.

(vi) *Hygiene and lunchroom facilities.*

(A) Handwashing facilities, permanent or temporary, shall be provided in accordance with 29 CFR 1910.141(d) (1)and (2) as soon as possible and in any event no later than 60 days after the effective date of this section.

(B) Change rooms, showers, and lunchroom facilities shall be completed as soon as possible and in any event no later than 1 year after the effective date of this section.

(vii) *Employee information and training.* Except for small businesses, defined under paragraph (p)(2)(i) above, employee information and training required by paragraph (m)(4) of this standard shall be provided as soon as possible and in any event no later than 90 days after the effective date of this standard. For small businesses, employee information and training required by paragraph (m)(4) of this standard shall be provided as soon as possible and in any event no later than 180 days after the effective date of this standard.

(viii) *Medical surveillance.* Except for small businesses, defined under paragraph (p)(2)(i) above, initial medical examinations required by paragraph (l) of this standard shall be provided as soon as possible and in any event no later than 90 days after the effective date of this standard. For small businesses, initial medical examinations required by paragraph (l) of this standard shall be provided as soon as possible and in any event no later than 180 days after the effective date of this standard.

(q) Appendices.

(1) Appendix C to this section is incorporated as part of this section, and compliance with its contents is mandatory.

(2) Except where portions of appendices A, B, D, E, and F to this section are expressly incorporated in requirements of this section, these appendices are purely informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

Appendix A—Substance Safety Data Sheet Cadmium

I. Substance Identification

A. Substance: Cadmium.

B. 8-Hour, Time-weighted-average, Permissible Exposure Limit (TWA PEL):

1. TWA PEL: Five micrograms of cadmium per cubic meter of air 5 $\mu g/m^3$, time-weighted average (TWA) for an 8-hour workday.

C. Appearance: Cadmium metal—soft, blue-white, malleable, lustrous metal or grayish-white powder. Some cadmium compounds may also appear as a brown, yellow, or red powdery substance.

II. Health Hazard Data

A. Routes of Exposure.

Cadmium can cause local skin or eye irritation. Cadmium can affect your health if you inhale it or if you swallow it.

B. Effects of Overexposure

1. Short-term (acute) exposure: Cadmium is much more dangerous by inhalation than by ingestion. High exposures to cadmium that may be immediately dangerous to life or health occur in jobs where workers handle large quantities of cadmium dust or fume; heat cadmium-containing compounds or cadmium-coated surfaces; weld with cadmium solders or cut cadmium-containing materials such as bolts.

2. Severe exposure may occur before symptoms appear. Early symptoms may include mild irritation of the upper respiratory tract, a sensation of constriction of the throat, a metallic taste and/or a cough. A period of 1–10 hours may precede the onset of rapidly progressing shortness of breath, chest pain, and flu-like symptoms with weakness, fever, headache, chills, sweating and muscular pain. Acute pulmonary edema usually develops within 24 hours and reaches a maximum by three days. If death from asphyxia does not occur, symptoms may resolve within a week.

3. Long-term (chronic) exposure. Repeated or long-term exposure to cadmium, even at relatively low concentrations, may result in kidney damage and an increased risk of cancer of the lung and of the prostate.

C. Emergency First Aid Procedures

1. Eye exposure: Direct contact may cause redness or pain. Wash eyes immediately with large amounts of water, lifting the upper and lower eyelids. Get medical attention immediately.

2. Skin exposure: Direct contact may result in irritation. Remove contaminated clothing and shoes immediately. Wash affected area with soap or mild detergent and large amounts of water. Get medical attention immediately.

3. Ingestion: Ingestion may result in vomiting, abdominal pain, nausea, diarrhea, headache and sore throat. Treatment for symptoms must be administered by medical personnel. Under no circumstances should the employer allow any person whom he retains, employs, supervises or controls to engage in therapeutic chelation. Such treatment is likely to translocate cadmium from pulmonary or other tissue to renal tissue. Get medical attention immediately.

4. Inhalation: If large amounts of cadmium are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Administer oxygen if available. Keep the affected person warm and at rest. Get medical attention immediately.

5. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, attempt rescue only after notifying at least one other person of the emergency and putting into effect established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

III. Employee Information

A. Protective Clothing and Equipment

1. Respirators: You may be required to wear a respirator for non-routine activities; in emergencies; while your employer is in the process of reducing cadmium exposures through engineering controls; and where engineering controls are not feasible. If respirators are worn in the future, they must have a joint Mine Safety and Health Administration (MSHA) and National Institute for Occupational Safety and Health (NIOSH) label of approval. Cadmium does not have a detectable odor except at levels well above the permissible exposure limits. If you can smell cadmium while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

2. Protective Clothing: You may be required to wear impermeable clothing, gloves, foot gear, a face shield, or other appropriate protective clothing to prevent skin contact with cadmium. Where protective clothing is required, your employer must provide clean garments to you as necessary to assure that the clothing protects you adequately. The employer must replace or repair protective clothing that has become torn or otherwise damaged.

3. Eye Protection: You may be required to wear splash-proof or dust resistant goggles to prevent eye contact with cadmium.

B. Employer Requirements

1. Medical: If you are exposed to cadmium at or above the action level, your employer is required to provide a medical examination, laboratory tests and a medical history according to the medical surveillance provisions under paragraph (l) of this standard. (See summary chart and tables in this Appendix A.) These tests shall be provided without cost to you. In addition, if you are accidentally exposed to cadmium under conditions known or suspected to constitute toxic exposure to cadmium, your employer is required to make special tests available to you.

2. Access to Records: All medical records are kept strictly confidential. You or your

representative are entitled to see the records of measurements of your exposure to cadmium. Your medical examination records can be furnished to your personal physician or designated representative upon request by you to your employer.

3. Observation of Monitoring: Your employer is required to perform measurements that are representative of your exposure to cadmium and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with, and must wear the protective clothing and equipment.

C. Employee Requirements

You will not be able to smoke, eat, drink, chew gum or tobacco, or apply cosmetics while working with cadmium in regulated areas. You will also not be able to carry or store tobacco products, gum, food, drinks or cosmetics in regulated areas because these products easily become contaminated with cadmium from the workplace and can therefore create another source unnecessary of cadmium exposure.

Some workers will have to change out of work clothes and shower at the end of the day, as part of their workday, in order to wash cadmium from skin and hair. Handwashing and cadmium-free eating facilities shall be provided by the employer and proper hygiene should always be performed before eating. It is also recommended that you do not smoke or use tobacco products, because among other things, they naturally contain cadmium. For further information, read the labeling on such products.

IV. Physician Information

A. Introduction

The medical surveillance provisions of paragraph (l) generally are aimed at accomplishing three main interrelated purposes: First, identifying employees at higher risk of adverse health effects from excess, chronic exposure to cadmium; second, preventing cadmium-induced disease; and third, detecting and minimizing existing cadmium-induced disease. The core of medical surveillance in this standard is the early and periodic monitoring of the employee's biological indicators of: (a) recent exposure to cadmium; (b) cadmium body burden; and (c) potential and actual kidney damage associated with exposure to cadmium.

The main adverse health effects associated with cadmium overexposure are lung cancer and kidney dysfunction. It is not yet known how to adequately biologically monitor human beings to specifically prevent cadmium-induced lung cancer. By contrast, the kidney can be monitored to provide prevention and early detection of cadmium-induced kidney damage. Since, for non-carcinogenic effects, the kidney is considered the primary target organ of chronic exposure to cadmium, the medical surveillance provisions of this standard effectively focus on cadmium-induced kidney disease. Within that focus, the aim, where possible, is to prevent the onset of such disease and, where necessary, to minimize such disease as may already exist. The by-products of successful prevention of kidney disease are anticipated to be the reduction and prevention of other cadmium-induced diseases.

B. Health Effects

The major health effects associated with cadmium overexposure are described below.

1. Kidney

The most prevalent non-malignant disease observed among workers chronically exposed to cadmium is kidney dysfunction. Initially, such dysfunction is manifested as proteinuria. The proteinuria associated with cadmium exposure is most commonly characterized by excretion of low-molecular weight proteins (15,000 to 40,000 MW) accompanied by loss of electrolytes, uric acid, calcium, amino acids, and phosphate. The compounds commonly excreted include: beta-2-microglobulin (β_2-M), retinol binding protein (RBP), immunoglobulin light chains, and lysozyme. Excretion of low molecular weight proteins are characteristic of damage to the proximal tubules of the kidney (Iwao *et al.*, 1980).

It has also been observed that exposure to cadmium may lead to urinary excretion of high-molecular weight proteins such as albumin, immunoglobulin G, and glycoproteins (ex. 29). Excretion of high-molecular weight proteins is typically indicative of damage to the glomeruli of the kidney. Bernard *et al.*, (1979) suggest that damage to the glomeruli and damage to the proximal tubules of the kidney may both be linked to cadmium exposure but they may occur independently of each other.

Several studies indicate that the onset of low-molecular weight proteinuria is a sign of irreversible kidney damage (Friberg *et al.*, 1974; Roels *et al.*, 1982; Piscator 1984; Elinder *et al.*, 1985; Smith *et al.*, 1986). Above specific levels of β_2-M associated with cadmium exposure it is unlikely that β_2-M levels return to normal even when cadmium exposure is eliminated by removal of the individual from the cadmium work environment (Friberg, ex. 29, 1990).

Some studies indicate that such proteinuria may be progressive; levels of β_2-M observed in the urine increase with time even after cadmium exposure has ceased. See, for example, Elinder *et al.*, *1985*. Such observations, however, are not universal, and it has been suggested that studies in which proteinuria has not been observed to progress may not have tracked patients for a sufficiently long time interval (*Jarup*, ex. 8–661).

When cadmium exposure continues after the onset of proteinuria, chronic nephrotoxicity may occur (Friberg, ex. 29). Uremia results from the inability of the glomerulus to adequately filter blood. This leads to severe disturbance of electrolyte concentrations and may lead to various clinical complications including kidney stones (L–140–50).

After prolonged exposure to cadmium, glomerular proteinuria, glucosuria, aminoaciduria, phosphaturia, and hypercalciuria may develop (exs. 8–86, 4–28, 14–18). Phosphate, calcium, glucose, and amino acids are essential to life, and under normal conditions, their excretion should be regulated by the kidney. Once low molecular weight proteinuria has developed, these elements dissipate from the human body. Loss of glomerular function may also occur, manifested by decreased glomerular filtration rate and increased serum creatinine. Severe cadmium-induced renal damage may eventually develop into chronic renal failure and uremia (ex. 55).

Studies in which animals are chronically exposed to cadmium confirm the renal effects observed in humans (Friberg *et al.*, 1986). Animal studies also confirm problems with calcium metabolism and related skeletal effects which have been observed among humans exposed to cadmium in addition to the renal effects. Other effects commonly reported in chronic animal studies include anemia, changes in liver morphology, immunosuppression and hypertension. Some of these effects may be associated with co-factors. Hypertension, for example, appears to be associated with diet as well as cadmium exposure. Animals injected with cadmium have also shown testicular necrosis (ex. 8–86B).

2. Biological Markers

It is universally recognized that the best measures of cadmium exposures and its effects are measurements of cadmium in biological fluids, especially urine and blood. Of the two, CdU is conventionally used to determine body burden of cadmium in workers without kidney disease. CdB is conventionally used to monitor for recent exposure to cadmium. In addition, levels of CdU and CdB historically have been used to predict the percent of the population likely to develop kidney disease (Thun *et al.*, Ex. L–140–50; WHO, Ex. 8–674; ACGIH, Exs. 8–667, 140–50).

The third biological parameter upon which OSHA relies for medical surveillance is Beta-2-microglobulin in urine (β_2-M), a low molecular weight protein. Excess β_2-M has been widely accepted by physicians and scientists as a reliable indicator of functional damage to the proximal tubule of the kidney (Exs. 8–447, 144–3–C, 4–47, L–140–45, 19–43–A).

Excess β_2-M is found when the proximal tubules can no longer reabsorb this protein in a normal manner. This failure of the proximal tubules is an early stage of a kind of kidney disease that commonly occurs among workers with excessive cadmium exposure. Used in conjunction with biological test results indicating abnormal levels of CdU and CdB, the finding of excess β_2-M can establish for an examining physician that any existing kidney disease is probably cadmium-related (Trs. 6/6/90, pp. 82–86, 122, 134). The upper limits of normal levels for cadmium in urine and cadmium in blood are 3 μg Cd/gram creatinine in urine and 5 μgCd/liter whole blood, respectively. These levels were derived from broad-based population studies.

Three issues confront the physicians in the use of β_2-M as a marker of kidney dysfunction and material impairment. First,

there are a few other causes of elevated levels of β_2-M not related to cadmium exposures, some of which may be rather common diseases and some of which are serious diseases (e.g., myeloma or transient flu, Exs. 29 and 8–086). These can be medically evaluated as alternative causes (Friberg, Ex. 29). Also, there are other factors that can cause β_2-M to degrade so that low levels would result in workers with tubular dysfunction. For example, regarding the degradation of β_2-M, workers with acidic urine (pH > 6) might have β_2M levels that are within the "normal" range when in fact kidney dysfunction has occurred (Ex. L–140–1) and the low molecular weight proteins are degraded in acid urine. Thus, it is very important that the pH of urine be measured, that urine samples be buffered as necessary (See Appendix F.), and that urine samples be handled correctly, i.e., measure the pH of freshly voided urine samples, then if necessary, buffer to pH > 6 (or above for shipping purposes), measure pH again and then, perhaps, freeze the sample for storage and shipping. (See also Appendix F.) Second, there is debate over the pathological significance of proteinuria, however, most world experts believe that β_2-M levels greater than 300 µg/g Cr are abnormal (Elinder, Ex. 55, Friberg, Ex. 29). Such levels signify kidney dysfunction that constitutes material impairment of health. Finally, detection of β_2-M at low levels has often been considered difficult, however, many laboratories have the capability of detecting excess β_2-M using simple kits, such as the Phadebas Delphia test, that are accurate to levels of 100 µg β_2-M/g Cr U (Ex. L–140–1).

Specific recommendations for ways to measure β_2-M and proper handling of urine samples to prevent degradation of β_2-M have been addressed by OSHA in Appendix F, in the section on laboratory standardization. All biological samples must be analyzed in a laboratory that is proficient in the analysis of that particular analyte, under paragraph (l)(1)(iv). [See Appendix F]. Specifically, under paragraph (l)(1)(iv), the employer is to assure that the collecting and handling of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (β_2-M) taken from employees is collected in a manner that assures reliability. The employer must also assure that analysis of biological samples of cadmium in urine (CdU), cadmium in blood (CdB), and beta-2 microglobulin in urine (β_2-M) taken from employees is performed in laboratories with demonstrated proficiency for that particular analyte. (See Appendix F.)

3. Lung and Prostate Cancer

The primary sites for cadmium-associated cancer appear to be the lung and the prostate (L–140–50). Evidence for an association between cancer and cadmium exposure derives from both epidemiological studies and animal experiments. Mortality from prostate cancer associated with cadmium is slightly elevated in several industrial cohorts, but the number of cases is small and there is not clear dose-response relationship. More substantive evidence exists for lung cancer.

The major epidemiological study of lung cancer was conducted by Thun *et al.*, (EX. 4–68). Adequate data on cadmium exposures were available to allow evaluation of dose-response relationships between cadmium exposure and lung cancer. A statistically significant excess of lung cancer attributed to cadmium exposure was observed in this study even when confounding variables such as co-exposure to arsenic and smoking habits were taken into consideration (Ex. L–140–50).

The primary evidence for quantifying a link between lung cancer and cadmium exposure from animal studies derives from two rat bioassay studies; one by Takenaka *et al.*, (1983), which is a study of cadmium chloride and a second study by Oldiges and Glaser (1990) of four cadmium compounds.

Based on the above cited studies, the U.S. Environmental Protection Agency (EPA) classified cadmium as "B1", a probable human carcinogen, in 1985 (Ex. 4–4). The International Agency for Research on Cancer (IARC) in 1987 also recommended that cadmium be listed as "2A", a probable human carcinogen (Ex. 4–15). The American Conference of Governmental Industrial Hygienists (ACGIH) has recently recommended that cadmium be labeled as a carcinogen. Since 1984, NIOSH has concluded that cadmium is possibly a human carcinogen and has recommended that exposures be controlled to the lowest level feasible.

4. Non-carcinogenic Effects

Acute pneumonitis occurs 10 to 24 hours after initial acute inhalation of high levels of cadmium fumes with symptoms such as fever and chest pain (Exs. 30, 8–86B). In extreme exposure cases pulmonary edema may develop and cause death several days after exposure. Little actual exposure measurement data is available on the level of airborne cadmium exposure that causes such immediate adverse lung effects, nonetheless, it is reasonable to believe a cadmium concentration of approximately 1 mg/m^3 over an eight hour period is "immediately dangerous" (55 FR 4052, ANSI; Ex. 8–86B).

In addition to acute lung effects and chronic renal effects, long term exposure to cadmium may cause other severe effects on the respiratory system. Reduced pulmonary function and chronic lung disease indicative of emphysema have been observed in workers who have had prolonged exposure to cadmium dust or fumes (Exs. 4–29, 4–22, 4–42, 4–50, 4–63). In a study of workers conducted by Kazantzis *et al.*, a statistically significant excess of worker deaths due to chronic bronchitis was found, which in his opinion was directly related to high cadmium exposures of 1 mg/m^3 or more (Tr. 6/8/90, pp. 156–157).

Cadmium need not be respirable to constitute a hazard. Inspirable cadmium particles that are too large to be respirable but small enough to enter the tracheobronchial region of the lung can lead to bronchoconstriction, chronic pulmonary disease, and cancer of that portion of the lung. All of these diseases have been associated with occupational exposure to cadmium (Ex. 8–86B). Particles that are constrained by their size to the extra-thoracic regions of the respiratory system such as the nose and maxillary sinuses can be swallowed through mucocillary clearance and be absorbed into the body (ACGIH, Ex. 8–692). The impaction of these particles in the upper airways can lead to anosmia, or loss of sense of smell, which is an early indication of overexposure among workers exposed to heavy metals. This condition is commonly reported among cadmium-exposed workers (Ex. 8–86B).

C. Medical Surveillance

In general, the main provisions of the medical surveillance section of the standard, under paragraphs (l)(1)–(17) of the regulatory text, are as follows:

1. Workers exposed above the action level are covered;

2. Workers with intermittent exposures are not covered;

3. Past workers who are covered receive biological monitoring for at least one year;

4. Initial examinations include a medical questionnaire and biological monitoring of cadmium in blood (CdB), cadmium in urine (CdU), and Beta-2-microglobulin in urine (β_2-M);

5. Biological monitoring of these three analytes is performed at least annually; full medical examinations are performed biennially;

6. Until five years from the effective date of the standard, medical removal is required when CdU is greater than 15 µg/gram creatinine (g Cr), or CdB is greater than 15 µg/liter whole blood (lwb), or β_2-M is greater than 1500 µg/g Cr, and CdB is greater than 5 µg/lwb or CdU is greater than 3 µg/g Cr;

7. Beginning five years after the standard is in effect, medical removal triggers will be reduced;

8. Medical removal protection benefits are to be provided for up to 18 months;

9. Limited initial medical examinations are required for respirator usage;

10. Major provisions are fully described under section (l) of the regulatory text; they are outlined here as follows:

A. Eligibility
B. Biological monitoring
C. Actions triggered by levels of CdU, CdB, and β_2-M (See Summary Charts and Tables in Attachment 1)
D. Periodic medical surveillance
E. Actions triggered by periodic medical surveillance (See Appendix A Summary Chart and Tables in Attachment 1)
F. Respirator usage
G. Emergency medical examinations
H. Termination examination
I. Information to physician
J. Physician's medical opinion
K. Medical removal protection
L. Medical removal protection benefits
M. Multiple physician review
N. Alternate physician review
O. Information employer gives to employee
P. Recordkeeping
Q. Reporting on OSHA form 200

11. The above mentioned summary of the medical surveillance provisions, the summary chart, and tables for the actions triggered at different levels of CdU, CdB and β_2-M (in Appendix A Attachment-1) are included only for the purpose of facilitating understanding of the provisions of paragraphs (l)(3) of the final cadmium standard. The summary of the provisions, the

summary chart, and the tables do not add to or reduce the requirements in paragraph (l)(3).

D. Recommendations to Physicians

1. It is strongly recommended that patients with tubular proteinuria are counseled on: the hazards of smoking; avoidance of nephrotoxins and certain prescriptions and over-the-counter medications that may exacerbate kidney symptoms; how to control diabetes and/or blood pressure; proper hydration, diet, and exercise (Ex. 19–2). A list of prominent or common nephrtoxins is attached. (See Appendix A Attachment-2.)

2. DO NOT CHELATE; KNOW WHICH DRUGS ARE NEPHROTOXINS OR ARE ASSOCIATED WITH NEPHRITIS.

3. The gravity of cadmium-induced renal damage is compounded by the fact there is no medical treatment to prevent or reduce the accumulation of cadmium in the kidney (Ex. 8–619). Dr. Friberg, a leading world expert on cadmium toxicity, indicated in 1992, that there is no form of chelating agent that could be used without substantial risk. He stated that tubular proteinuria has to be treated in the same way as other kidney disorders (Ex. 29).

4. After the results of a workers' biological monitoring or medical examination are received the employer is required to provide an information sheet to the patient, briefly explaining the significance of the results. (See Attachment 3 of this Appendix A.)

5. For additional information the physician is referred to the following additional resources:

a. The physician can always obtain a copy of the preamble, with its full discussion of the health effects, from OSHA's Computerized Information System (OCIS).

b. The Docket Officer maintains a record of the rulemaking. The Cadmium Docket (H–057A), is located at 200 Constitution Ave. NW., Room N–2625, Washington, DC 20210; telephone: 202–523–7894.

c. The following articles and exhibits in particular from that docket (H–057A):

Exhibit number—Author and paper title

8–447.—Lauwerys et. al., Guide for physicians, *Health Maintenance of Workers Exposed to Cadmium* published by the Cadmium Council.

4–67.—Takenaka, S., H. Oldiges, H. Konig, D. Hochrainer, G. Oberdorster. "Carcinogenicity of Cadmium Chloride Aerosols in Wistar Rats". *JNCI* 70:367373, 1983. (32)

4–68.—Thun, M.J., T.M. Schnoor, A.B. Smith, W.E. Halperin, R.A. Lemen. "Mortality Among a Cohort of U.S. Cadmium Production Workers—An Update." *JNCI* 74(2):325–33, 1985. (8)

4–25.—Elinder, C.G., Kjellstrom, T., Hogstedt, C., *et al.*, "Cancer Mortality of Cadmium Workers." *Brit. J. Ind. Med.* 42:651–655, 1985. (14)

4–26.—Ellis, K.J. et al., "Critical Concentrations of Cadmium in Human Renal Cortex: Dose Effect Studies to Cadmium Smelter Workers." *J. Toxicol. Environ. Health* 7:691–703, 1981. (76)

4–27.—Ellis, K.J., S.H. Cohn and T.J. Smith. "Cadmium Inhalation Exposure Estimates: Their Significance with Respect to Kidney and Liver Cadmium Burden." *J. Toxicol. Environ. Health* 15:173–187, 1985.

4–28.—Falck, F.Y., Jr., Fine, L.J., Smith, R.G., McClatchey, K.D., Annesley, T., England, B., and Schork, A.M. "Occupational Cadmium Exposure and Renal Status." *Am J. Ind. Med.* 4:541, 1983. (64)

8–86A. Friberg, L., C.G. Elinder, et al., *Cadmium and Health a Toxicological and Epidemiological Appraisal Volume I Exposure, Dose, and Metabolism*. CRC Press, Inc., Boca Raton, FL, 1986. (Available from the OSHA Technical Data Center)

8–86B. Friberg, L., C.G. Elinder, et al. *Cadmium and Health: A Toxicological and Epidemiological Appraisal Volume II Effects and Response*. CRC Press, Inc., Boca Raton, FL, 1986. (Available from the OSHA Technical Data Center)

L–140–45. Elinder, C.G., "Cancer Morality of Cadmium Workers", *Brit. J. Ind. Med.*, 42, 651–655, 1985.

L–140–50. Thun, M., Elinder, C.G., Friberg, L, "Scientific Basis for an Occupational Standard for Cadmium, *Am. J. Ind. Med.*, 20; 629–642, 1991.

V. Information Sheet

The information sheet (Appendix A Attachment-3.) or an equally explanatory one should be provided to you after any biological monitoring results are reviewed by the physician, or where applicable, after any medical examination.

Appendix A—Attachment 1: Summary Chart and Tables A and B of Actions Triggered by Biological Monitoring

Appendix A Summary Chart: Section (1)(3) Medical Surveillance

Categorizing Biological Monitoring Results

(A) Biological monitoring results categories are set forth in Appendix A Table A for the periods ending December 31, 1998 and for the period beginning January 1, 1999.

(B) The results of the biological monitoring for the initial medical exam and the subsequent exams shall determine an employee's biological monitoring result category.

Actions Triggered by Biological Monitoring

(A)(i) The actions triggered by biological monitoring for an employee are set forth in Appendix A Table B.

(ii) The biological monitoring results for each employee under section (1)(3) shall determine the actions required for that employee. That is, for any employee in biological monitoring category C, the employer will perform all of the actions for which there is an X in column C of Appendix A Table B.

(iii) An employee is assigned the alphabetical category ("A" being the lowest) depending upon the test results of the three biological markers.

(iv) An employee is assigned category A if monitoring results for all three biological markers fall at or below the levels indicated in the table listed for category A.

(v) An employee is assigned category B if any monitoring result for any of the three biological markers fall within the range of levels indicated in the table listed for category B, providing no result exceeds the levels listed for category B.

(vi) An employee is assigned category C if any monitoring result for any of the three biological markers are above the levels listed for category C.

(B) The user of Appendix A Tables A and B should know that these tables are provided only to facilitate understanding of the relevant provisions of paragraph (l)(3) of this section. Appendix A Tables A and B are not meant to add to or subtract from the requirements of those provisions.

Appendix A—Table A

Categorization of Biological Monitoring Results

Biological marker	Monitoring result categories		
	A	B	C
Applicable through 1998 only:			
Cadmium in urine (CdU); (μg/g creatinine)	≤ 3	> 3 and ≤ 15	> 15
β_2-microglobulin (β_2-M); (μg/g creatinine)	≤ 300	> 300 and ≤ 1500	[1]> 1500
Cadmium in blood (CdB); (μg/liter whole blood)	≤ 5	> 5 and ≤ 15	> 15
Applicable beginning January 1, 1999:			
Cadmium in urine (CdU); (μg/g creatinine)	≤ 3	> 3 and ≤ 7	> 7
β_2-microglobulin (β_2-M); (μg/g creatinine)	≤ 300	> 300 and ≤ 750	[2]> 750
Cadmium in blood (CdB); (μg/liter whole blood)	≤ 5	> 5 and ≤ 10	> 10

[1] If an employee's β_2-M levels are above 1,500 μg/g creatinine, in order for mandatory medical removal to be required (See Appendix A Table B.), either the employee's CdU level must also be > 3 μg/g creatinine or CdB level must also be > 5 μg/liter whole blood

[2] If an employee's β_2-M levels are above 750 μg/g creatinine, in order for mandatory medical removal to be required (See Appendix A Table B.), either the employee's CdU level must also be > 3 μg/g creatinine or CdB level must also be > 5 μg/liter whole blood.

Appendix A—Table B

Actions Determined by Biological Monitoring

This table presents the actions required based on the monitoring result in Appendix A Table A. Each item is a separate requirement in citing noncompliance. For example, a medical examination within 90 days for an employee in category B is separate from the requirement to administer a periodic medical examination for category B employees on an annual basis.

Required actions	Monitoring result category		
	A[1]	B[1]	C[1]
(1) Biological monitoring:			
(a) Annual	X		
(b) Semiannual		X	
(c) Quarterly			X
(2) Medical examination:			
(a) Biennial	X		
(b) Annual		X	
(c) Semiannual			X
(d) Within 90 days		X	X
(3) Assess within two weeks:			
(a) Excess cadmium exposure		X	X
(b) Work practices		X	X
(c) Personal hygiene		X	X
(d) Respirator usage		X	X
(e) Smoking history		X	X
(f) Hygiene facilities		X	X
(g) Engineering controls		X	X
(h) Correct within 30 days		X	X
(i) Periodically assess exposures			X
(4) Discretionary medical removal:		X	X
(5) Mandatory medical removal:			[2]X

[1] For all employees covered by medical surveillance exclusively because of exposures prior to the effective date of this standard, if they are in Category A, the employer shall follow the requirements of paragraphs (l)(3)(i)(B) and (l)(4)(v)(A). If they are in Category B or C, the employer shall follow the requirements of paragraphs (l)(4)(v)(B)–(C).

[2] See footnote Appendix A Table A.

Appendix A—Attachment 2: List of Medications

A list of the more common medications that a physician, and the employee, may wish to review is likely to include some of the following: (1) anticonvulsants: paramethadione, phenytoin, trimethadone; (2) antihypertensive drugs: captopril, methyldopa; (3) antimicrobials: aminoglycosides, amphotericin B, cephalosporins, ethambutol; (4) antineoplastic agents: cisplatin, methotrexate, mitomycin-C, nitrosoureas, radiation; (4) sulfonamide diuretics: acetazolamide, chlorthalidone, furosemide, thiazides; (5) halogenated alkanes, hydrocarbons, and solvents that may occur in some settings: carbon tetrachloride, ethylene glycol, toluene; iodinated radiographic contrast media; nonsteroidal anti-inflammatory drugs; and, (7) other miscellaneous compounds: acetominophen, allopurinol, amphetamines, azathioprine, cimetidine, cyclosporine, lithium, methoxyflurane, methysergide, D-penicillamine, phenacetin, phenendione. A list of drugs associated with acute interstitial nephritis includes: (1) antimicrobial drugs: cephalosporins, chloramphenicol, colistin, erythromycin, ethambutol, isoniazid, paraaminosalicylic acid, penicillins, polymyxin B, rifampin, sulfonamides, tetracyclines, and vancomycin; (2) other

miscellaneous drugs: allopurinol, antipyrene, azathioprine, captopril, cimetidine, clofibrate, methyldopa, phenindione, phenylpropanolamine, phenytoin, probenecid, sulfinpyrazone, sulfonamid diuretics, triamterene; and, (3) metals: bismuth, gold.

This list have been derived from commonly available medical textbooks (e.g., Ex. 14–18). The list has been included merely to facilitate the physician's, employer's, and employee's understanding. The list does not represent an official OSHA opinion or policy regarding the use of these medications for particular employees. The use of such medications should be under physician discretion.

Appendix A—Attachment 3

Biological Monitoring and Medical Examination Results

Employee _____

Testing Date _____

Cadmium in Urine _____ µg/g Cr

Cadmium in Blood _____ µg/lwb

Beta-2-microglobulin in Urine _____ µg/g Cr

Normal Levels: ≤3 µg/g Cr, ≤5 µg/lwb, ≤300 µg/g Cr

Physical Examination Results: N/A_____Satisfactory _____ Unsatisfactory_____(see physician again)

Physician's Review of Pulmonary Function Test: N/A_____Normal _____Abnormal_____

Next biological monitoring or medical examination scheduled for _____

The biological monitoring program has been designed for three main purposes: (1) to identify employees at risk of adverse health effects from excess, chronic exposure to cadmium; (2) to prevent cadmium-induced disease(s); and (3) to detect and minimize existing cadmium-induced disease(s).

The levels of cadmium in the urine and blood provide an estimate of the total amount of cadmium in the body. The amount of a specific protein in the urine (beta-2-microglobulin) indicates changes in kidney function. All three tests must be evaluated together. A single mildly elevated result may not be important if testing at a later time indicates that the results are normal and the workplace has been evaluated to decrease possible sources of cadmium exposure. The levels of cadmium or beta-2-microglobulin may change over a period of days to months and the time needed for those changes to occur is different for each worker.

If the results for biological monitoring are above specific "high levels" [cadmium urine greater than 10 micrograms per gram of creatinine (µg/g Cr), cadmium blood greater than 10 micrograms per liter of whole blood (µg/lwb), or beta-2-microglobulin greater than 1000 micrograms per gram of creatinine (µg/g Cr)], the worker has a much greater chance of developing other kidney diseases.

One way to measure for kidney function is by measuring beta-2-microglobulin in the urine. Beta-2-microglobulin is a protein which is normally found in the blood as it is being filtered in the kidney, and the kidney reabsorbs or returns almost all of the beta-2-microglobulin to the blood. A very small amount (less than 300 µg/g Cr in the urine) of beta-2-microglobulin is not reabsorbed into the blood, but is released in the urine. If cadmium damages the kidney, the amount of beta-2-microglobulin in the urine increases because the kidney cells are unable to reabsorb the beta-2-microglobulin normally. An increase in the amount of beta-2-microglobulin in the urine is a very early sign of kidney dysfunction. A small increase in beta-2-microglobulin in the urine will serve as an early warning sign that the worker may be absorbing cadmium from the air, cigarettes contaminated in the workplace, or eating in areas that are cadmium contaminated.

Even if cadmium causes permanent changes in the kidney's ability to reabsorb beta-2-microglobulin, and the beta-2-microglobulin is above the "high levels", the loss of kidney function may not lead to any serious health problems. Also, renal function naturally declines as people age. The risk for changes in kidney function for workers who have biological monitoring results between the "normal values" and the "high levels" is not well known. Some people are more cadmium-tolerant, while others are more cadmium-susceptible.

For anyone with even a slight increase of beta-2-microglobulin, cadmium in the urine, or cadmium in the blood, it is very important to protect the kidney from further damage. Kidney damage can come from other sources than excess cadmium-exposure so it is also recommended that if a worker's levels are "high" he/she should receive counseling about drinking more water; avoiding cadmium-tainted tobacco and certain medications (nephrotoxins, acetaminophen); controlling diet, vitamin intake, blood pressure and diabetes; etc.

Appendix B—Substance Technical Guidelines for Cadmium

I. Cadmium Metal

A. Physical and Chemical Data

1. *Substance Identification*

Chemical name: Cadmium.

Formula: Cd.

Molecular Weight: 112.4.

Chemical Abstracts Service (CAS) Registry No.: 7740–43–9.

Other Identifiers: RETCS EU9800000; EPA D006; DOT 2570 53.

Synonyms: Colloidal Cadmium: Kadmium (German): CI 77180.

2. *Physical data*

Boiling point: (760 mm Hg): 765 degrees C.

Melting point: 321 degrees C.

Specific Gravity: (H_2O=@ 20°C): 8.64.

Solubility: Insoluble in water; soluble in dilute nitric acid and in sulfuric acid.

Appearance: soft, blue-white, malleable, lustrous metal or grayish-white powder.

B. Fire, Explosion and Reactivity Data

1. *Fire*

Fire and Explosion Hazards: The finely divided metal is pyrophoric, that is the dust is a severe fire hazard and moderate explosion hazard when exposed to heat or flame. Burning material reacts violently with extinguishing agents such as water, foam, carbon dioxide, and halons.

Flash point: flamable (dust).

Extinguishing media: Dry sand, dry dolomite, dry graphite, or sodimum chloride.

2. *Reactivity*

Conditions contributing to instability: Stable when kept in sealed containers under normal temperatures and pressure, but dust may ignite upon contact with air. Metal tarnishes in moist air.

Incompatibilities: Ammonium nitrate, fused: reacts violently or explosively with cadmium dust below 20°C. Hydrozoic acid: violent explosion occurs after 30 minutes. Acids: reacts violently, forms hydrogen gas. Oxidizing agents or metals: strong reaction with cadmium dust. Nitryl fluoride at slightly elevated temperature: glowing or white incandescence occurs. Selenium: reacts exothermically. Ammonia: corrosive reaction. Sulfur dioxide: corrosive reaction. Fire extinguishing agents (water, foam, carbon dioxide, and halons): reacts violently. Tellurium: incandescent reaction in hydrogen atmosphere.

Hazardous decomposition products: The heated metal rapidly forms highly toxic, brownish fumes of oxides of cadmium.

C. Spill, Leak and Disposal Procedures

1. *Steps to be taken if the materials is released or spilled*

Do not touch spilled material. Stop leak if you can do it without risk. Do not get water inside container. For large spills, dike spill for later disposal. Keep unnecessary people away. Isolate hazard area and deny entry. The Superfund Amendments and Reauthorization Act of 1986 Section 304 requires that a release equal to or greater than the reportable quantity for this substance (1 pound) must be immediately reported to the local emergency planning committee, the state emergency response commission, and the National Response Center (800) 424–8802; in Washington, D.C. metropolitan area (202) 426–2675.

II. Cadmium Oxide

A. Physical and Chemical Data

1. *Substance identification*

Chemical name: Cadmium Oxide.

Formula: CdO.

Molecular Weight: 128.4.

CAS No.: 1306–19–0.

Other Identifiers: RTECS EV1929500.

Synonyms: Kadmu tlenek (Polish).

2. *Physical data*

Boiling point (760 mm Hg): 950 degrees C decomposes.

Melting point: 1500°C.

Specific Gravity: (H_2O = 1 @ 20°oC): 7.0.

Solubility: Insoluble in water; soluble in acids and alkalines.

Appearance: Red or brown crystals.

B. Fire, Explosion and Reactivity Data

1. *Fire*

Fire and Explosion Hazards: Negligible fire hazard when exposed to heat or flame.

Flash point: Nonflammable.

Extinguishing media: Dry chemical, carbon dioxide, water spray or foam.

2. *Reactivity*

Conditions contributing to instability: Stable under normal temperatures and pressures.

Incompatibilities: Magnesium may reduce CdO_2 explosively on heating.

Hazardous decomposition products: Toxic fumes of cadmium.

C. Spill Leak and Disposal Procedures

1. *Steps to be taken if the material is released or spilled*

Do not touch spilled material. Stop leak if you can do it without risk. For small spills, take up with sand or other absorbent material and place into containers for later disposal. For small dry spills, use a clean shovel to place material into clean, dry container and then cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard area and deny entry. The Superfund Amendments and Reauthorization Act of 1986 Section 304 requires that a release equal to or greater than the reportable quantity for this substance (1 pound) must be immediately reported to the local emergency planning committee, the state emergency response commission, and the National Response Center (800) 424–8802; in Washington, D.C. metropolitan area (202) 426–2675.

III. Cadmium Sulfide

A. Physical and Chemical Data

1. *Substance Identification*

Chemical name: Cadmium sulfide.

Formula: CdS.

Molecular weight: 144.5.

CAS No. 1306–23–6.

Other Identifiers: RTECS EV3150000.

Synonyms: Aurora yellow; Cadmium Golden 366; Cadmium Lemon Yellow 527; Cadmium Orange; Cadmium Primrose 819; Cadmium Sulphide; Cadmium Yellow; Cadmium Yellow 000; Cadmium Yellow Conc. Deep; Cadmium Yellow Conc. Golden; Cadmium Yellow Conc. Lemon; Cadmium Yellow Conc. Primrose; Cadmium Yellow Oz. Dark; Cadmium Yellow Primrose 47–1400; Cadmium Yellow 10G Conc.; Cadmium Yellow 892; Cadmopur Golden Yellow N; Cadmopur Yellow; Capsebon; C.I. 77199; C.I. Pigment Orange 20; CI Pigment Yellow 37; Ferro Lemon Yellow; Ferro Orange Yellow; Ferro Yellow; Greenockite; NCI–C02711.

2. *Physical data*

Boiling point (760 mm. Hg): sublines in N_2 at 980°C.

Melting point: 1750 degrees C (100 atm).

Specific Gravity: (H_2O= 1@ 20°C): 4.82.

Solubility: Slightly soluble in water; soluble in acid.

Appearance: Light yellow or yellow-orange crystals.

B. Fire, Explosion and Reactivity Data

1. *Fire*

Fire and Explosion Hazards: Neglisible fire hazard when exposed to heat or flame.

Flash point: Nonflamable.

Extinguishing media: Dry chemical, carbon dioxide, water spray or foam.

2. *Reactivity*

Conditions contributing to instability: Generally non-reactive under normal conditions. Reacts with acids to form toxic hydrogen sulfide gas.

Incompatibilities: Reacts vigorously with iodinemonochloride.

Hazardous decomposition products: Toxic fumes of cadmium and sulfur oxides.

C. Spill Leak and Disposal Procedures

1. *Steps to be taken if the material is released or spilled.*

Do not touch spilled material. Stop leak if you can do it without risk. For small, dry spills, with a clean shovel place material into clean, dry container and cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard and deny entry.

IV. Cadmium Chloride

A. Physical and Chemical Data

1. *Substance Identification*

Chemical name: Cadmium chloride.

Formula: $CdCl_2$.

Molecular weight: 183.3.

CAS No. 10108–64–2.

Other Indentifiers: RTECS EY0175000.

Synonyms: Caddy; Cadmium dichloride; NA 2570 (DOT); UI-CAD; dichlorocadmium.

2. *Physical data*

Boiling point (760 mm Hg): 960 degrees C.

Melting point: 568 degrees C.

Specific Gravity: (H_2O = 1 @ 20 °C): 4.05.

Solubility: Soluble in water (140 g/100 cc); soluble in acetone.

Appearance: small, white crystals.

B. Fire, Explosion and Reactivity Data

1. *Fire*

Fire and Explosion Hazards: Negligible fire and negligible explosion hazard in dust form when exposed to heat or flame.

Flash point: Nonflamable.

Extinguishing media: Dry chemical, carbon dioxide, water spray or foam.

2. *Reactivity*

Conditions contributing to instability: Generally stable under normal temperatures and pressures.

Incompatibilities: Bromine triflouride rapidly attacks cadmium chloride. A mixture of potassium and cadmium chloride may produce a strong explosion on impact.

Hazardous decomposition products: Thermal decomposition may release toxic fumes of hydrogen chloride, chloride, chlorine or oxides of cadmium.

C. Spill Leak and Disposal Procedures

1. *Steps to be taken if the material is released or spilled.*

Do not touch spilled material. Stop leak if you can do it without risk. For small, dry spills, with a clean shovel place material into clean, dry container and cover. Move containers from spill area. For larger spills, dike far ahead of spill for later disposal. Keep unnecessary people away. Isolate hazard and deny entry. The Superfund Amendments and Reauthorization Act of 1986 Section 304 requires that a release equal to or greater than the reportable quantity for this substance (100 pounds) must be immediately reported to the local emergency planning committee, the state emergency response commission, and the National Response Center (800) 424–8802; in Washington, D.C. Metropolitan area (202) 426–2675.

Appendix C—Qualitative and Quantitative Fit Testing Procedures

I. Fit Test Protocols

A. General

The employer shall include the following provisions in the fit test procedures. These provisions apply to both qualitative fit testing (QLFT) and quantitative fit testing (QNFT). All testing is to be conducted annually.

1. The test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask; or three sizes of full facepiece. Respirators of each size must be provided from at least two manufacturers.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use; it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted, maintained and used properly, will provide substantial protection.

4. The test subject shall be instructed to hold each facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose;

(b) Room for eye protection;

(c) Room to talk; and

(d) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip; and

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described below or in ANSI Z88.2–1980. Before conducting the negative or positive pressure test, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly

while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

(a). *Positive pressure test.* Close off the exhalation valve and exhale gently onto the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

(b). *Negative pressure test.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s). Inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician trained in respiratory disease or pulmonary medicine to determine, in accordance with paragraph (1), (2) and (3) of this standard, whether the test subject can wear a respirator while performing her or his duties.

11. The test subject shall be given the opportunity to wear the successfully fitted respirator for a period of two weeks. If at any time during this period the respirator becomes uncomfortable, the test subject shall be given the opportunity to select a different facepiece and to be retested.

12. The employer shall maintain a record of the fit test administered to an employee. The record shall contain at least the following information:

(a) Name of employee;

(b) Type of respirator;

(c) Brand, size of respirator;

(d) Date of test; and

(e) Where QNFT is used, the fit factor and strip chart recording or other recording of the results of the test. The record shall be maintained until the next fit test is administered.

13. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

14. Test Exercises. The test subject shall perform exercises, in the test environment, in the manner described below:

(a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(b) Deep breathing. In a normal standing position, without talking, the subject shall breathe slowly and deeply, taking care so as to not hyperventilate.

(c) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

(f) Grimace. The test subject shall grimace by smiling or frowning.

(g) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) Normal breathing. Same as exercise 1. Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall assure that persons administering QLFTs are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

(a) Odor threshold screening. The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1-liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated and shall not be connected to the same recirculating ventilation system.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled, dried off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl acetate fit test

(1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors. The cartridges or masks shall be changed at least weekly.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the head exercises; and to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the respirator fit is inadequate. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the respirator fit was inadequate, the subject shall return to the selection room and remove the respirator, repeat the odor sensitivity test, select and put on another respirator, return to the test chamber and again begin the procedure described in paragraph (I)(B)(2)(b) (1) through (7) of this appendix. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When a respirator is found that passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test. To keep the test area from becoming contaminated, the used towels shall be kept in a self sealing bag so there is no significant IAA concentration build-up in the test chamber during subsequent tests.

3. Irritant Fume Protocol

(a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its characteristic odor.

(c) Break both ends of a ventilation smoke tube containing stannic oxychloride, such as the MSA part No. 5645, or equivalent. Attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute.

(d) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 14 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

4. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) Threshold screening as well as fit testing subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾ inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her wide open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer the test conductor shall spray the threshold check solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution consists of 0.83 grams of sodium saccharin USP in 1 cc of warm water. It can be prepared by putting 1 cc of the fit test solution (see (b)(5) below) in 100 cc of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 cc of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure

(1) The test subject may not eat, drink (except plain water), or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 cc of warm water.

(6) As before, the test subject shall breathe through the open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I.A. 14 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried".

C. Quantitative Fit Test (QNFT) Protocol

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

2. Definitions

(a) Quantitative fit test. The test is performed in a test chamber. The normal air-purifying element of the respirator is replaced by a high-efficiency particulate air (HEPA) filter in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(b) Challenge agent means the aerosol, gas or vapor introduced into a test chamber so that its concentration inside and outside the respirator may be measured.

(c) Test subject means the person wearing the respirator for quantitative fit testing.

(d) Normal standing position means standing erect and straight with arms down along the sides and looking straight ahead.

(e) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(f) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(g) "Fit Factor" means the ratio of challenge agent concentration outside with respect to the inside of a respirator inlet covering (facepiece or enclosure).

3. Apparatus

(a) Instrumentation. Aerosol generation, dilution, and measurement systems using corn oil or sodium chloride as test aerosols shall be used for quantitative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter supplied by the same manufacturer.

(d) The sampling instrument shall be selected so that a strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration in the test chamber shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator.

(g) The test chamber and test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent inside the test chamber constant to within a 10 percent variation for the duration of the test.

(i) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event inside the test chamber and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. Procedural Requirements

(a) When performing the initial positive or negative pressure test the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these tests.

(b) An abbreviated screening isoamyl acetate test or irritant fume test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. When performing a screening isoamyl acetate test, combination high-efficiency organic vapor cartridges/canisters shall be used.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be overtightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested. If two of the three required tests are terminated, the fit shall be deemed inadequate.

(h) In order to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator (e.g. half mask respirator, full facepiece respirator).

(i) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration inside the respirator.

(2) The average test chamber concentration is the arithmetic average of the test chamber concentration at the beginning and of the end of the test.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak concentration.

(ii) Maximum peak concentration.

(iii) Integration by calculation of the area under the individual peak for each exercise. This includes computerized integration.

(j) Interpretation of test results. The fit factor established by the quantitative fit testing shall be the lowest of the three fit factor values calculated from the three required fit tests.

(k) The test subject shall not be permitted to wear a half mask, or full facepiece respirator unless a minimum fit factor equivalent to at least 10 times the hazardous exposure level is obtained.

(l) Filters used for quantitative fit testing shall be replaced at least weekly, or whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced daily (when used) or sooner if there is any indication of breakthrough by a test agent.

Appendix D—Occupational Health History Interview With Reference to Cadmium Exposure

Directions

(To be read by employee and signed prior to the interview)

Please answer the questions you will be asked as completely and carefully as you can. These questions are asked of everyone who works with cadmium. You will also be asked to give blood and urine samples. The doctor will give your employer a written opinion on whether you are physically capable of working with cadmium. Legally, the doctor cannot share personal information you may tell him/her with your employer. The following information is considered strictly confidential. The results of the tests will go to you, your doctor and your employer. You will also receive an information sheet explaining the results of any biological monitoring or physical examinations performed.

If you are just being hired, the results of this interview and examination will be used to:

(1) Establish your health status and see if working with cadmium might be expected to cause unusual problems,

(2) Determine your health status today and see if there are changes over time,

(3) See if you can wear a respirator safely.

If you are not a new hire:

OSHA says that everyone who works with cadmium can have periodic medical examinations performed by a doctor. The reasons for this are:

(a) If there are changes in your health, either because of cadmium or some other reason, to find them early,

(b) To prevent kidney damage.

Please sign below.

I have read these directions and understand them:

Employee signature

Date

Thank you for answering these questions.

(Suggested Format)

Name

Age

Social Security #

Company

Job

Type of Preplacement Exam:
[ ] Periodic
[ ] Termination
[ ] Initial
[ ] Other

Blood Pressure

Pulse Rate

1. How long have you worked at the job listed above?
[ ] not yet hired
[ ] number of months
[ ] number of years

2. Job Duties Etc.

3. Have you *ever* been told by a doctor that you had bronchitis?
[ ] yes
[ ] no

If yes, how long ago?
[ ] number of months
[ ] number of years

4. Have you *ever* been told by a doctor that you had emphysema?
[ ] yes
[ ] no

If yes, how long ago?
[ ] number of years
[ ] number of months

5. Have you *ever* been told by a doctor that you had other lung problems?
[ ] yes
[ ] no

If yes, please describe type of lung problems and when you had these problems.

6. In the past year, have you had a cough?
[ ] yes
[ ] no

If yes, did you cough up sputum?
[ ] yes
[ ] no

If yes, how long did the cough with sputum production last?
[ ] less than 3 months
[ ] 3 months or longer

If yes, for how many years have you had episodes of cough with sputum production lasting this long?
[ ] less than one
[ ] 1
[ ] 2
[ ] longer than 2

7. Have you ever smoked cigarettes?
[ ] yes
[ ] no

8. Do you now smoke cigarettes?
[ ] yes
[ ] no

9. If you smoke or have smoked cigarettes, for how many years have you smoked, or did you smoke?
[ ] less than 1 year
[ ] number of years

What is or was the greatest number of packs per day that you have smoked?
[ ] number of packs

If you quit smoking cigarettes, how many years ago did you quit?
[ ] less than 1 year
[ ] number of years

How many packs a day do you now smoke?
[ ] number of packs per day

10. Have you ever been told by a doctor that you had a kidney or urinary tract disease or disorder?
[ ] yes
[ ] no

11. Have you ever had any of these disorders?

Kidney stones
[ ] yes [ ] no

Protein in urine
[ ] yes [ ] no

Blood in urine
[ ] yes [ ] no

Difficulty urinating
[ ] yes [ ] no

Other kidney/Urinary disorders
[ ] yes [ ] no

Please describe problems, age, treatment, and follow up for any kidney or urinary problems you have had:

12. Have you ever been told by a doctor or other health care provider who took your blood pressure that your blood pressure was high?
[ ] yes
[ ] no

13. Have you ever been advised to take any blood pressure medication?
[ ] yes
[ ] no

14. Are you presently taking any blood pressure medication?
[ ] yes
[ ] no

15. Are you presently taking any other medication?
[ ] yes
[ ] no

16. Please list any blood pressure or other medications and describe how long you have been taking each one:

Medicine	How long taken

Medicine	How long taken

17. Have you ever been told by a doctor that you have diabetes? (sugar in your blood or urine)
[ ] yes
[ ] no

If yes, do you presently see a doctor about your diabetes?
[ ] yes
[ ] no

If yes, how do you control your blood sugar?
[ ] diet alone
[ ] diet plus oral medicine
[ ] diet plus insulin (injection)

18. Have you ever been told by a doctor that you had:

anemia
[ ] yes [ ] no

a low blood count?
[ ] yes [ ] no

19. Do you presently feel that you tire or run out of energy sooner than normal or sooner than other people your age?
[ ] yes
[ ] no

If yes, for how long have you felt that you tire easily?
[ ] less than 1 year
[ ] number of years

20. Have you given blood within the last year?
[ ] yes
[ ] no

If yes, how many times?
[ ] number of times

How long ago was the last time you gave blood?
[ ] less than 1 month
[ ] number of months

21. Within the last year have you had any injuries with heavy bleeding?
[ ] yes
[ ] no

If yes, how long ago?
[ ] less than 1 month
[ ] number of months

Describe:

22. Have you recently had any surgery?
[ ] yes
[ ] no

If yes, please describe:

23. Have you seen any blood lately in your stool or after a bowel movement?
[ ] yes
[ ] no

24. Have you ever had a test for blood in your stool?
[ ] yes
[ ] no

If yes, did the test show any blood in the stool?
[ ] yes
[ ] no

What further evaluation and treatment were done?

The following questions pertain to the ability to wear a respirator. Additional information for the physician can be found in The Respiratory Protective Devices Manual.

25. Have you ever been told by a doctor that you have asthma?
[ ] yes
[ ] no
If yes, are you presently taking any medication for asthma? Mark all that apply.
[ ] shots
[ ] pills
[ ] inhaler
26. Have you ever had a heart attack?
[ ] yes
[ ] no
If yes, how long ago?
[ ] number of years
[ ] number of months
27. Have you ever had pains in your chest?
[ ] yes
[ ] no
If yes, when did it usually happen?
While resting [ ]
While working [ ]
While exercising [ ]
Activity didn't matter [ ]
28. Have you ever had a thyroid problem?
[ ] yes
[ ] no
29. Have you ever had a seizure or fits?
[ ] yes
[ ] no
30. Have you ever had a stroke (cerebrovascular accident)?
[ ] yes
[ ] no
31. Have you ever had a ruptured eardrum or a serious hearing problem?
[ ] yes
[ ] no
32. Do you now have a claustrophobia, meaning fear of crowded or closed in spaces or any psychological problems that would make it hard for you to wear a respirator?
[ ] yes
[ ] no

The following questions pertain to reproductive history.

33. Have you or your partner had a problem conceiving a child?
[ ] yes
[ ] no
If yes, specify:
[ ] self
[ ] present mate
[ ] previous mate
34. Have you or your partner consulted a physician for a fertility or other reproductive problem?
[ ] yes
[ ] no
If yes, specify who consulted the physician:
[ ] self
[ ] spouse/partner
[ ] self and partner
If yes, specify diagnosis made: _____

35. Have you or your partner ever conceived a child resulting in a miscarriage, still birth or deformed offspring?
[ ] yes
[ ] no
If yes, specify:
[ ] miscarriage
[ ] still birth
[ ] deformed offspring
If outcome was a deformed offspring, please specify type: _____

36. Was this outcome a result of a pregnancy of:
[ ] yours with present partner
[ ] yours with a previous partner
37. Did the timing of any abnormal pregnancy outcome coincide with present employment?
[ ] yes
[ ] no
List dates of occurrences: _____

38. What is the occupation of your spouse or partner?

For Women Only

39. Do you have menstrual periods?
[ ] yes
[ ] no
Have you had menstrual irregularities?
[ ] yes
[ ] no
If yes, specify type: _____

If yes, what was the approximated date this problem began? _____
Approximate date problem stopped? _____

For Men Only

40. Have you ever been diagnosed by a physician as having prostate gland problem(s)?
[ ] yes
[ ] no
If yes, please describe type of problem(s) and what was done to evaluate and treat the problem(s) :

Appendix E—Cadmium in Workplace Atmospheres

Method Number: ID–189.

Matrix: Air.

OSHA Permissible Exposure Limits: 5 μg/m³ (TWA) 2.5 μg/m³ (Action Level TWA).

Collection Procedure: A known volume of air is drawn through a 37-mm diameter filter cassette containing a 0.8-μm mixed cellulose ester membrane filter (MCEF).

Recommended Air Volume: 960 L.

Recommended Sampling Rate: 2.0 L/min.

Analytical Procedure: Air filter samples are digested with nitric acid. After digestion, a small amount of hydrochloric acid is added. The samples are then diluted to volume with deionized water and analyzed by either flame atomic absorption spectroscopy (AAS) or flameless atomic absorption spectroscopy using a heated graphite furnace atomizer (AAS–HGA).

Detection Limits:

Qualitative: 0.2 μg/m³ for a 200 L sample by Flame AAS; 0.007 μg/m³ for a 60 L sample by AAS–HGA

Quantitative: 0.70 μg/m³ for a 200 L sample by Flame AAS; 0.025 μg/m³ for a 60 L sample by AAS–HGA

Precision and Accuracy: *Flame AAS Analysis, AAS–HGA Analysis.*

VALIDATION LEVEL

	2.5 to 10 μg/m³ for a 400 L air vol.	1.25 to 5.0 μg/m³ for a 60 L air vol.
CV_1 (pooled)	0.010	0.043
Analytical Bias	+4.0%	−5.8%
Overall Analytical Error	±6.0%	±14.2%

Method Classification: Validated.

Date: June, 1992.

Inorganic Service Branch II, OSHA Salt Lake Technical Center, Salt Lake City, Utah.

Commercial manufacturers and products mentioned in this method are for descriptive use only and do not constitute endorsements by USDOL-OSHA. Similar products from other sources can be substituted.

1. Introduction

1.1. Scope—This method describes the collection of airborne elemental cadmium and cadmium compounds on 0.8-µm mixed cellulose ester membrane filters and their subsequent analysis by either flame atomic absorption spectroscopy (AAS) or flameless atomic absorption spectroscopy using a heated graphite furnace atomizer (AAS-HGA). It is applicable for both TWA and Action Level TWA Permissible Exposure Level (PEL) measurements. The two atomic absorption analytical techniques included in the method do not differentiate between cadmium fume and cadmium dust samples. They also do not differentiate between elemental cadmium and its compounds.

1.2. Principle—Airborne elemental cadmium and cadmium compounds are collected on a 0.8-µm mixed cellulose ester membrane filter (MCEF). The air filter samples are digested with concentrated nitric acid to destroy the organic matrix and dissolve the cadmium analytes. After digestion, a small amount of concentrated hydrochloric acid is added to help dissolve other metals which may be present. The samples are diluted to volume with deionized water and then aspirated into the oxidizing air/acetylene flame of an atomic absorption spectrophotometer for analysis of elemental cadmium. If the concentration of cadmium in a sample solution is too low for quantitation by this flame AAS analytical technique, and the sample is to be averaged with other samples for TWA calculations, aliquots of the sample and a matrix modifier are later injected onto a L'vov platform in a pyrolytically-coated graphite tube of a Zeeman atomic absorption spectrophotometer/graphite furnace assembly for analysis of elemental cadmium. The matrix modifier is added to stabilize the cadmium metal and minimize sodium chloride as an interference during the high temperature charring step of the analysis (5.1., 5.2.).

1.3. History—Previously, two OSHA sampling and analytical methods for cadmium were used concurrently (5.3., 5.4.). Both of these methods also required 0.8-µm mixed cellulose ester membrane filters for the collection of air samples. These cadmium air filter samples were analyzed by either flame atomic absorption spectroscopy (5.3.) or inductively coupled plasma/atomic emission spectroscopy (ICP-AES) (5.4.). Neither of these two analytical methods have adequate sensitivity for measuring workplace exposure to airborne cadmium at the new lower TWA and Action Level TWA PEL levels when consecutive samples are taken on one employee and the sample results need to be averaged with other samples to determine a single TWA.

The inclusion of two atomic absorption analytical techniques in the new sampling and analysis method for airborne cadmium permits quantitation of sample results over a broad range of exposure levels and sampling periods. The flame AAS analytical technique included in this method is similar to the previous procedure given in the General Metals Method ID–121 (5.3.) with some modifications. The sensitivity of the AAS–HGA analytical technique included in this method is adequate to measure exposure levels at 1/10 the Action Level TWA, or lower, when less than full-shift samples need to be averaged together.

1.4. Properties (5.5.)—Elemental cadmium is a silver-white, blue-tinged, lustrous metal which is easily cut with a knife. It is slowly oxidized by moist air to form cadmium oxide. It is insoluble in water, but reacts readily with dilute nitric acid. Some of the physical properties and other descriptive information of elemental cadmium are given below:

CAS No.7440–43–9

Atomic Number—48
Atomic Symbol—Cd
Atomic Weight—112.41
Melting Point—321 °C
Boiling Point—765 °C
Density—8.65 g/mL (25 °C)

The properties of specific cadmium compounds are described in reference 5.5.

1.5. Method Performance—A synopsis of method performance is presented below. Further information can be found in Section 4.

1.5.1. The qualitative and quantitative detection limits for the flame AAS analytical technique are 0.04 µg (0.004 µg/mL) and 0.14 µg (0.014 µg/mL) cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.2 µg/m³ and 0.70 µg/m³ for a 200 L air volume.

1.5.2. The qualitative and quantitative detection limits for the AAS–HGA analytical technique are 0.44 ng (0.044 ng/mL) and 1.5 ng (0.15 ng/mL) cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.007 µg/m³ and 0.025 µg/m³ for a 60 L air volume.

1.5.3. The average recovery by the flame AAS analytical technique of 17 spiked MCEF samples containing cadmium in the range of 0.5 to 2.0 times the TWA target concentration of 5 µg/m³ (assuming a 400 L air volume) was 104.0% with a pooled coefficient of variation (CV_1) of 0.010. The flame analytical technique exhibited a positive bias of +4.0% for the validated concentration range. The overall analytical error (OAE) for the flame AAS analytical technique was ±6.0%.

1.5.4. The average recovery by the AAS–HGA analytical technique of 18 spiked MCEF samples containing cadmium in the range of 0.5 to 2.0 times the Action Level TWA target concentration of 2.5 µg/m³ (assuming a 60 L air volume) was 94.2% with a pooled coefficient of variation (CV_1) of 0.043. The AAS–HGA analytical technique exhibited a negative bias of −5.8% for the validated concentration range. The overall analytical error (OAE) for the AAS–HGA analytical technique was ±14.2%.

1.5.5. Sensitivity in flame atomic absorption is defined as the characteristic concentration of an element required to produce a signal of 1% absorbance (0.0044 absorbance units). Sensitivity values are listed for each element by the atomic absorption spectrophotometer manufacturer and have proved to be a very valuable diagnostic tool to determine if instrumental parameters are optimized and if the instrument is performing up to specification. The sensitivity of the spectrophotometer used in the validation of the flame AAS analytical technique agreed with the manufacturer specifications (5.6.); the 2 µg/mL cadmium standard gave an absorbance reading of 0.350 abs. units.

1.5.6. Sensitivity in graphite furnace atomic absorption is defined in terms of the characteristic mass, the number of picograms required to give an integrated absorbance value of 0.0044 absorbance-second (5.7.). Data suggests that under Stabilized Temperature Platform Furnace (STPF) conditions (see Section 1.6.2.), characteristic mass values are transferable between properly functioning instruments to an accuracy of about 20% (5.2.). The characteristic mass for STPF analysis of cadmium with Zeeman background correction listed by the manufacturer of the instrument used in the validation of the AAS–HGA analytical technique was 0.35 pg. The experimental characteristic mass value observed during the determination of the working range and detection limits of the AAS–HGA analytical technique was 0.41 pg.

1.6. Interferences

1.6.1. High concentrations of silicate interfere in determining cadmium by flame AAS (5.6.). However, silicates are not significantly soluble in the acid matrix used to prepare the samples.

1.6.2. Interferences, such as background absorption, are reduced to a minimum in the AAS–HGA analytical technique by taking full advantage of the Stabilized Temperature Platform Furnace (STPF) concept. STPF includes all of the following parameters (5.2.):

a. Integrated Absorbance,
b. Fast Instrument Electronics and Sampling Frequency,
c. Background Correction,
d. Maximum Power Heating,
e. Atomization off the L'vov platform in a pyrolytically coated graphite tube,
f. Gas Stop during Atomization,
g. Use of Matrix Modifiers.

1.7. Toxicology (5.14.)

Information listed within this section is synopsis of current knowledge of the physiological effects of cadmium and is not intended to be used as the basis for OSHA policy.

IARC classifies cadmium and certain of its compounds as Group 2A carcinogens (probably carcinogenic to humans). Cadmium fume is intensely irritating to the respiratory tract. Workplace exposure to cadmium can cause both chronic and acute effects. Acute effects include tracheobronchitis, pneumonitis, and pulmonary edema. Chronic effects include anemia, rhinitis/anosmia, pulmonary emphysema, proteinuria and lung cancer. The primary target organs for chronic disease are the kidneys (non-carcinogenic) and the lungs (carcinogenic).

2. Sampling

2.1. Apparatus

2.1.1. Filter cassette unit for air sampling: A 37-mm diameter mixed cellulose ester membrane filter with a pore size of 0.8-µm contained in a 37-mm polystyrene two- or three-piece cassette filter holder (part no. MAWP 037 A0, Millipore Corp., Bedford,

MA). The filter is supported with a cellulose backup pad. The cassette is sealed prior to use with a shrinkable gel band.

2.1.2. A calibrated personal sampling pump whose flow is determined to an accuracy of ±5% at the recommended flow rate with the filter cassette unit in line.

2.2. Procedure

2.2.1. Attach the prepared cassette to the calibrated sampling pump (the backup pad should face the pump) using flexible tubing. Place the sampling device on the employee such that air is sampled from the breathing zone.

2.2.2. Collect air samples at a flow rate of 2.0 L/min. If the filter does not become overloaded, a full-shift (at least seven hours) sample is strongly recommended for TWA and Action Level TWA measurements with a maximum air volume of 960 L. If overloading occurs, collect consecutive air samples for shorter sampling periods to cover the full workshift.

2.2.3. Replace the end plugs into the filter cassettes immediately after sampling. Record the sampling conditions.

2.2.4. Securely wrap each sample filter cassette end-to-end with an OSHA Form 21 sample seal.

2.2.5. Submit at least one blank sample with each set of air samples. The blank sample should be handled the same as the other samples except that no air is drawn through it.

2.2.6. Ship the samples to the laboratory for analysis as soon as possible in a suitable container designed to prevent damage in transit.

3. Analysis

3.1. Safety Precautions

3.1.1. Wear safety glasses, protective clothing and gloves at all times.

3.1.2. Handle acid solutions with care. Handle all cadmium samples and solutions with extra care (see Sect. 1.7.). Avoid their direct contact with work area surfaces, eyes, skin and clothes. Flush acid solutions which contact the skin or eyes with copious amounts of water.

3.1.3. Perform all acid digestions and acid dilutions in an exhaust hood while wearing a face shield. To avoid exposure to acid vapors, do not remove beakers containing concentrated acid solutions from the exhaust hood until they have returned to room temperature and have been diluted or emptied.

3.1.4. Exercise care when using laboratory glassware. Do not use chipped pipets, volumetric flasks, beakers or any glassware with sharp edges exposed in order to avoid the possibility of cuts or abrasions.

3.1.5. Never pipet by mouth.

3.1.6. Refer to the instrument instruction manuals and SOPs (5.8., 5.9.) for proper and safe operation of the atomic absorption spectrophotometer, graphite furnace atomizer and associated equipment.

3.1.7. Because metallic elements and other toxic substances are vaporized during AAS flame or graphite furnace atomizer operation, it is imperative that an exhaust vent be used. Always ensure that the exhaust system is operating properly during instrument use.

3.2. Apparatus for Sample and Standard Preparation

3.2.1. Hot plate, capable of reaching 150° C, installed in an exhaust hood.

3.2.2. Phillips beakers, 125 mL.

3.2.3. Bottles, narrow-mouth, polyethylene or glass with leakproof caps: used for storage of standards and matrix modifier.

3.2.4. Volumetric flasks, volumetric pipets, beakers and other associated general laboratory glassware.

3.2.5. Forceps and other associated general laboratory equipment.

3.3. Apparatus for Flame AAS Analysis

3.3.1. Atomic absorption spectrophotometer consisting of a(an):

Nebulizer and burner head.

Pressure regulating devices capable of maintaining constant oxidant and fuel pressures.

Optical system capable of isolating the desired wavelength of radiation (228.8 nm).

Adjustable slit.

Light measuring and amplifying device.

Display, strip chart, or computer interface for indicating the amount of absorbed radiation.

Cadmium hollow cathode lamp or electrodeless discharge lamp (EDL) and power supply.

3.3.2. Oxidant: compressed air, filtered to remove water, oil and other foreign substances.

3.3.3. Fuel: standard commercially available tanks of acetylene dissolved in acetone; tanks should be equipped with flash arresters. CAUTION: Do not use grades of acetylene containing solvents other than acetone because they may damage the PVC tubing used in some instruments.

3.3.4. Pressure-reducing valves: two gauge, two-stage pressure regulators to maintain fuel and oxidant pressures somewhat higher than the controlled operating pressures of the instrument.

3.3.5. Exhaust vent installed directly above the spectrophotometer burner head.

3.4. Apparatus for AAS–HGA Analysis

3.4.1. Atomic absorption spectrophotometer consisting of a(an):

Heated graphite furnace atomizer (HGA) with argon purge system.

Pressure-regulating devices capable of maintaining constant argon purge pressure.

Optical system capable of isolating the desired wavelength of radiation (228.8 nm).

Adjustable slit.

Light measuring and amplifying device.

Display, strip chart, or computer interface for indicating the amount of absorbed radiation (as integrated absorbance, peak area).

Background corrector: Zeeman or deuterium arc. The Zeeman background corrector is recommended.

Cadmium hollow cathode lamp or electrodeless discharge lamp (EDL) and power supply.

Autosampler capable of accurately injecting 5 to 20 µL sample aliquots onto the L'vov Platform in a graphite tube.

3.4.2. Pyrolytically-coated graphite tubes containing solid, pyrolytic L'vov platforms.

3.4.3. Polyethylene sample cups, 2.0 to 2 5 mL, for use with the autosampler.

3.4.4. Inert purge gas for graphite furnace atomizer: compressed gas cylinder of purified argon.

3.4.5. Two gauge, two-stage pressure regulator for the argon gas cylinder.

3.4.6. Cooling water supply for graphite furnace atomizer.

3.4.7. Exhaust vent installed directly above the graphite furnace atomizer.

3.5. Reagents

All reagents should be ACS analytical reagent grade or better.

3.5.1. Deionized water with a specific conductance of less than 10 µS.

3.5.2. Concentrated nitric acid, HNO_3.

3.5.3. Concentrated hydrochloric acid, HCl.

3.5.4. Ammonium phosphate, monobasic, $NH_4H_2PO_4$.

3.5.5. Magnesium nitrate, $Mg(NO_3)_2 \cdot 6H_2O$.

3.5.6. Diluting solution (4% HNO_3, 0.4% HCl): Add 40 mL HNO_3 and 4 mL HCl carefully to approximately 500 mL deionized water and dilute to 1 L with deionized water.

3.5.7. Cadmium standard stock solution, 1,000 µg/mL: Use a commercially available certified 1,000 µg/mL cadmium standard or, alternatively, dissolve 1.0000 g of cadmium metal in a minimum volume of 1:1 HCl and dilute to 1 L with 4% HNO_3. Observe expiration dates of commercial standards. Properly dispose of commercial standards with no expiration dates or prepared standards one year after their receipt or preparation date.

3.5.8. Matrix modifier for AAS–HGA analysis: Dissolve 1.0 g $NH_4H_2PO_4$ and 0.15 g $Mg(NO_3)_2 \cdot 6H_20$ in approximately 200 mL deionized water. Add 1 mL HNO_3 and dilute to 500 mL with deionized water.

3.5.9 Nitric Acid, 1:1 HNO_3/DI H_2O mixture: Carefully add a measured volume of concentrated HNO_3 to an equal volume of DI H_2O.

3.5.10. Nitric acid, 10% v/v: Carefully add 100 mL of concentrated HNO_3 to 500 mL of DI H_2O and dilute to 1 L.

3.6. Glassware Preparation

3.6.1. Clean Phillips beakers by refluxing with 1:1 nitric acid on a hot plate in a fume hood. Thoroughly rinse with deionized water and invert the beakers to allow them to drain dry.

3.6.2. Rinse volumetric flasks and all other glassware with 10% nitric acid and deionized water prior to use.

3.7. Standard Preparation for Flame AAS Analysis

3.7.1. Dilute stock solutions: Prepare 1, 5, 10 and 100 µg/mL cadmium standard stock solutions by making appropriate serial dilutions of 1,000 µg/mL cadmium standard stock solution with the diluting solution described in Section 3.5.6.

3.7.2. Working standards: Prepare cadmium working standards in the range of 0.02 to 2.0 µg/mL by making appropriate serial dilutions of the dilute stock solutions with the same diluting solution. A suggested method of preparation of the working standards is given below.

Working standard (µg/mL)	Std solution (µg/mL)	Aliquot (mL)	Final vol (mL)
0.02	1	10	500
.05	5	5	500
.1	10	5	500
.2	10	10	500
.5	10	25	500
1	100	5	500
2	100	10	500

Store the working standards in 500-mL, narrow-mouth polyethylene or glass bottles with leakproof caps. Prepare every twelve months.

3.8. Standard Preparation for AAS–HGA Analysis

3.8.1. Dilute stock solutions: Prepare 10, 100 and 1,000 ng/mL cadmium standard stock solutions by making appropriate ten-fold serial dilutions of the 1,000 µg/mL cadmium standard stock solution with the diluting solution described in Section 3.5.6.

3.8.2. Working standards: Prepare cadmium working standards in the range of 0.2 to 20 ng/mL by making appropriate serial dilutions of the dilute stock solutions with the same diluting solution. A suggested method of preparation of the working standards is given below.

Working standard (ng/mL)	Std solution (ng/mL)	Aliquot (mL)	Final vol (mL)
0.2	10	2	100
.5	10	5	100
1	10	10	100
2	100	2	100
5	100	5	100
10	100	10	100
20	1,000	2	100

Store the working standards in narrow-mouth polyethylene or glass bottles with leakproof caps. Prepare monthly.

3.9. Sample Preparation

3.9.1. Carefully transfer each sample filter with forceps from its filter cassette unit to a clean, separate 125-mL Phillips beaker along with any loose dust found in the cassette. Label each Phillips beaker with the appropriate sample number.

3.9.2. Digest the sample by adding 5 mL of concentrated nitric acid (HNO_3) to each Phillips beaker containing an air filter sample. Place the Phillips beakers on a hot plate in an exhaust hood and heat the samples until approximately 0.5 mL remains. The sample solution in each Phillips beaker should become clear. If it is not clear, digest the sample with another portion of concentrated nitric acid.

3.9.3. After completing the HNO_3 digestion and cooling the samples, add 40 µL (2 drops) of concentrated HCl to each air sample solution and then swirl the contents. Carefully add about 5 mL of deionized water by pouring it down the inside of each beaker.

3.9.4. Quantitatively transfer each cooled air sample solution from each Phillips beaker to a clean 10-mL volumetric flask. Dilute each flask to volume with deionized water and mix well.

3.10. Flame AAS Analysis

Analyze all of the air samples for their cadmium content by flame atomic absorption spectroscopy (AAS) according to the instructions given below.

3.10.1. Set up the atomic absorption: spectrophotometer for the air/acetylene flame analysis of cadmium according to the SOP (5.8.) or the manufacturer's operational instructions. For the source lamp, use the cadmium hollow cathode or electrodeless discharge lamp operated at the manufacturer's recommended rating for continuous operation. Allow the lamp to warm up 10 to 20 min or until the energy output stabilizes. Optimize conditions such as lamp position, burner head alignment, fuel and oxidant flow rates, etc. See the SOP or specific instrument manuals for details. Instrumental parameters for the Perkin-Elmer Model 603 used in the validation of this method are given in Attachment 1.

3.10.2. Aspirate and measure the absorbance of a standard solution of cadmium. The standard concentration should be within the linear range. For the instrumentation used in the validation of this method a 2 µg/mL cadmium standard gives a net absorbance reading of about 0.350 abs. units (see Section 1.5.5.) when the instrument and the source lamp are performing to manufacturer specifications.

3.10.3. To increase instrument response, scale expand the absorbance reading of the aspirated 2 µg/mL working standard approximately four times. Increase the integration time to at least 3 seconds to reduce signal noise.

3.10.4. Autozero the instrument while aspirating a deionized water blank. Monitor the variation in the baseline absorbance reading (baseline noise) for a few minutes to insure that the instrument, source lamp and associated equipment are in good operating condition.

3.10.5. Aspirate the working standards and samples directly into the flame and record their absorbance readings. Aspirate the deionized water blank immediately after every standard or sample to correct for and monitor any baseline drift and noise. Record the baseline absorbance reading of each deionized water blank. Label each standard and sample reading and its accompanying baseline reading.

3.10.6. It is recommended that the entire series of working standards be analyzed at the beginning and end of the analysis of a set of samples to establish a concentration-response curve, ensure that the standard readings agree with each other and are reproducible. Also, analyze a working standard after every five or six samples to monitor the performance of the spectrophotometer. Standard readings should agree within ±10 to 15% of the readings obtained at the beginning of the analysis.

3.10.7. Bracket the sample readings with standards during the analysis. If the absorbance reading of a sample is above the absorbance reading of the highest working standard, dilute the sample with diluting solution and reanalyze. Use the appropriate dilution factor in the calculations.

3.10.8. Repeat the analysis of approximately 10% of the samples for a check of precision.

3.10.9. If possible, analyze quality control samples from an independent source as a check on analytical recovery and precision.

3.10.10. Record the final instrument settings at the end of the analysis. Date and label the output.

3.11. AAS–HGA Analysis

Initially analyze all of the air samples for their cadmium content by flame atomic absorption spectroscopy (AAS) according to the instructions given in Section 3.10. If the concentration of cadmium in a sample solution is less than three times the quantitative detection limit [0.04 µg/mL (40 ng/mL) for the instrumentation used in the validation] and the sample results are to be averaged with other samples for TWA calculations, proceed with the AAS–HGA analysis of the sample as described below.

3.11.1. Set up the atomic absorption spectrophotometer and HGA for flameless atomic absorption analysis of cadmium according to the SOP (5.9.) or the manufacturer's operational instructions and allow the instrument to stabilize. The graphite furnace atomizer is equipped with a pyrolytically coated graphite tube containing a pyrolytic platform. For the source lamp, use a cadmium hollow cathode or electrodeless discharge lamp operated at the manufacturer's recommended setting for graphite furnace operation. The Zeeman background corrector and EDL are recommended for use with the L'vov platform. Instrumental parameters for the Perkin-Elmer Model 5100 spectrophotometer and Zeeman HGA–600 graphite furnace used in the validation of this method are given in Attachment 2.

3.11.2. Optimize the energy reading of the spectrophotometer at 228.8 nm by adjusting the lamp position and the wavelength according to the manufacturer's instructions.

3.11.3. Set up the autosampler to inject a 5-µL aliquot of the working standard, sample or reagent blank solution onto the L'vov platform along with a 10 – µL overlay of the matrix modifier.

3.11.4. Analyze the reagent blank (diluting solution, Section 3.5.6.) and then autozero the instrument before starting the analysis of a set of samples. It is recommended that the reagent blank be analyzed several times during the analysis to assure the integrated absorbance (peak area) reading remains at or near zero.

3.11.5. Analyze a working standard approximately midway in the linear portion of the working standard range two or three times to check for reproducibility and sensitivity (see Sections 1.5.5. and 1.5.6.) before starting the analysis of samples. Calculate the experimental characteristic mass value from the average integrated absorbance reading and injection volume of the analyzed working standard. Compare this value to the manufacturer's suggested value as a check of proper instrument operation.

3.11.6. Analyze the reagent blank, working standard, and sample solutions. Record and label the peak area (abs-sec) readings and the peak and background peak profiles on the printer/plotter.

3.11.7. It is recommended the entire series of working standards be analyzed at the beginning and end of the analysis of a set of samples. Establish a concentration-response curve and ensure standard readings agree with each other and are reproducible. Also, analyze a working standard after every five or six samples to monitor the performance of the system. Standard readings should agree within ±15% of the readings obtained at the beginning of the analysis.

3.11.8. Bracket the sample readings with standards during the analysis. If the peak area reading of a sample is above the peak area reading of the highest working standard, dilute the sample with the diluting solution and reanalyze. Use the appropriate dilution factor in the calculations.

3.11.9. Repeat the analysis of approximately 10% of the samples for a check of precision.

3.11.10. If possible, analyze quality control samples from an independent source as a check of analytical recovery and precision.

3.11.11. Record the final instrument settings at the end of the analysis. Date and label the output.

3.12. Calculations

Note: Standards used for HGA analysis are in ng/mL. Total amounts of cadmium from calculations will be in ng (not µg) unless a prior conversion is made.

3.12.1. Correct for baseline drift and noise in flame AAS analysis by subtracting each baseline absorbance reading from its corresponding working standard or sample absorbance reading to obtain the net absorbance reading for each standard and sample.

3.12.2. Use a least squares regression program to plot a concentration-response curve of net absorbance reading (or peak area for HGA analysis) versus concentration (µg/mL or ng/mL) of cadmium in each working standard.

3.12.3. Determine the concentration (µg/mL or ng/mL) of cadmium in each sample from the resulting concentration-response curve. If the concentration of cadmium in a sample solution is less than three times the quantitative detection limit [0.04 µg/mL (40 ng/mL) for the instrumentation used in the validation of the method] and if consecutive samples were taken on one employee and the sample results are to be averaged with other samples to determine a single TWA, reanalyze the sample by AAS–HGA as described in Section 3.11. and report the AAS–HGA analytical results.

3.12.4. Calculate the total amount (µg or ng) of cadmium in each sample from the sample solution volume (mL):

$$W = (C)(\text{sample vol, mL})(DF)$$

Where:

W = Total cadmium in sample

C = Calculated concentration of cadmium

DF = Dilution Factor (if applicable)

3.12.5. Make a blank correction for each air sample by subtracting the total amount of cadmium in the corresponding blank sample from the total amount of cadmium in the sample.

3.12.6. Calculate the concentration of cadmium in an air sample (mg/m³ or µg/m³) by using one of the following equations:

$$\text{mg/m}^3 = W_{bc}/(\text{Air vol sampled, L})$$

or

$$\mu\text{g/m}^3 = (W_{bc})(1{,}000\ \text{ng}/\mu\text{g})/(\text{Air vol sampled, L})$$

Where:

W_{bc} = blank corrected total µg cadmium in the sample. (1µg = 1,000 ng)

4. Backup Data

4.1. Introduction

4.1.1. The purpose of this evaluation is to determine the analytical method recovery, working standard range, and qualitative and quantitative detection limits of the two atomic absorption analytical techniques included in this method. The evaluation consisted of the following experiments:

1. An analysis of 24 samples (six samples each at 0.1, 0.5, 1 and 2 times the TWA–PEL) for the analytical method recovery study of the flame AAS analytical technique.

2. An analysis of 18 samples (six samples each at 0.5, 1 and 2 times the Action Level TWA–PEL) for the analytical method recovery study of the AAS–HGA analytical technique.

3. Multiple analyses of the reagent blank and a series of standard solutions to determine the working standard range and the qualitative and quantitative detection limits for both atomic absorption analytical techniques.

4.1.2. The analytical method recovery results at all test levels were calculated from concentration-response curves and statistically examined for outliers at the 99% confidence level. Possible outliers were determined using the Treatment of Outliers test (5.10.). In addition, the sample results of the two analytical techniques, at 0.5, 1.0 and 2.0 times their target concentrations, were tested for homogeneity of variances also at the 99% confidence level. Homogeneity of the coefficients of variation was determined using the Bartlett's test (5.11.). The overall analytical error (OAE) at the 95% confidence level was calculated using the equation (5.12.):

$$OAE = \pm\left[|\text{Bias}| + (1.96)(CV_1(\text{pooled}))(100\%)\right]$$

4.1.3. A derivation of the International Union of Pure and Applied Chemistry (IUPAC) detection limit equation (5.13.) was used to determine the qualitative and quantitative detection limits for both atomic absorption analytical techniques:

$$C_{ld} = k(sd)/m \qquad \text{(Equation 1)}$$

Where:

C_{ld}=the smallest reliable detectable concentration an analytical instrument can determine at a given confidence level.

k=3 for the Qualitative Detection Limit at the 99.86% Confidence Level.

=10 for the Quantitative Detection Limit at the 99.99% Confidence Level.

sd=standard deviation of the reagent blank (Rbl) readings.

m=analytical sensitivity or slope as calculated by linear regression.

4.1.4. Collection efficiencies of metallic fume and dust atmospheres on 0.8-µm mixed cellulose ester membrane filters are well documented and have been shown to be excellent (5.11.). Since elemental cadmium and the cadmium component of cadmium compounds are nonvolatile, stability studies of cadmium spiked MCEF samples were not performed.

4.2. Equipment

4.2.1. A Perkin-Elmer (PE) Model 603 spectrophotometer equipped with a manual gas control system, a stainless steel nebulizer, a burner mixing chamber, a flow spoiler and a 10 cm. (one-slot) burner head was used in the experimental validation of the flame AAS analytical technique. A PE cadmium hollow cathode lamp, operated at the manufacturer's recommended current setting for continuous operation (4 mA), was used as the source lamp. Instrument parameters are listed in Attachment 1.

4.2.2. A PE Model 5100 spectrophotometer, Zeeman HGA–600 graphite furnace atomizer and AS–60 HGA autosampler were used in

the experimental validation of the AAS-HGA analytical technique. The spectrophotometer was equipped with a PE Series 7700 professional computer and Model PR-310 printer. A PE System 2 cadmium electrodeless discharge lamp, operated at the manufacturer's recommended current setting for modulated operation (170 mA), was used as the source lamp. Instrument parameters are listed in Attachment 2.

4.3. Reagents

4.3.1. J.T. Baker Chem. Co. (Analyzed grade) concentrated nitric acid, 69.0–71.0%, and concentrated hydrochloric acid, 36.5–38.0%, were used to prepare the samples and standards.

4.3.2. Ammonium phosphate, monobasic, $NH_4H_2PO_4$ and magnesium nitrate, $Mg(NO_3)_2 \cdot 6H_2O$, both manufactured by the Mallinckrodt Chem. Co., were used to prepare the matrix modifier for AAS–HGA analysis.

4.4. Standard Preparation for Flame AAS Analysis

4.4.1. Dilute stock solutions: Prepared 0.01, 0.1, 1, 10 and 100 µg/mL cadmium standard stock solutions by making appropriate serial dilutions of a commercially available 1,000 µg/mL cadmium standard stock solution (RICCA Chemical Co., Lot # A102) with the diluting solution (4% HNO_3, 0.4% HCl).

4.4.2. Analyzed Standards: Prepared cadmium standards in the range of 0.001 to 2.0 µg/mL by pipetting 2 to 10 mL of the appropriate dilute cadmium stock solution into a 100-mL volumetric flask and diluting to volume with the diluting solution. (See Section 3.7.2.)

4.5. Standard Preparation for AAS–HGA Analysis

4.5.1. Dilute stock solutions: Prepared 1, 10, 100 and 1,000 µg/mL cadmium standard stock solutions by making appropriate serial dilutions of a commercially available 1,000 µg/mL cadmium standard stock solution (J.T. Baker Chemical Co., Instra-analyzed, Lot # D22642) with the diluting solution (4% HNO_3, 0.4% HCl).

4.5.2. Analyzed Standards: Prepared cadmium standards in the range of 0.1 to 40 ng/mL by pipetting 2 to 10 mL of the appropriate dilute cadmium stock solution into a 100-mL volumetric flask and diluting to volume with the diluting solution. (See Section 3.8.2.)

4.6. Detection Limits and Standard Working Range for Flame AAS Analysis

4.6.1. Analyzed the reagent blank solution and the entire series of cadmium standards in the range of 0.001 to 2.0 µg/mL three to six times according to the instructions given in Section 3.10. The diluting solution (4% HNO_3, 0.4% HCl) was used as the reagent blank. The integration time on the PE 603 spectrophotometer was set to 3.0 seconds and a four-fold expansion of the absorbance reading of the 2.0 µg/mL cadmium standard was made prior to analysis. The 2.0 µg/mL standard gave a net absorbance reading of 0.350 abs. units prior to expansion in agreement with the manufacturer's specifications (5.6.).

4.6.2. The net absorbance readings of the reagent blank and the low concentration Cd standards from 0.001 to 0.1 µg/mL and the statistical analysis of the results are shown in Table I. The standard deviation, sd, of the six net absorbance readings of the reagent blank is 1.05 abs. units. The slope, m, as calculated by a linear regression plot of the net absorbance readings (shown in Table II) of the 0.02 to 1.0 µg/mL cadmium standards versus their concentration is 772.7 abs. units/(µg/mL).

4.6.3. If these values for sd and the slope, m, are used in Eqn. 1 (Sect. 4.1.3.), the qualitative and quantitative detection limits as determined by the IUPAC Method are:

$$C_{ld} = (3)(1.05 \text{ abs. units}) / (772.7 \text{ abs. units}/(\mu g/mL))$$
$$= 0.0041\ \mu g/mL \text{ for the qualitative detection limit.}$$

$$C_{ld} = (10)(1.05 \text{ abs. units}) / (772.7 \text{ abs. units}/(\mu g/mL))$$
$$= 0.014\ \mu g/mL \text{ for the quantitative detection limit.}$$

The qualitative and quantitative detection limits for the flame AAS analytical technique are 0.041 µg and 0.14 µg cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.2 µg/m³ and 0.70 µg/m³ for a 200 L air volume.

4.6.4. The recommended Cd standard working range for flame AAS analysis is 0.02 to 2.0 µg/mL. The net absorbance readings of the reagent blank and the recommended working range standards and the statistical analysis of the results are shown in Table II. The standard of lowest concentration in the working range, 0.02 µg/mL, is slightly greater than the calculated quantitative detection limit, 0.014 µg/mL. The standard of highest concentration in the working range, 2.0 µg/mL, is at the upper end of the linear working range suggested by the manufacturer (5.6.). Although the standard net absorbance readings are not strictly linear at concentrations above 0.5 µg/mL, the deviation from linearity is only about 10% at the upper end of the recommended standard working range. The deviation from linearity is probably caused by the four-fold expansion of the signal suggested in the method. As shown in Table II, the precision of the standard net absorbance readings are excellent throughout the recommended working range; the relative standard deviations of the readings range from 0.009 to 0.064.

4.7. Detection Limits and Standard Working Range for AAS-HGA Analysis

4.7.1. Analyzed the reagent blank solution and the entire series of cadmium standards in the range of 0.1 to 40 ng/mL according to the instructions given in Section 3.11. The diluting solution (4% HNO_3, 0.4% HCl) was used as the reagent blank. A fresh aliquot of the reagent blank and of each standard was used for every analysis. The experimental characteristic mass value was 0.41 pg, calculated from the average peak area (abs-sec) reading of the 5 ng/mL standard which is approximately midway in the linear portion of the working standard range. This agreed within 20% with the characteristic mass value, 0.35 pg, listed by the manufacturer of the instrument (5.2.).

4.7.2. The peak area (abs-sec) readings of the reagent blank and the low concentration Cd standards from 0.1 to 2.0 ng/mL and statistical analysis of the results are shown in Table III. Five of the reagent blank peak area readings were zero and the sixth reading was 1 and was an outlier. The near lack of a blank signal does not satisfy a strict interpretation of the IUPAC method for determining the detection limits. Therefore, the standard deviation of the six peak area readings of the 0.2 ng/mL cadmium standard, 0.75 abs-sec, was used to calculate the detection limits by the IUPAC method. The slope, m, as calculated by a linear regression plot of the peak area (abs-sec) readings (shown in Table IV) of the 0.2 to 10 ng/mL cadmium standards versus their concentration is 51.5 abs-sec/(ng/mL).

4.7.3. If 0.75 abs-sec (sd) and 51.5 abs-sec/(ng/mL) (m) are used in Eqn. 1 (Sect. 4.1.3.), the qualitative and quantitative detection limits as determined by the IUPAC method are:

$$C_{ld} = (3)(0.75 \text{ abs-sec}) / (51.5 \text{ abs-sec}/(\text{ng/mL}))$$
$$= 0.044 \text{ ng/mL for the qualitative detection limit.}$$

$$C_{ld} = (10)(0.75 \text{ abs-sec}) / (51.5 \text{ abs-sec}/(\text{ng/mL}))$$
$$= 0.15 \text{ ng/mL for the quantitative detection limit.}$$

The qualitative and quantitative detection limits for the AAS–HGA analytical technique are 0.44 ng and 1.5 ng cadmium, respectively, for a 10 mL solution volume. These correspond, respectively, to 0.007 µg/m³ and 0.025 µg/m³ for a 60 L air volume.

4.7.4. The peak area (abs-sec) readings of the Cd standards from 0.2 to 40 ng/mL and the statistical analysis of the results are given in Table IV. The recommended standard working range for AAS–HGA analysis is 0.2 to 20 ng/mL. The standard of lowest concentration in the recommended working range is slightly greater than the calculated quantitative detection limit, 0.15 ng/mL. The deviation from linearity of the peak area readings of the 20 ng/mL standard, the highest concentration standard in the recommended working range, is approximately 10%. The deviations from linearity of the peak area readings of the 30 and 40 ng/mL standards are significantly greater than 10%. As shown in Table IV, the precision of the peak area readings are satisfactory throughout the recommended working range; the relative standard deviations of the readings range from 0.025 to 0.083.

4.8. Analytical Method Recovery for Flame AAS Analysis

4.8.1. Four sets of spiked MCEF samples were prepared by injecting 20 µL of 10, 50, 100 and 200 µg/mL dilute cadmium stock solutions on 37 mm diameter filters (part no. AAWP 037 00, Millipore Corp., Bedford, MA) with a calibrated micropipet. The dilute stock solutions were prepared by making appropriate serial dilutions of a commercially available 1,000 µg/mL cadmium standard stock solution (RICCA Chemical Co., Lot #A102) with the diluting solution (4% HNO_3, 0.4% HCl). Each set contained six samples and a sample blank. The amount of cadmium in the prepared sets were equivalent to 0.1, 0.5, 1.0 and 2.0 times the TWA PEL target concentration of 5 µg/m³ for a 400 L air volume.

4.8.2. The air-dried spiked filters were digested and analyzed for their cadmium content by flame atomic absorption spectroscopy (AAS) following the procedure described in Section 3. The 0.02 to 2.0 µg/mL cadmium standards (the suggested working range) were used in the analysis of the spiked filters.

4.8.3. The results of the analysis are given in Table V. One result at 0.5 times the TWA PEL target concentration was an outlier and was excluded from statistical analysis. Experimental justification for rejecting it is that the outlier value was probably due to a spiking error. The coefficients of variation for the three test levels at 0.5 to 2.0 times the TWA PEL target concentration passed the Bartlett's test and were pooled.

4.8.4. The average recovery of the six spiked filter samples at 0.1 times the TWA PEL target concentration was 118.2% with a coefficient of variation (CV_1) of 0.128. The average recovery of the spiked filter samples in the range of 0.5 to 2.0 times the TWA target concentration was 104.0% with a pooled coefficient of variation (CV_1) of 0.010. Consequently, the analytical bias found in these spiked sample results over the tested concentration range was +4.0% and the OAE was ±6.0%. #

4.9. Analytical Method Recovery for AAS–HGA Analysis

4.9.1. Three sets of spiked MCEF samples were prepared by injecting 15 µL of 5, 10 and 20 µg/mL dilute cadmium stock solutions on 37 mm diameter filters (part no. AAWP 037 00, Millipore Corp., Bedford, MA) with a calibrated micropipet. The dilute stock solutions were prepared by making appropriate serial dilutions of a commercially available certified 1,000 µg/mL cadmium standard stock solution (Fisher Chemical Co., Lot #913438–24) with the diluting solution (4% HNO_3, 0.4% HCl). Each set contained six samples and a sample blank. The amount of cadmium in the prepared sets were equivalent to 0.5, 1 and 2 times the Action Level TWA target concentration of 2.5 µg/m³ for a 60 L air volume.

4.9.2. The air-dried spiked filters were digested and analyzed for their cadmium content by flameless atomic absorption spectroscopy using a heated graphite furnace atomizer following the procedure described in Section 3. A five-fold dilution of the spiked filter samples at 2 times the Action Level TWA was made prior to their analysis. The 0.05 to 20 ng/mL cadmium standards were used in the analysis of the spiked filters.

4.9.3. The results of the analysis are given in Table VI. There were no outliers. The coefficients of variation for the three test levels at 0.5 to 2.0 times the Action Level TWA PEL passed the Bartlett's test and were pooled. The average recovery of the spiked filter samples was 94.2% with a pooled coefficient of variation (CV_1) of 0.043. Consequently, the analytical bias was −5.8% and the OAE was ±14.2%.

4.10. Conclusions

The experiments performed in this evaluation show the two atomic absorption analytical techniques included in this method to be precise and accurate and have sufficient sensitivity to measure airborne cadmium over a broad range of exposure levels and sampling periods.

5. References

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TABLE I.—CD DETECTION LIMIT STUDY

[Flame AAS Analysis]

STD (µg/mL)	Absorbance reading at 228.8 nm		Statistical analysis
Reagent Blank	5	2	n = 6.
	4	3	mean = 3.50.
	4	3	std dev = 1.05.
			CV = 0.30.
0.001	6	6	n = 6.
	2	4	mean = 5.00.
	6	6	std dev = 1.67.
			CV = 0.335.
0.002	5	7	n = 6.
	7	3	mean = 5.50.
	7	4	std dev = 1.76.
			CV = 0.320.
0.005	7	7	n = 6.
	8	8	mean = 7.33.
	8	6	std dev = 0.817.
			CV = 0.111.
0.010	10	9	n = 6.
	10	13	mean = 10.3.
	10	10	std dev = 1.37.
			CV = 0.133.
0.020	20	23	n = 6.
	20	22	mean = 20.8.
	20	20	std dev = 1.33.
			CV = 0.064.
0.050	42	42	n = 6.
	42	42	mean = 42.5.
	42	45	std dev = 1.22.
			CV = 0.029.
0.10	84		n = 3
	80		mean = 82.3.
	83		std dev = 2.08.
			CV = 0.025.

TABLE II.—CD STANDARD WORKING RANGE STUDY

[Flame AAS Analysis]

STD(µg/mL)	Absorbance reading at 228.8 nm		Statistical analysis
Reagent Blank	5	2	n=6.
	4	3	mean=3.50.
	4	3	std dev=1.05.
			CV=0.30.
0.020	20	23	n=6.
	20	22	mean=20.8.
	D20	20	std dev=1.33.
			CV=0.064.
0.050	42	42	n=6.
	42	42	mean=42.5.
	42	45	std dev=1.22.
			CV=0.029
0.10	84		n=3.
	80		mean=82.3.
	83		std dev=2.08.
			CV=0.025.
0.20	161		n=3.
	161		mean=160.0.
	158		std dev=1.73.
			CV=0.011.
0.50	391		n=3.
	389		mean=391.0.

TABLE II.—CD STANDARD WORKING RANGE STUDY—Continued

[Flame AAS Analysis]

STD(μg/mL)	Absorbance reading at 228.8 nm	Statistical analysis
	393	std dev=2.00.
		CV=0.005.
1.00	760	n=3.
	748	mean=753.3.
	752	std dev=6.11.
		CV=0.008.
2.00	1416	n=3.
	1426	mean=1414.3.
	1401	std dev=12.6.
		CV=0.009.

TABLE III.—CD DETECTION LIMIT STUDY

[AAS–HGA Analysis]

STD (ng/mL)	Peak area readings X 10^3 at 228.8 nm		Statistical analysis
Reagent Blank	0	0	n = 6.
	0	1	mean = 0.167.
	0	0	std dev = 0.41.
			CV = 2.45.
0.1	8	6	n = 6.
	5	7	mean = 7.7.
	13	7	std dev = 2.8.
			CV = 0.366.
0.2	11	13	n = 6.
	11	12	mean = 11.8.
	12	12	std dev = 0.75.
			CV = 0.064.
0.5	28	33	n = 6.
	26	28	mean = 28.8.
	28	30	std dev = 2.4.
			CV = 0.083.
1.0	52	55	n = 6.
	56	58	mean = 54.8.
	54	54	std dev = 2.0.
			CV = 0.037.
2.0	101	112	n = 6.
	110	110	mean = 108.8.
	110	110	std dev = 3.9.
			CV = 0.036.

TABLE IV.—CD STANDARD WORKING RANGE STUDY

[AAS-HGA Analysis]

STD (ng/mL)	Peak area readings × 10^3 at 228.8 nm		Statistical analysis
0.2	11	13	n=6.
	11	12	mean=11.8.
	12	12	std dev=0.75.
			CV=0.064.
0.5	28	33	n=6.
	26	28	mean=28.8.
	28	30	std dev=2.4.
			CV=0.083.
1.0	52	55	n=6.
	56	58	mean=54.8.
	54	54	std dev=2.0.
			CV=0.037.
2.0	101	112	n=6
	110	110	mean=108.8.
	110	110	std dev=3.9.
			CV=0.036.
5.0	247	265	n=6.
	268	275	mean=265.5.
	259	279	std dev=11.5.
			CV=0.044.

TABLE IV.—CD STANDARD WORKING RANGE STUDY—Continued

[AAS-HGA Analysis]

STD (ng/mL)	Peak area readings × 10^3 at 228.8 nm		Statistical analysis
10.0	495	520	n=6.
	523	513	mean=516.7.
	516	533	std dev=12.7.
			CV=0.025.
20.0	950	953	n=6.
	951	958	mean=941.8.
	949	890	std dev=25.6.
			CV=0.027.
30.0	1269	1291	n=6.
	1303	1307	mean=1293.
	1295	1290	std dev=13.3.
			CV=0.010.
40.0	1505	1567	n=6.
	1535	1567	mean=1552.
	1566	1572	std dev=26.6.
			CV=0.017.

TABLE V.—ANALYTICAL METHOD RECOVERY [FLAME AAS ANALYSIS]

Test level								
0.5x			1.0x			2.0x		
µg taken	µg found	Percent rec.	µg taken	µg found	Percent rec.	µg taken	µg found	Percent rec.
1.00	1.0715	107.2	2.00	2.0688	103.4	4.00	4.1504	103.8
1.00	1.0842	108.4	2.00	2.0174	100.9	4.00	4.1108	102.8
1.00	1.0842	108.4	2.00	2.0431	102.2	4.00	4.0581	101.5
1.00	*1.0081	*100.8	2.00	2.0431	102.2	4.00	4.0844	102.1
1.00	1.0715	107.2	2.00	2.0174	100.9	4.00	4.1504	103.8
1.00	1.0842	108.4	2.00	2.0045	100.2	4.00	4.1899	104.7
n=	5			6				6
mean=	107.9			101.6				103.1
std dev=	0.657			1.174				1.199
CV_1=	0.006			0.011				0.012
				CV_1(pooled)=0.010				

*—Rejected as an outlier—this value did not pass the outlier T-test at the 99% confidence level.

Test level		
0.1x		
µg taken	µg found	Percent Rec.
0.200	0.2509	125.5
0.200	0.2509	125.5
0.200	0.2761	138.1
0.200	0.2258	112.9
0.200	0.2258	112.9
0.200	0.1881	94.1

n= 6
mean= 118.2
std dev= 15.1
CV_1= 0.128

TABLE VI.—ANALYTICAL METHOD RECOVERY

[AAS-HGA Analysis]

Test Level								
0.5x			1.0x			2.0x		
ng taken	ng found	Percent rec.	ng taken	ng found	Percent rec.	ng taken	ng found	Percent rec.
75	71.23	95.0	150	138.00	92.0	300	258.43	86.1
75	71.47	95.3	150	138.29	92.2	300	258.46	86.2
75	70.02	93.4	150	136.30	90.9	300	280.55	93.5
75	77.34	103.1	150	146.62	97.7	300	288.34	96.1

TABLE VI.—ANALYTICAL METHOD RECOVERY—Continued

[AAS-HGA Analysis]

Test Level								
0.5x			1.0x			2.0x		
ng taken	ng found	Percent rec.	ng taken	ng found	Percent rec.	ng taken	ng found	Percent rec.
75	78.32	104.4	150	145.17	96.8	300	261.74	87.2
75	71.96	95.9	150	144.88	96.6	300	277.22	92.4
n=	6			6				6
mean=	97.9			94.4				90.3
std dev=	4.66			2.98				4.30
CV1=	0.048			0.032				0.048
	CV[1] (pooled) = 0.043							

Attachment 1

Instrumental Parameters for Flame AAS Analysis

Atomic Absorption Spectrophotometer (Perkin-Elmer Model 603)
Flame: Air/Acetylene—lean, blue
Oxidant Flow: 55
Fuel Flow: 32
Wavelength: 228.8 nm
Slit: 4 (0.7 nm)
Range: UV
Signal: Concentration (4 exp)
Integration Time: 3 sec

Attachment 2

Instrumental Parameters for HGA Analysis

Atomic Absorption Spectrophotometer (Perkin-Elmer Model 5100)

Signal Type: Zeeman AA
Slitwidth: 0.7 nm
Wavelength: 228.8 nm
Measurement: Peak Area
Integration Time: 6.0 sec
BOC Time: 5 sec
BOC = Background Offset Correction

ZEEMAN GRAPHITE FURNACE

(Perkin-Elmer Model HGA-600)

Step	Ramp Time (sec)	Hold Time (sec)	Temp. (°C)	Argon Flow (mL/min)	Read (sec)
(1)Predry	5	10	90	300	—
(2)Dry	30	10	140	300	—
(3)Char	10	20	900	300	—
(4)Cool Down	1	8	30	300	—
(5)Atomize	0	5	1600	0	−1
(6)Burnout	1	8	2500	300	—

Appendix F—Nonmandatory Protocol for Biological Monitoring 1.0 Introduction

Under the final OSHA cadmium rule (29 CFR 1910), monitoring of biological specimens and several periodic medical examinations are required for eligible employees. These medical examinations are to be conducted regularly, and medical monitoring is to include the periodic analysis of cadmium in blood (CDB), cadmium in urine (CDU) and beta-2-microglobulin in urine (B2MU). As CDU and B2MU are to be normalized to the concentration of creatinine in urine (CRTU), then CRTU must be analyzed in conjunction with CDU and B2MU analyses.

The purpose of this protocol is to provide procedures for establishing and maintaining the quality of the results obtained from the analyses of CDB, CDU and B2MU by commercial laboratories. Laboratories conforming to the provisions of this nonmandatory protocol shall be known as "participating laboratories." The biological monitoring data from these laboratories will be evaluated by physicians responsible for biological monitoring to determine the conditions under which employees may continue to work in locations exhibiting airborne-cadmium concentrations at or above defined actions levels (see paragraphs (1)(3) and (1)(4) of the final rule). These results also may be used to support a decision to remove workers from such locations.

Under the medical monitoring program for cadmium, blood and urine samples must be collected at defined intervals from workers by physicians responsible for medical monitoring; these samples are sent to commerical laboratories that perform the required analyses and report results of these analyses to the responsible physicians. To ensure the accuracy and reliability of these laboratory analyses, the laboratories to which samples are submitted should participate in an ongoing and efficacious proficiency testing program. Availability of proficiency testing programs may vary with the analyses performed.

To test proficiency in the analysis of CDB, CDU and B2MU, a laboratory should participate either in the interlaboratory comparison program operated by the Centre de Toxicologie du Quebec (CTQ) or an equivalent program. (Currently, no laboratory in the U.S. performs proficiency testing on CDB, CDU or B2MU.) Under this program, CTQ sends participating laboratories 18 samples of each analyte (CDB, CDU and/or B2MU) annually for analysis. Participating laboratories must return the results of these analyses to CTQ within four to five weeks after receiving the samples.

The CTQ program pools analytical results from many participating laboratories to derive consensus mean values for each of the samples distributed. Results reported by each laboratory then are compared against these consensus means for the analyzed samples to determine the relative performance of each laboratory. The proficiency of a participating laboratory is a function of the extent of agreement between results submitted by the participating laboratory and the consensus values for the set of samples analyzed.

Proficiency testing for CRTU analysis (which should be performed with CDU and B2MU analyses to evaluate the results properly) also is recommended. In the U.S., only the College of American Patholgists (CAP) currently conducts CRTU proficiency testing; participating laboratories should be accredited for CRTU analysis by the CAP.

Results of the proficiency evaluations will be forwarded to the participating laboratory by the proficiency-testing laboratory, as well as to physicians designated by the participating laboratory to receive this information. In addition, the participating laboratory should, on request, submit the results of their internal Quality Assurance/Qualitly Control (QA/QC) program for each analytic procedure (i.e., CDB, CDU and/or B2MU) to physicians designated to receive the proficiency results. For participating laboratories offering CDU and/or B2MU analyses, QA/QC documentation also should be provided for CRTU analysis. (Laboratories should provide QA/QC information regarding CRTU analysis directly to the requesting physician if they perform the analysis in-house; if CRTU analysis is performed by another laboratory under contract, this information should be provided to the physician by the contract laboratory.)

QA/QC information, along with the actual biological specimen measurements, should be provided to the responsible physician using standard formats. These physicians then may collate the QA/QC information with proficiency test results to compare the relative performance of laboratories, as well as to facilitate evaluation of the worker monitoring data. This information supports decisions made by the physician with regard to the biological monitoring program, and for mandating medical removal.

This protocol describes procedures that may be used by the responsible physicians to identify laboratories most likely to be proficient in the analysis of samples used in the biological monitoring of cadmium; also provided are procedures for record keeping and reporting by laboratories participating in proficiency testing programs, and

recommendations to assist these physicians in interpreting analytical results determined by participating laboratories. As the collection and handling of samples affects the quality of the data, recommendations are made for these tasks. Specifications for analytical methods to be used in the medical monitoring program are included in this protocol as well.

In conclusion, this document is intended as a supplement to characterize and maintain the quality of medical monitoring data collected under the final cadmium rule promulgated by OSHA (29 CFR 1910). OSHA has been granted authority under the Occupational Safety and Health Act of 1970 to protect workers from the effects of exposure to hazardous substances in the work place and to mandate adequate monitoring of workers to determine when adverse health effects may be occurring. This nonmandatory protocol is intended to provide guidelines and recommendations to improve the accuracy and reliability of the procedures used to analyze the biological samples collected as part of the medical monitoring program for cadmium.

2.0 Definitions

When the terms below appear in this protocol, use the following definitions.

Accuracy: A measure of the bias of a data set. Bias is a systematic error that is either inherent in a method or caused by some artifact or idiosyncracy of the measurement system. Bias is characterized by a consistent deviation (positive or negative) in the results from an accepted reference value.

Arithmetic Mean: The sum of measurements in a set divided by the number of measurements in a set.

Blind Samples: A quality control procedure in which the concentration of analyze in the samples should be unknown to the analyst at the time that the analysis is performed.

Coefficient of Variation: The ratio of the standard deviation of a set of measurements to the mean (arithmetic or geometric) of the measurements.

Compliance Samples: Samples from exposed workers sent to a participating laboratory for analysis.

Control Charts: Graphic representations of the results for quality control samples being analyzed by a participating laboratory.

Control Limits: Statistical limits which define when an analytic procedure exceeds acceptable parameters; control limits provide a method of assessing the accuracy of analysts, laboratories, and discrete analytic runs.

Control Samples: Quality control samples.

F/T: The measured amount of an analyte divided by the theoretical value (defined below) for that analyte in the sample analyzed; this ratio is a measure of the recovery for a quality control sample.

Geometric Mean: The natural antilog of the mean of a set of natural log-transformed data.

Geometric Standard Deviation: The antilog of the standard deviation of a set of natural log-transformed data.

Limit of Detection: Using a predifined level of confidence, this is the lowest measured value at which some of the measured material is likely to have come from the sample.

Mean: A central tendency of a set of data; in this protocol, this mean is defined as the *arithmetic mean* (see definition of *arithmetic mean* above) unless stated otherwise.

Performance: A measure of the overall quality of data reported by laboratory.

Pools: Groups of quality-control samples to be established for each target value (defined below) of an analyte. For the protocol provided in attachment 3, for example, the theoretical value of the quality control samples of the pool must be within a range defined as plus or minus (±) 50% of the target value. Within each analyte pool, there must be quality control samples of at least 4 theoretical values.

Precision: The extent of agreement between repeated, independent measurements of the same quantity of an analyte.

Proficiency: The ability to satisfy a specified level of analyte performance.

Proficiency Samples: Specimens, the values of which are unknown to anyone at a participating laboratory, and which are submitted by a participating laboratory for proficiency testing.

Quality or Data Quality: A measure of the confidence in the measurement value.

Quality Control (QC) Samples: Specimens, the value of which is unknown to the analyst, but is known to the appropriate QA/QC personnel of a participating laboratory; when used as part of a laboratory QA/QC program, the theoretical values of these samples should not be known to the analyst until the analyses are complete. QC samples are to be run in sets consisting of one QC sample from each pool (see definition of "pools" above).

Sensitivity: For the purposes of this protocol, the limit of detection.

Standard Deviation: A measure of the distribution or spread of a data set about the mean; the standard deviation is equal to the positive square root of the variance, and is expressed in the same units as the original measurements in the data set.

Standards: Samples with values known by the analyst and used to calibrate equipment and to check calibration throughout an analytic run. In a laboratory QA/QC program, the values of the standards must exceed the values obtained for compliance samples such that the lowest standard value is near the limit of detection and the highest standard is higher than the highest compliance sample or QC sample. Standards of at least three different values are to be used for calibration, and should be constructed from at least 2 different sources.

Target Value: Those values of CDB, CDU or B2MU which trigger some action as prescribed in the medical surveillance section of the regulatory text of the final cadmium rule. For CDB, the target values are 5, 10 and 15 µg/l. For CDU, the target values are 3, 7 and 15 µg/g CRTU. For B2MU, the target value are 300, 750 and 1500 µg/g CRTU. (Note that target values may vary as a function of time.)

Theoretical Value (or Theoretical Amount): The reported concentration of a quality-control sample (or calibration standard) derived from prior characterizations of the sample.

Value or Measurement Value: The numerical result of a measurement.

Variance: A measure of the distribution or spread of a data set about the mean; the variance is the sum of the squares of the differences between the mean and each discrete measurement divided by one less than the number of measurements in the data set.

3.0 Protocol

This protocol provides procedures for characterizing and maintaining the quality of analytic results derived for the medical monitoring program mandated for workers under the final cadmium rule.

3.1 Overview

The goal of this protocol is to assure that medical monitoring data are of sufficient quality to facilitate proper interpretation. The data quality objectives (DQOs) defined for the medical monitoring program are summarized in Table 1. Based on available information, the DQOs presented in Table 1 should be achievable by the majority of laboratories offering the required analyses commercially; OSHA recommends that only laboratories meeting these DQOs be used for the analysis of biological samples collected for monitoring cadmium exposure.

TABLE 1.—RECOMMENDED DATA QUALITY OBJECTIVES (DQOS) FOR THE CADMIUM MEDICAL MONITORING PROGRAM

Analyte/concentration pool	Limit of detection	Precision (CV)	Accuracy
Cadmium in blood	0.5 µg/l		±1 µg/l or 15% of the mean.
≤2 µg/l		40%	
>2 µg/l		20%	
Cadmium in urine	0.5 µg/g creatinine		±1 µg/l or 15% of the mean.
≤2 µg/l creatinine		40%	
>2 µg/l creatinine		20%	
β-2-Microglobulin in urine	100 µg/g creatinine		± 15% of the mean.
100 µg/g creatinine		5%	

To satisfy the DQOs presented in Table 1, OSHA provides the following guidelines:

1. Procedures for the collection and handling of blood and urine are specified (Section 3.4.1 of this protocol);

2. Preferred analytic methods for the analysis of CDB, CDU and B2MU are defined (and a method for the determination of CRTU also is specified since CDU and B2MU results are to be normalized to the level of CRTU).

3. Procedures are described for identifying laboratories likely to provide the required analyses in an accurate and reliable manner;

4. These guidelines (Sections 3.2.1 to 3.2.3, and Section 3.3) include recommendations regarding internal QA/QC programs for participating laboratories, as well as levels of proficiency through participation in an interlaboratory proficiency program;

5. Procedures for QA/QC record keeping (Section 3.3.2), and for reporting QC/QA results are described (Section 3.3.3); and,

6. Procedures for interpreting medical monitoring results are specified (Section 3.4.3).

Methods recommended for the biological monitoring of eligible workers are:

1. The method of Stoeppler and Brandt (1980) for CDB determinations (limit of detection: 0.5 µg/l);

2. The method of Pruszkowska et al. (1983) for CDU determinations (limit of detection: 0.5 µg/l of urine); and,

3. The Pharmacia Delphia test kit (Pharmacia 1990) for the determination of B2MU (limit of detection: 100 µg/l urine).

Because both CDU and B2MU should be reported in µg/g CRTU, an independent determination of CRTU is recommended. Thus, both the OSHA Salt Lake City Technical Center (OSLTC) method (OSHA, no date) and the Jaffe method (Du Pont, no date) for the determination of CRTU are specified under this protocol (i.e., either of these 2 methods may be used). Note that although detection limits are not reported for either of these CRTU methods, the range of measurements expected for CRTU (0.9–1.7 µg/l) are well above the likely limit of detection for either of these methods (Harrison, 1987).

Laboratories using alternate methods should submit sufficient data to the responsible physicians demonstrating that the alternate method is capable of satisfying the defined data quality objectives of the program. Such laboratories also should submit a QA/QC plan that documents the performance of the alternate method in a manner entirely equivalent to the QA/QC plans proposed in Section 3.3.1.

3.2 Duties of the Responsible Physician

The responsible physician will evaluate biological monitoring results provided by participating laboratories to determine whether such laboratories are proficient and have satisfied the QA/QC recommendations. In determining which laboratories to employ for this purpose, these physicians should review proficiency and QA/QC data submitted to them by the participating laboratories.

Participating laboratories should demonstrate proficiency for each analyte (CDU, CDB and B2MU) sampled under the biological monitoring program. Participating laboratories involved in analyzing CDU and B2MU also should demonstrate proficiency for CRTU analysis, or provide evidence of a contract with a laboratory proficient in CRTU analysis.

3.2.1 Recommendations for Selecting Among Existing Laboratories

OSHA recommends that existing laboratories providing commercial analyses for CDB, CDU and/or B2MU for the medical monitoring program satisfy the following criteria:

1. Should have performed commercial analyses for the appropriate analyte (CDB, CDU and/or B2MU) on a regular basis over the last 2 years;

2. Should provide the responsible physician with an internal QA/QC plan;

3. If performing CDU or B2MU analyses, the participating laboratory should be accredited by the CAP for CRTU analysis, and should be enrolled in the corresponding CAP survey (note that alternate credentials may be acceptable, but acceptability is to be determined by the responsible physician); and,

4. Should have enrolled in the CTQ interlaboratory comparison program for the appropriate analyte (CDB, CDU and/or B2MU).

Participating laboratories should submit appropriate documentation demonstrating compliance with the above criteria to the responsible physician. To demonstrate compliance with the first of the above criteria, participating laboratories should submit the following documentation for each analyte they plan to analyze (note that each document should cover a period of at least 8 consecutive quarters, and that the period designated by the term "regular analyses" is at least once a quarter):

1. Copies of laboratory reports providing results from regular analyses of the appropriate analyte (CDB, CDU and/or B2MU);

2. Copies of 1 or more signed and executed contracts for the provision of regular analyses of the appropriate analyte (CDB, CDU and/or B2MU); or,

3. Copies of invoices sent to 1 or more clients requesting payment for the provision of regular analyses of the appropriate analyte (CDB, CDU and/or B2MU). Whatever the form of documentation submitted, the specific analytic procedures conducted should be identified directly. The forms that are copied for submission to the responsible physician also should identify the laboratory which provided these analyses.

To demonstrate compliance with the second of the above criteria, a laboratory should submit to the responsible physician an internal QA/QC plan detailing the standard operating procedures to be adopted for satisfying the recommended QA/QC procedures for the analysis of each specific analyte (CDB, CDU and/or B2MU). Procedures for internal QA/QC programs are detailed in Section 3.3.1 below.

To satisfy the third of the above criteria, laboratories analyzing for CDU or B2MU also should submit a QA/QC plan for creatinine analysis (CRTU); the QA/QC plan and characterization analyses for CRTU must come from the laboratory performing the CRTU analysis, even if the CRTU analysis is being performed by a contract laboratory.

Laboratories enrolling in the CTQ program (to satisfy the last of the above criteria) must remit, with the enrollment application, an initial fee of approximately $100 per analyte. (Note that this fee is only an estimate, and is subject to revision without notice.) Laboratories should indicate on the application that they agree to have proficiency test results sent by the CTQ directly to the physicians designated by participating laboratories.

Once a laboratory's application is processed by the CTQ, the laboratory will be assigned a code number which will be provided to the laboratory on the initial confirmation form, along with identification of the specific analytes for which the laboratory is participating. Confirmation of participation will be sent by the CTQ to physicians designated by the applicant laboratory.

3.2.2 Recommended Review of Laboratories Selected to Perform Analyses

Six months after being selected initially to perform analyte determinations, the status of participating laboratories should be reviewed by the responsible physicians. Such reviews should then be repeated every 6 months or whenever additional proficiency or QA/QC documentation is received (whichever occurs first).

As soon as the responsible physician has received the CTQ results from the first 3 rounds of proficiency testing (i.e., 3 sets of 3 samples each for CDB, CDU and/or B2MU) for a participating laboratory, the status of the laboratory's continued participation should be reviewed. Over the same initial 6-month period, participating laboratories also should provide responsible physicians the results of their internal QA/QC monitoring program used to assess performance for each analyte (CDB, CDU and/or B2MU) for which the laboratory performs determinations. This information should be submitted using appropriate forms and documentation.

The status of each participating laboratory should be determined for each analyte (i.e., whether the laboratory satisfies minimum proficiency guidelines based on the proficiency samples sent by the CTQ and the results of the laboratory's internal QA/QC program). To maintain competency for analysis of CDB, CDU and/or B2MU during the first review, the laboratory should satisfy performance requirements for at least 2 of the 3 proficiency samples provided in each of the 3 rounds completed over the 6-month period. Proficiency should be maintained for the analyte(s) for which the laboratory conducts determinations.

To continue participation for CDU and/or B2MU analyse, laboratories also should either maintain accreditation for CRTU analysis in the CAP program and participate in the CAP surveys, or they should contract the CDU and B2MU analyses to a laboratory which satisfies these requirements (or which can provide documentation of accreditation/participation in an equivalent program).

The performance requirement for CDB analysis is defined as an analytical result within ±1µg/l blood or 15% of the consensus mean (whichever is greater). For samples

exhibiting a consensus mean less than 1 μg/l, the performance requirement is defined as a concentration between the detection limit of the analysis and a maximum of 2 μg/l. The purpose for redefining the acceptable interval for low CDB values is to encourage proper reporting of the actual values obtained during measurement; laboratories, therefore, will not be penalized (in terms of a narrow range of acceptability) for reporting measured concentrations smaller than 1 μg/l.

The performance requirement for CDU analysis is defined as an analytical result within ±1μg/l urine or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus mean less than 1 μg/l urine, the performance requirement is defined as a concentration between the detection limit of the analysis and a maximum of 2 μg/l urine. Laboratories also should demonstrate proficiency in creatinine analysis as defined by the CAP. Note that reporting CDU results, other than for the CTQ proficiency samples (i.e., compliance samples), should be accompanied with results of analyses for CRTU, and these 2 sets of results should be combined to provide a measure of CDU in units of μg/g CRTU.

The performance requirement for B2MU is defined as analytical results within ±15% of the consensus mean. Note that reporting B2MU results, other than for CTQ proficiency samples (i.e., compliance samples), should be accompanied with results of analyses for CRTU, and these 2 sets of results should be combined to provide a measure of B2MU in units of μg/g CRTU.

There are no recommended performance checks for CRTU analyses. As stated previously, laboratories performing CRTU analysis in support of CDU or B2MU analyses should be accredited by the CAP, and participating in the CAP's survey for CRTU.

Following the first review, the status of each participating laboratory should be reevaluated at regular intervals (i.e., corresponding to receipt of results from each succeeding round of proficiency testing and submission of reports from a participating laboratory's internal QA/QC program).

After a year of collecting proficiency test results, the following proficiency criterion should be added to the set of criteria used to determine the participating laboratory's status (for analyzing CDB, CDU and/or B2MU): A participating laboratory should not fail performance requirements for more than 4 samples from the 6 most recent consecutive rounds used to assess proficiency for CDB, CDU and/or B2MU separately (i.e., a total of 18 discrete proficiency samples for each analyte). Note that this requirement does *not* replace, but supplements, the recommendation that a laboratory should satisfy the performance criteria for at least 2 of the 3 samples tested for each round of the program.

3.2.3 Recommendations for Selecting Among Newly-Formed Laboratories (or Laboratories That Previously Failed To Meet the Protocol Guidelines)

OSHA recommends that laboratories that have not previously provided commercial analyses of CDB, CDU and/or B2MU (or have done so for a period less than 2 years), or which have provided these analyses for 2 or more years but have not conformed previously with these protocol guidelines, should satisfy the following provisions for each analyte for which determinations are to be made prior to being selected to analyze biological samples under the medical monitoring program:

1. Submit to the responsible physician an internal QA/QC plan detailing the standard operating procedures to be adopted for satisfying the QA/QC guidelines (guidelines for internal QA/QC programs are detailed in Section 3.3.1;

2. Submit to the responsible physician the results of the initial characterization analyses for each analyte for which determinations are to be made;

3. Submit to the responsible physician the results, for the initial 6-month period, of the internal QA/QC program for each analyte for which determinations are to be made (if no commercial analyses have been conducted previously, a minimum of 2 mock standardization trials for each analyte should be completed per month for a 6-month period;

4. Enroll in the CTQ program for the appropriate analyte for which determinations are to be made, and arrange to have the CTQ program submit the initial confirmation of participation and proficiency test results directly to the designated physicians. Note that the designated physician should receive results from 3 completed rounds from the CTQ program before approving a laboratory for participation in the biological monitoring program;

5. Laboratories seeking participation for CDU and/or B2MU analyses should submit to the responsible physician documentation of accreditation by the CAP for CRTU analyses performed in conjunction with CDU and/or B2MU determinations (if CRTU analyses are conducted by a contract laboratory, this laboratory should submit proof of CAP accreditation to the responsible physician); and,

6. Documentation should be submitted on an appropriate form.

To participate in CDB, CDU and/or B2MU analyses, the laboratory should satisfy the above criteria for a minimum of 2 of the 3 proficiency samples provided in each of the 3 rounds of the CTQ program over a 6-month period; this procedure should be completed for each appropriate analyte. Proficiency should be maintained for each analyte to continue participation. Note that laboratories seeking participation for CDU or B2MU also should address the performance requirements for CRTU, which involves providing evidence of accreditation by the CAP and participation in the CAP surveys (or an equivalent program).

The performance requirement for CDB analysis is defined as an analytical result within ±1 μg/l or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus mean less than 1 μg/l, the performance requirement is defined as a concentration between the detection limit of the analysis and a maximum of 2 μg/l. The purpose of redefining the acceptable interval for low CDB values is to encourage proper reporting of the actual values obtained during measurement; laboratories, therefore, will not be penalized (in terms of a narrow range of acceptability) for reporting measured concentrations less than 1 μg/l.

The performance requirement for CDU analysis is defined as an analytical result within ±1 μg/l urine or 15% of the consensus mean (whichever is greater). For samples exhibiting a consensus mean less than 1 μg/l urine, the performance requirement is defined as a concentration that falls between the detection limit of the analysis and a maximum of 2 μg/l urine. Performance requirements for the companion CRTU analysis (defined by the CAP) also should be met. Note that reporting CDU results, other than for CTQ proficiency testing (i.e., compliance samples), should be accompanied with results of CRTU analyses, and these 2 sets of results should be combined to provide a measure of CDU in units of μg/g CRTU.

The performance requirement for B2MU is defined as an analytical result within ± 15% of the consensus mean. Note that reporting B2MU results, other than for CTQ proficiency testing should be accompanied with results of CRTU analysis, these two sets of results should be combined to provide a measure of B2MU in units of μg/g CRTU.

Once a new laboratory has been approved by the responsible physician for conducting analyte determinations, the status of this approval should be reviewed periodically by the responsible physician as per the criteria presented under Section 3.2.2.

Laboratories which have failed previously to gain approval of the responsible physician for conducting determinations of 1 or more analytes due to lack of compliance with the criteria defined above for existing laboratories (Section 3.2.1), may obtain approval by satisfying the criteria for newly-formed laboratories defined under this section; for these laboratories, the second of the above criteria may be satisfied by submitting a new set of characterization analyses for each analyte for which determinations are to be made.

Reevaluation of these laboratories is discretionary on the part of the responsible physician. Reevaluation, which normally takes about 6 months, may be expedited if the laboratory can achieve 100% compliance with the proficiency test criteria using the 6 samples of each analyte submitted to the CTQ program during the first 2 rounds of proficiency testing.

For laboratories seeking reevaluation for CDU or B2MU analysis, the guidelines for CRTU analyses also should be satisfied, including accreditation for CRTU analysis by the CAP, and participation in the CAP survey program (or accreditation/participation in an equivalent program).

3.2.4 Future Modifications to the Protocol Guidelines

As participating laboratories gain experience with analyses for CDB, CDU and B2MU, it is anticipated that the performance achievable by the majority of laboratories should improve until it approaches that reported by the research groups which developed each method. OSHA, therefore, may choose to recommend stricter performance guidelines in the future as the

overall performance of participating laboratories improves.

3.3 Guidelines for Record Keeping and Reporting

To comply with these guidelines, participating laboratories should satisfy the above-stated performance and proficiency recommendations, as well as the following internal QA/QC, record keeping, and reporting provisions.

If a participating laboratory fails to meet the provisions of these guidelines, it is recommended that the responsible physician disapprove further analyses of biological samples by that laboratory until it demonstrates compliance with these guidelines. On disapproval, biological samples should be sent to a laboratory that can demonstrate compliance with these guidelines, at least until the former laboratory is reevaluated by the responsible physician and found to be in compliance.

The following record keeping and reporting procedures should be practiced by participating laboratories.

3.3.1 Internal Quality Assurance/Quality Control Procedures

Laboratories participating in the cadmium monitoring program should develop and maintain an internal quality assurance/quality control (QA/QC) program that incorporates procedures for establishing and maintaining control for each of the analytic procedures (determinations of CDB, CDU and/or B2MU) for which the laboratory is seeking participation. For laboratories analyzing CDU and/or B2MU, a QA/QC program for CRTU also should be established.

Written documentation of QA/QC procedures should be described in a formal QA/QC plan; this plan should contain the following information: Sample acceptance and handling procedures (i.e., chain-of-custody); sample preparation procedures; instrument parameters; calibration procedures; and, calculations. Documentation of QA/QC procedures should be sufficient to identify analytical problems, define criteria under which analysis of compliance samples will be suspended, and describe procedures for corrective actions.

3.3.1.1 QA/QC procedures for establishing control of CDB and CDU analyses

The QA/QC program for CDB and CDU should address, at a minimum, procedures involved in calibration, establishment of control limits, internal QC analyses and maintaining control, and corrective-action protocols. Participating laboratory should develop and maintain procedures to assure that analyses of compliance samples are within control limits, and that these procedures are documented thoroughly in a QA/QC plan.

A nonmandatory QA/QC protocol is presented in Attachment 1. This attachment is illustrative of the procedures that should be addressed in a proper QA/QC program.

Calibration. Before any analytic runs are conducted, the analytic instrument should be calibrated. Calibration should be performed at the beginning of each day on which QC and/or compliance samples are run. Once calibration is established, QC or compliance samples may be run. Regardless of the type of samples run, about every fifth sample should serve as a standard to assure that calibration is being maintained.

Calibration is being maintained if the standard is within ±15% of its theoretical value. If a standard is more than ±15% of its theoretical value, the run has exceeded control limits due to calibration error; the entire set of samples then should be reanalyzed after recalibrating or the results should be recalculated based on a statistical curve derived from that set of standards.

It is essential that the value of the highest standard analyzed be higher than the highest sample analyzed; it may be necessary, therefore, to run a high standard at the end of the run, which has been selected based on results obtained over the course of the run (i.e., higher than any standard analyzed to that point).

Standards should be kept fresh; as samples age, they should be compared with new standards and replaced if necessary.

Internal Quality Control Analyses. Internal QC samples should be determined interspersed with analyses of compliance samples. At a minimum, these samples should be run at a rate of 5% of the compliance samples or at least one set of QC samples per analysis of compliance samples, whichever is greater. If only two samples are run, they should contain different levels of cadmium.

Internal QC samples may be obtained as commercially-available reference materials and/or they may be internally prepared. Internally-prepared samples should be well characterized and traced, or compared to a reference material for which a consensus value is available.

Levels of cadmium contained in QC samples should not be known to the analyst prior to reporting the results of the analysis.

Internal QC results should be plotted or charted in a manner which describes sample recovery and laboratory control limits.

Internal Control Limits. The laboratory protocol for evaluating internal QC analyses per control limits should be clearly defined. Limits may be based on statistical methods (e.g., as 2σ from the laboratory mean recovery), or on proficiency testing limits (e.g., ±1 µg or 15% of the mean, whichever is greater).

Statistical limits that exceed ±40% should be reevaluated to determine the source error in the analysis.

When laboratory limits are exceeded, analytic work should terminate until the source of error is determined and corrected; compliance samples affected by the error should be reanalyzed. In addition, the laboratory protocol should address any unusual trends that develop which may be biasing the results. Numerous, consecutive results above or below laboratory mean recoveries, or outside laboratory statistical limits, indicate that problems may have developed.

Corrective Actions. The QA/QC plan should document in detail specific actions taken if control limits are exceeded or unusual trends develop. Corrective actions should be noted on an appropriate form, accompanied by supporting documentation.

In addition to these actions, laboratories should include whatever additional actions are necessary to assure that accurate data are reported to the responsible physicians.

Reference Materials. The following reference materials may be available:

Cadmium in Blood (CDB)

1. Centre de Toxicologie du Quebec, Le Centre Hospitalier de l'Universite Laval, 2705 boul. Laurier, Quebec, Que., Canada G1V 4G2. (Prepared 6 times per year at 1–15 µg Cd/l.)

2. H. Marchandise, Community Bureau of Reference-BCR, Directorate General XII, Commission of the European Communities, 200, rue de la Loi, B–1049, Brussels, Belgium. (Prepared as Bl CBM–1 at 5.37 µg Cd/l, and Bl CBM–2 at 12.38 µg Cd/l.)

3. Kaulson Laboratories Inc., 691 Bloomfield Ave., Caldwell, NJ 07006; tel: (201) 226–9494, FAX (201) 226–3244. (Prepared as #0141 [As, Cd, Hg, Pb] at 2 levels.)

Cadmium in Urine (CDU)

1. Centre de Toxicologie du Quebec, Le Centre Hospitalier de l'Universite Laval, 2705 boul. Laurier, Quebec, Que., Canada G1V 4G2. (Prepared 6 times per year.)

2. National Institute of Standards and Technology (NIST), Dept. of Commerce, Gaithersburg, MD; tel: (301) 975–6776. (Prepared as SRM 2670 freeze-dried urine [metals]; set includes normal and elevated levels of metals; cadmium is certified for elevated level of 88.0 µg/1 in reconstituted urine.)

3. Kaulson Laboratories Inc., 691 Bloomfield Ave., Caldwell, NJ 07006; tel: (201) 226–9494, FAX (201) 226–3244. (Prepared as #0140 [As, Cd, Hg, Pb] at 2 levels.)

3.3.1.2 QA/QC procedures for establishing control of B2MU

A written, detailed QA/QC plan for B2MU analysis should be developed. The QA/QC plan should contain a protocol similar to those protocols developed for the CDB/CDU analyses. Differences in analyses may warrant some differences in the QA/QC protocol, but procedures to ensure analytical integrity should be developed and followed.

Examples of performance summaries that can be provided include measurements of accuracy (i.e., the means of measured values verses target values for the control samples) and precision (i.e., based on duplicate analyses). It is recommended that the accuracy and precision measurements be compared to those reported as achievable by the Pharmacia Delphia kit (Pharmacia 1990) to determine if and when unsatisfactory analyses have arisen. If the measurement error of 1 or more of the control samples is more than 15%, the run exceeds control limits. Similarly, this decision is warranted when the average CV for duplicate samples is greater than 5%.

3.3.2 Procedures for Record Keeping

To satisfy reporting requirements for commercial analyses of CDB, CDU and/or B2MU performed for the medical monitoring program mandated under the cadmium rule, participating laboratories should maintain

the following documentation for each analyte:

1. For each analytic instrument on which analyte determinations are made, records relating to the most recent calibration and QC sample analyses;

2. For these instruments, a tabulated record for each analyte of those determinations found to be within and outside of control limits over the past 2 years;

3. Results for the previous 2 years of the QC sample analyses conducted under the internal QA/QC program (this information should be: Provided for each analyte for which determinations are made and for each analytic instrument used for this purpose, sufficient to demonstrate that internal QA/QC programs are being executed properly, and consistent with data sent to responsible physicians).

4. Duplicate copies of monitoring results for each analyte sent to clients during the previous 5 years, as well as associated information; supporting material such as chain-of custody forms also should be retained; and,

5. Proficiency test results and related materials received while participating in the CTQ interlaboratory program over the past 2 years; results also should be tabulated to provide a serial record of relative error (derived per Section 3.3.3 below).

3.3.3 Reporting Procedures

Participating laboratories should maintain these documents: QA/QC program plans; QA/QC status reports; CTQ proficiency program reports; and, analytical data reports. The information that should be included in these reports is summarized in Table 2; a copy of each report should be sent to the responsible physician.

TABLE 2. REPORTING PROCEDURES FOR LABORATORIES PARTICIPATING IN THE CADMIUM MEDICAL MONITORING PROGRAM

Report	Frequency (time frame)	Contents
1 QA/QC Program Plan	Once (initially)	A detailed description of the QA/QC protocol to be established by the laboratory to maintain control of analyte determinations.
2 QA/QC Status Report	Every 2 months	Results of the QC samples incorporated into regular runs for each instrument (over the period since the last report).
3 Proficiency Report	Attached to every data report	Results from the last full year of proficiency samples submitted to the CTQ program.
		Results of the 100 most recent QC samples incorporated into regular runs for each instrument.
4 Analytical Data Report	For all reports of data results	Date the sample was received.
		Date the sample was analyzed.
		Appropriate chain-of-custody information.
		Types of analyses performed.
		Results of the requested analyses.
		Copy of the most current proficiency report.

As noted in Section 3.3.1, a QA/QC program plan should be developed that documents internal QA/QC procedures (defined under Section 3.3.1) to be implemented by the participating laboratory for each analyte; this plan should provide a list identifying each instrument used in making analyte determinations.

A QA/QC status report should be written bimonthly for each analyte. In this report, the results of the QC program during the reporting period should be reported for each analyte in the following manner: The number (N) of QC samples analyzed during the period; a table of the target levels defined for each sample and the corresponding measured values; the mean of F/T value (as defined below) for the set of QC samples run during the period; and use of $\bar{X}\pm2\hat{\sigma}$ (as defined below) for the set of QC samples run during the period as a measure of precision.

As noted in Section 2, an F/T value for a QC sample is the ratio of the measured concentration of analyte to the established (i.e., reference) concentration of analyte for that QC sample. The equation below describes the derivation of the mean for F/T values, $\bar{X}$, (with N being the total number of samples analyzed):

$$\overline{X}=\frac{\sum(F/T)}{N}$$

The standard deviation, σ, for these measurements is derived using the following equation (note that 2σ is twice this value):

$$\sigma=\left[\frac{\sum\left(F/T-\overline{X}\right)^2}{n-1}\right]^{\frac{1}{2}}$$

The nonmandatory QA/QC protocol (see Attachment 1) indicates that QC samples should be divided into several discrete pools, and a separate estimate of precision for each pool then should be derived. Several precision estimates should be provided for concentrations which differ in average value. These precision measures may be used to document improvements in performance with regard to the combined pool.

Participating laboratories should use the CTQ proficiency program for each analyte. Results of this program will be sent by CTQ directly to physicians designated by the participating laboratories. Proficiency results from the CTQ program are used to establish the accuracy of results from each participating laboratory, and should be provided to responsible physicians for use in trend analysis. A proficiency report consisting of these proficiency results should accompany data reports as an attachment.

For each analyte, the proficiency report should include the results from the 6 previous proficiency rounds in the following format:

1. Number (N) of samples analyzed;

2. Mean of the target levels, $(1/N)\Sigma T_i$, with T_i being a consensus mean for the sample;

3. Mean of the measurements, $(1/N)\Sigma M_i$, with M_i being a sample measurement;

4. A measure of error defined by:

$$(1/N)\sum\left(T_i-M_i\right)^2$$

Analytical data reports should be submitted to responsible physicians directly. For each sample, report the following information: The date the sample was received; the date the sample was analyzed; appropriate chain-of-custody information; the type(s) of analyses performed; and, the results of the analyses. This information should be reported on a form similar to the form provided an appropriate form. The most recent proficiency program report should accompany the analytical data reports (as an attachment).

Confidence intervals for the analytical results should be reported as $X\pm2\hat{\sigma}$, with X being the measured value and $2\hat{\sigma}$ the standard deviation calculated as described above.

For CDU or B2MU results, which are combined with CRTU measurements for proper reporting, the 95% confidence limits are derived from the limits for CDU or B2MU, (p), and the limits for CRTU, (q), as follows:

$$\frac{X}{Y}\pm\left(\frac{1}{Y^2}\right)\left(Y^2\times p^2+X^2\times q^2\right)^{\frac{1}{2}}$$

For these calculations, $X \pm p$ is the measurement and confidence limits for CDU or B2MU, and $Y \pm q$ is the measurement and confidence limit for CRTU.

Participating laboratories should notify responsible physicians as soon as they receive information indicating a change in their accreditation status with the CTQ or the CAP. These physicians should not be expected to wait until formal notice of a

status change has been received from the CTQ or the CAP.

3.4 Instructions to Physicians

Physicians responsible for the medical monitoring of cadmium-exposed workers must collect the biological samples from workers; they then should select laboratories to perform the required analyses, and should interpret the analytic results.

3.4.1 Sample Collection and Holding Procedures

Blood Samples. The following procedures are recommended for the collection, shipment and storage of blood samples for CDB analysis to reduce analytical variability; these recommendations were obtained primarily through personal communications with J.P. Weber of the CTQ (1991), and from reports by the Centers for Disease Control (CDC, 1986) and Stoeppler and Brandt (1980).

To the extent possible, blood samples should be collected from workers at the same time of day. Workers should shower or thoroughly wash their hands and arms before blood samples are drawn. The following materials are needed for blood sample collection: Alcohol wipes; sterile gauze sponges; band-aids; 20 gauge, 1.5-in. stainless steel needles (sterile); preprinted labels; tourniquets; vacutainer holders; 3-ml "metal free" vacutainer tubes (i.e., dark-blue caps), with EDTA as an anticoagulant; and, styrofoam vacutainer shipping containers.

Whole blood samples are taken by venipuncture. Each bluecapped tube should be labeled or coded for the worker and company before the sample is drawn. (Blue-capped tubes are recommended instead of red-capped tubes because the latter may consist of red coloring pigment containing cadmium, which could contaminate the samples.) Immediately after sampling, the vacutainer tubes must be thoroughly mixed by inverting the tubes at least 10 times manually or mechanically using a Vortex device (for 15 sec). Samples should be refrigerated immediately or stored on ice until they can be packed for shipment to the participating laboratory for analysis.

The CDC recommends that blood samples be shipped with a "cool pak" to keep the samples cold during shipment. However, the CTQ routinely ships and receives blood samples for cadmium analysis that have not been kept cool during shipment. The CTQ has found no deterioration of cadmium in biological fluids that were shipped via parcel post without a cooling agent, even though these deliveries often take 2 weeks to reach their destination.

Urine Samples. The following are recommended procedures for the collection, shipment and storage of urine for CDU and B2MU analyses, and were obtained primarily through personal communications with J.P. Weber of the CTQ (1991), and from reports by the CDC (1986) and Stoeppler and Brandt (1980).

Single "spot" samples are recommended. As B2M can degrade in the bladder, workers should first empty their bladder and then drink a large glass of water at the start of the visit. Urine samples then should be collected within 1 hour. Separate samples should be collected for CDU and B2MU using the following materials: Sterile urine collection cups (250 ml); small sealable plastic bags; preprinted labels; 15-ml polypropylene or polyethylene screw-cap tubes; lab gloves ("metal free"); and, preservatives (as indicated).

The sealed collection cup should be kept in the plastic bag until collection time. The workers should wash their hands with soap and water before receiving the collection cup. The collection cup should not be opened until just before voiding and the cup should be sealed immediately after filling. It is important that the inside of the container and cap are not touched by, or come into contact with, the body, clothing or other surfaces.

For CDU analyzes, the cup is swirled gently to resuspend any solids, and the 15-ml tube is filled with 10–12 ml urine. The CDC recommends the addition of 100 µl concentrated HNO_3 as a preservative before sealing the tube and then freezing the sample. The CTQ recommends minimal handling and does not acidify their interlaboratory urine reference materials prior to shipment, nor do they freeze the sample for shipment. At the CTQ, if the urine sample has much sediment, the sample is acidified in the lab to free any cadmium in the precipitate.

For B2M, the urine sample should be collected directly into a polyethylene bottle previously washed with dilute nitric acid. The pH of the urine should be measured and adjusted to 8.0 with 0.1 N NaOH immediately following collection. Samples should be frozen and stored at −20°C until testing is performed. The B2M in the samples should be stable for 2 days when stored at 2–8°C, and for at least 2 months at −20°C. Repeated freezing and thawing should be avoided to prevent denaturing the B2M (Pharmacia 1990).

3.4.2 Recommendations for Evaluating Laboratories

Using standard error data and the results of proficiency testing obtained from CTQ, responsible physicians can make an informed choice of which laboratory to select to analyze biological samples. In general, laboratories with small standard errors and little disparity between target and measured values tend to make precise and accurate sample determinations. Estimates of precision provided to the physicians with each set of monitoring results can be compared to previously-reported proficiency and precision estimates. The latest precision estimates should be at least as small as the standard error reported previously by the laboratory. Moreover, there should be no indication that precision is deteriorating (i.e., increasing values for the precision estimates). If precision is deteriorating, physicians may decide to use another laboratory for these analyses. QA/QC information provided by the participating laboratories to physicians can, therefore, assist physicians in evaluating laboratory performance.

3.4.3 Use and Interpretation of Results

When the responsible physician has received the CDB, CDU and/or B2MU results, these results must be compared to the action levels discussed in the final rule for cadmium. The comparison of the sample results to action levels is straightforward. The measured value reported from the laboratory can be compared directly to the action levels; if the reported value exceeds an action level, the required actions must be initiated.

4.0 Background

Cadmium is a naturally-occurring environmental contaminant to which humans are continually exposed in food, water, and air. The average daily intake of cadmium by the U.S. population is estimated to be 10–20 µg/day. Most of this intake is via ingestion, for which absorption is estimated at 4–7% (Kowal et al. 1979). An additional nonoccupational source of cadmium is smoking tobacco; smoking a pack of cigarettes a day adds an additional 2–4 µg cadmium to the daily intake, assuming absorption via inhalation of 25–35% (Nordberg and Nordberg 1988; Friberg and Elinder 1988; Travis and Haddock 1980).

Exposure to cadmium fumes and dusts in an occupational setting where air concentrations are 20–50 µg/m³ results in an additional daily intake of several hundred micrograms (Friberg and Elinder 1988, p. 563). In such a setting, occupational exposure to cadmium occurs primarily via inhalation, although additional exposure may occur through the ingestion of material via contaminated hands if workers eat or smoke without first washing. Some of the particles that are inhaled initially may be ingested when the material is deposited in the upper respiratory tract, where it may be cleared by mucociliary transport and subsequently swallowed.

Cadmium introduced into the body through inhalation or ingestion is transported by the albumin fraction of the blood plasma to the liver, where it accumulates and is stored principally as a bound form complexed with the protein metallothionein. Metallothionein-bound cadmium is the main form of cadmium subsequently transported to the kidney; it is these 2 organs, the liver and kidney, in which the majority of the cadmium body burden accumulates. As much as one half of the total body burden of cadmium may be found in the kidneys (Nordberg and Nordberg 1988).

Once cadmium has entered the body, elimination is slow; about 0.02% of the body burden is excreted per day via urinary/fecal elimination. The whole-body half-life of cadmium is 10–35 years, decreasing slightly with increasing age (Travis and Haddock 1980).

The continual accumulation of cadmium is the basis for its chronic noncarcinogenic toxicity. This accumulation makes the kidney the target organ in which cadmium toxicity usually is first observed (Piscator 1964). Renal damage may occur when cadmium levels in the kidney cortex approach 200 µg/g wet tissue-weight (Travis and Haddock 1980).

The kinetics and internal distribution of cadmium in the body are complex, and depend on whether occupational exposure to cadmium is ongoing or has terminated. In general, cadmium in blood is related principally to recent cadmium exposure, while cadmium in urine reflects cumulative

exposure (i.e., total body burden)(Lauwerys et al. 1976; Friberg and Elinder 1988).

4.1 Health Effects

Studies of workers in a variety of industries indicate that chronic exposure to cadmium may be linked to several adverse health effects including kidney dysfunction, reduced pulmonary function, chronic lung disease and cancer (Federal Register 1990). The primary sites for cadmium-associated cancer appear to be the lung and the prostate.

Cancer. Evidence for an association between cancer and cadmium exposure comes from both epidemiological studies and animal experiments. Pott (1965) found a statistically significant elevation in the incidence of prostate cancer among a cohort of cadmium workers. Other epidemiology studies also report an elevated incidence of prostate cancer; however, the increases observed in these other studies were not statistically significant (Meridian Research, Inc. 1989).

One study (Thun et al. 1985) contains sufficiently quantitative estimates of cadmium exposure to allow evaluation of dose-response relationships between cadmium exposure and lung cancer. A statistically significant excess of lung cancer attributed to cadmium exposure was found in this study, even after accounting for confounding variables such as coexposure to arsenic and smoking habits (Meridian Research, Inc. 1989).

Evidence for quantifying a link between lung cancer and cadmium exposure comes from a single study (Takenaka et al. 1983). In this study, dose-response relationships developed from animal data were extrapolated to humans using a variety of models. OSHA chose the multistage risk model for estimating the risk of cancer for humans using these animal data. Animal injection studies also suggest an association between cadmium exposure and cancer, particularly observations of an increased incidence of tumors at sites remote from the point of injection. The International Agency for Research on Cancer (IARC) (Supplement 7, 1987) indicates that this, and related, evidence is sufficient to classify cadmium as an animal carcinogen. However, the results of these injection studies cannot be used to quantify risks attendant to human occupational exposures due to differences in routes of exposure (Meridian Research, Inc. 1989).

Based on the above-cited studies, the U.S. Environmental Protection Agency (EPA) classifies cadmium as "B1," a probable human carcinogen (USEPA 1985). IARC in 1987 recommended that cadmium be listed as a probable human carcinogen.

Kidney Dysfunction. The most prevalent nonmalignant effect observed among workers chronically exposed to cadmium is kidney dysfunction. Initially, such dysfunction is manifested by proteinuria (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989). Proteinuria associated with cadmium exposure is most commonly characterized by excretion of low-molecular weight proteins (15,000–40,000 MW), accompanied by loss of electrolytes, uric acid, calcium, amino acids, and phosphate. Proteins commonly excreted include β-2-microglobulin (B2M), retinolbinding protein (RBP), immunoglobulin light chains, and lysozyme. Excretion of low molecular weight proteins is characteristic of damage to the proximal tubules of the kidney (Iwao et al. 1980).

Exposure to cadmium also may lead to urinary excretion of high-molecular weight proteins such as albumin, immunoglobulin G, and glycoproteins (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989). Excretion of high-molecular weight proteins is indicative of damage to the glomeruli of the kidney. Bernard et al. (1979) suggest that cadmium-associated damage to the glomeruli and damage to the proximal tubules of the kidney develop independently of each other, but may occur in the same individual.

Several studies indicate that the onset of low-molecular weight proteinuria is a sign of irreversible kidney damage (Friberg et al. 1974; Roels et al. 1982; Piscator 1984; Elinder et al. 1985; Smith et al. 1986). For many workers, once sufficiently elevated levels of B2M are observed in association with cadmium exposure, such levels do not appear to return to normal even when cadmium exposure is eliminated by removal of the worker from the cadmium-contaminated work environment (Friberg, exhibit 29, 1990).

Some studies indicate that cadmium-induced proteinuria may be progressive; levels of B2MU increase even after cadmium exposure has ceased (Elinder et al. 1985). Other researchers have reached similar conclusions (Frieburg testimony, OSHA docket exhibit 29, Elinder testimony, OSHA docket exhibit 55, and OSHA docket exhibits 8–86B). Such observations are not universal, however (Smith et al. 1986; Tsuchiya 1976). Studies in which proteinuria has not been observed, however, may have initiated the reassessment too early (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989; Roels 1989).

A quantitative assessment of the risks of developing kidney dysfunction as a result of cadmium exposure was performed using the data from Ellis et al. (1984) and Falck et al. (1983). Meridian Research, Inc. (1989) and Roth Associates, Inc. (1989) employed several mathematical models to evaluate the data from the 2 studies, and the results indicate that cumulative cadmium exposure levels between 5 and 100 μg-years/m^3 correspond with a one-in-a-thousand probability of developing kidney dysfunction.

When cadmium exposure continues past the onset of early kidney damage (manifested as proteinuria), chronic nephrotoxicity may occur (Meridian Research, Inc. 1989; Roth Associates, Inc. 1989). Uremia, which is the loss of the glomerulus' ability to adequately filter blood, may result. This condition leads to severe disturbance of electrolyte concentrations, which may result in various clinical complications including atherosclerosis, hypertension, pericarditis, anemia, hemorrhagic tendencies, deficient cellular immunity, bone changes, and other problems. Progression of the disease may require dialysis or a kidney transplant.

Studies in which animals are chronically exposed to cadmium confirm the renal effects observed in humans (Friberg et al. 1986). Animal studies also confirm cadmium-related problems with calcium metabolism and associated skeletal effects, which also have been observed among humans. Other effects commonly reported in chronic animal studies include anemia, changes in liver morphology, immunosuppression and hypertension. Some of these effects may be associated with cofactors; hypertension, for example, appears to be associated with diet, as well as with cadmium exposure. Animals injected with cadmium also have shown testicular necrosis.

4.2 Objectives for Medical Monitoring

In keeping with the observation that renal disease tends to be the earliest clinical manifestation of cadmium toxicity, the final cadmium standard mandates that eligible workers must be medically monitored to prevent this condition (as well as cadmimum-induced cancer). The objectives of medical-monitoring, therefore, are to: Identify workers at significant risk of adverse health effects from excess, chronic exposure to cadmium; prevent future cases of cadmium-induced disease; detect and minimize existing cadmium-induced disease; and, identify workers most in need of medical intervention.

The overall goal of the medical monitoring program is to protect workers who may be exposed continuously to cadmium over a 45-year occupational lifespan. Consistent with this goal, the medical monitoring program should assure that:

1. Current exposure levels remain sufficiently low to prevent the accumulation of cadmium body burdens sufficient to cause disease in the future by monitoring CDB as an indicator of recent cadmium exposure;

2. Cumulative body burdens, especially among workers with undefined historical exposures, remain below levels potentially capable of leading to damage and disease by assessing CDU as an indicator of cumulative exposure to cadmium; and,

3. Health effects are not occurring among exposed workers by determining B2MU as an early indicator of the onset of cadmium-induced kidney disease.

4.3 Indicators of Cadmium Exposure and Disease

Cadmium is present in whole blood bound to albumin, in erythrocytes, and as a metallothionein-cadmium complex. The metallothionein-cadmium complex that represents the primary transport mechanism for cadmium delivery to the kidney. CDB concentrations in the general, nonexposed population average 1 μg Cd/l whole blood, with smokers exhibiting higher levels (see Section 5.1.6). Data presented in Section 5.1.6 shows that 95% of the general population not occupationally exposed to cadmium have CDB levels less than 5 μg Cd/l.

If total body burdens of cadmium remain low, CDB concentrations indicate recent exposure (i.e., daily intake). This conclusion is based on data showing that cigarette smokers exhibit CDB concentrations of 2–7 μg/l depending on the number of cigarettes smoked per day (Nordberg and Nordberg 1988), while CDB levels for those who quit smoking return to general population values

(approximately 1 μg/l) within several weeks (Lauwerys et al. 1976). Based on these observations, Lauwerys et al. (1976) concluded that CDB has a biological half-life of a few weeks to less than 3 months. As indicated in Section 3.1.6, the upper 95th percentile for CDB levels observed among those who are not occupationally exposed to cadmium is 5 μg/l, which suggests that the absolute upper limit to the range reported for smokers by Nordberg and Nordberg may have been affected by an extreme value (i.e., beyond 2σ above the mean).

Among occupationally-exposed workers, the occupational history of exposure to cadmium must be evaluated to interpret CDB levels. New workers, or workers with low exposures to cadmium, exhibit CDB levels that are representative of recent exposures, similar to the general population. However, for workers with a history of chronic exposure to cadmium, who have accumulated significant stores of cadmium in the kidneys/liver, part of the CDB concentrations appear to indicate body burden. If such workers are removed from cadmium exposure, their CDB levels remain elevated, possibly for years, reflecting prior long-term accumulation of cadmium in body tissues. This condition tends to occur, however, only beyond some threshold exposure value, and possibly indicates the capacity of body tissues to accumulate cadmium which cannot be excreted readily (Friberg and Elinder 1988; Nordberg and Nordberg 1988).

CDU is widely used as an indicator of cadmium body burdens (Nordberg and Nordberg 1988). CDU is the major route of elimination and, when CDU is measured, it is commonly expressed either as μg Cd/l urine (unadjusted), μg Cd/l urine (adjusted for specific gravity), or μg Cd/g CRTU (see Section 5.2.1). The metabolic model for CDU is less complicated than CDB, since CDU is dependent in large part on the body (i.e., kidney) burden of cadmium. However, a small proportion of CDU still be attributed to recent cadmium exposure, particularly if exposure to high airborne concentrations of cadmium occurred. Note that CDU is subject to larger interindividual and day-to-day variations than CDB, so repeated measurements are recommended for CDU evaluations.

CDU is bound principally to metallothionein, regardless of whether the cadmium originates from metallothionein in plasma or from the cadmium pool accumulated in the renal tubules. Therefore, measurement of metallothionein in urine may provide information similar to CDU, while avoiding the contamination problems that may occur during collection and handling urine for cadmium analysis (Nordberg and Nordberg 1988). However, a commercial method for the determination of metallothionein at the sensitivity levels required under the final cadmium rule is not currently available; therefore, analysis of CDU is recommended.

Among the general population not occupationally exposed to cadmium, CDU levels average less than 1 μg/l (see Section 5.2.7). Normalized for creatinine (CRTU), the average CDU concentration of the general population is less than 1 μg/g CRTU. As cadmium accumulates over the lifespan, CDU increases with age. Also, cigarette smokers may eventually accumulate twice the cadmium body burden of nonsmokers, CDU is slightly higher in smokers than in nonsmokers, even several years after smoking cessation (Nordberg and Nordberg 1988). Despite variations due to age and smoking habits, 95% of those not occupationally exposed to cadmium exhibit levels of CDU less than 3 μg/g CRTU (based on the data presented in Section 5.2.7).

About 0.02% of the cadmium body burden is excreted daily in urine. When the critical cadmium concentration (about 200 ppm) in the kidney is reached, or if there is sufficient cadmium-induced kidney dysfunction, dramatic increases in CDU are observed (Nordberg and Nordberg 1988). Above 200 ppm, therefore, CDU concentrations cease to be an indicator of cadmium body burden, and are instead an index of kidney failure.

Proteinuria is an index of kidney dysfunction, and is defined by OSHA to be a material impairment. Several small proteins may be monitored as markers for proteinuria. Below levels indicative of proteinuria, these small proteins may be early indicators of increased risk of cadmium-induced renal tubular disease. Analytes useful for monitoring cadmium-induced renal tubular damage include:

1. β-2-Microglobulin (B2M), currently the most widely used assay for detecting kidney dysfunction, is the best characterized analyte available (Iwao et al. 1980; Chia et al. 1989);

2. Retinol Binding Protein (RBP) is more stable than B2M in acidic urine (i.e., B2M breakdown occurs if urinary pH is less than 5.5; such breakdown may result in false [i.e., low] B2M values [Bernard and Lauwerys, 1990]);

3. N-Acetyl-B-Glucosaminidase (NAG) is the analyte of an assay that is simple, inexpensive, reliable, and correlates with cadmium levels under 10 μg/g CRTU, but the assay is less sensitive than RBP or B2M (Kawada et al. 1989);

4. Metallothionein (MT) correlates with cadmium and B2M levels, and may be a better predictor of cadmium exposure than CDU and B2M (Kawada et al. 1989);

5. Tamm-Horsfall Glycoprotein (THG) increases slightly with elevated cadmium levels, but this elevation is small compared to increases in urinary albumin, RBP, or B2M (Bernard and Lauwerys 1990);

6. Albumin (ALB), determined by the biuret method, is not sufficiently sensitive to serve as an early indicator of the onset of renal disease (Piscator 1962);

7. Albumin (ALB), determined by the Amido Black method, is sensitive and reproducible, but involves a time-consuming procedure (Piscator 1962);

8. Glycosaminoglycan (GAG) increases among cadmium workers, but the significance of this effect is unknown because no relationship has been found between elevated GAG and other indices of tubular damage (Bernard and Lauwerys 1990);

9. Trehalase seems to increase earlier than B2M during cadmium exposure, but the procedure for analysis is complicated and unreliable (Iwata et al. 1988); and,

10. Kallikrein is observed at lower concentrations among cadmium-exposed workers than among normal controls (Roels et al. 1990).

Of the above analytes, B2M appears to be the most widely used and best characterized analyte to evaluate the presence/absence, as well as the extent of, cadmium-induced renal tubular damage (Kawada, Koyama, and Suzuki 1989; Shaikh and Smith 1984; Nogawa 1984). However, it is important that samples be collected and handled so as to minimize B2M degradation under acidic urine conditions.

The threshold value of B2MU commonly used to indicate the presence of kidney damage 300 μg/g CRTU (Kjellstrom et al. 1977a; Buchet et al. 1980; and Kowal and Zirkes 1983). This value represents the upper 95th or 97.5th percentile level of urinary excretion observed among those without tubular dysfunction (Elinder, exbt L–140–45, OSHA docket H057A). In agreement with these conclusions, the data presented in Section 5.3.7 of this protocol generally indicate that the level of 300 μg/g CRTU appears to define the boundary for kidney dysfunction. It is not clear, however, that this level represents the upper 95th percentile of values observed among those who fail to demonstrate proteinuria effects.

Although elevated B2MU levels appear to be a fairly specific indicator of disease associated with cadmium exposure, other conditions that may lead to elevated B2MU levels include high fevers from influenza, extensive physical exercise, renal disease unrelated to cadmium exposure, lymphomas, and AIDS (Iwao et al. 1980; Schardun and van Epps 1987). Elevated B2M levels observed in association with high fevers from influenza or from extensive physical exercise are transient, and will return to normal levels once the fever has abated or metabolic rates return to baseline values following exercise. The other conditions linked to elevated B2M levels can be diagnosed as part of a properly-designed medical examination. Consequently, monitoring B2M, when accompanied by regular medical examinations and CDB and CDU determinations (as indicators of present and past cadmium exposure), may serve as a specific, early indicator of cadmium-induced kidney damage.

4.4 Criteria for Medical Monitoring of Cadmium Workers

Medical monitoring mandated by the final cadmium rule includes a combination of regular medical examinations and periodic monitoring of 3 analytes: CDB, CDU and B2MU. As indicated above, CDB is monitored as an indicator of current cadmium exposure, while CDU serves as an indicator of the cadmium body burden; B2MU) is assessed as an early marker of irreversible kidney damage and disease.

The final cadmium rule defines a series of action levels that have been developed for each of the 3 analytes to be monitored. These action levels serve to guide the responsible physician through a decision-making process. For each action level that is exceeded, a specific response is mandated. The sequence of action levels, and the

attendant actions, are described in detail in the final cadmium rule.

Other criteria used in the medical decision-making process relate to tests performed during the medical examination (including a determination of the ability of a worker to wear a respirator). These criteria, however, are not affected by the results of the analyte determinations addressed in the above paragraphs and, consequently, will not be considered further in these guidelines.

4.5 Defining to Quality and Proficiency of the Analyte Determinations

As noted above in Sections 2 and 3, the quality of a measurement should be defined along with its value to properly interpret the results. Generally, it is necessary to know the accuracy and the precision of a measurement before it can be properly evaluated. The precision of the data from a specific laboratory indicates the extent to which the repeated measurements of the same sample vary within that laboratory. The accuracy of the data provides an indication of the extent to which these results deviate from average results determined from many laboratories performing the same measurement (i.e., in the absence of an independent determination of the true value of a measurement). Note that terms are defined operationally relative to the manner in which they will be used in this protocol. Formal definitions for the terms in italics used in this section can be found in the list of definitions (Section 2).

Another data quality criterion required to properly evaluate measurement results is the limit of detection of that measurement. For measurements to be useful, the range of the measurement which is of interest for biological monitoring purposes must lie entirely above the limit of detection defined for that measurement.

The overall quality of a laboratory's results is termed the performance of that laboratory. The degree to which a laboratory satisfies a minimum performance level is referred to as the proficiency of the laboratory. A successful medical monitoring program, therefore, should include procedures developed for monitoring and recording laboratory performance; these procedures can be used to identify the most proficient laboratories.

5.0 Overview of Medical Monitoring Tests for CDB, CDU, B2MU and CRTU

To evaluate whether available methods for assessing CDB, CDU, B2MU and CRTU are adequate for determining the parameters defined by the proposed action levels, it is necessary to review procedures available for sample collection, preparation and analysis. A variety of techniques for these purposes have been used historically for the determination of cadmium in biological matrices (including CDB and CDU), and for the determination of specific proteins in biological matrices (including B2MU). However, only the most recent techniques are capable of satisfying the required accuracy, precision and sensitivity (i.e., limit of detection) for monitoring at the levels mandated in the final cadmium rule, while still facilitating automated analysis and rapid processing.

5.1 Measuring Cadmium in Blood (CDB)

Analysis of biological samples for cadmium requires strict analytical discipline regarding collection and handling of samples. In addition to occupational settings, where cadmium contamination would be apparent, cadmium is a ubiquitous environmental contaminant, and much care should be exercised to ensure that samples are not contaminated during collection, preparation or analysis. Many common chemical reagents are contaminated with cadmium at concentrations that will interfere with cadmium analysis; because of the widespread use of cadmium compounds as colored pigments in plastics and coatings, the analyst should continually monitor each manufacturer's chemical reagents and collection containers to prevent contamination of samples.

Guarding against cadmium contamination of biological samples is particularly important when analyzing blood samples because cadmium concentrations in blood samples from nonexposed populations are generally less than 2 µg/l (2 ng/ml), while occupationally-exposed workers can be at medical risk to cadmium toxicity if blood concentrations exceed 5 µg/l (ACGIH 1991 and 1992). This narrow margin between exposed and unexposed samples requires that exceptional care be used in performing analytic determinations for biological monitoring for occupational cadmium exposure.

Methods for quantifying cadmium in blood have improved over the last 40 years primarily because of improvements in analytical instrumentation. Also, due to improvements in analytical techniques, there is less need to perform extensive multi-step sample preparations prior to analysis. Complex sample preparation was previously required to enhance method sensitivity (for cadmium), and to reduce interference by other metals or components of the sample.

5.1.1 Analytical Techniques Used to Monitor Cadmium in Biological Matrices

A number of analytical techniques have been used for determining cadmium concentrations in biological materials. A summary of the characteristics of the most widely employed techniques is presented in Table 3. The technique most suitable for medical monitoring for cadmium is atomic absorption spectroscopy (AAS).

TABLE 3.—COMPARISON OF ANALYTICAL PROCEDURES/INSTRUMENTATION FOR DETERMINATION OF CADMIUM IN BIOLOGICAL SAMPLES

Analytical procedure	Limit of detection [ng/(g or ml)]	Specified biological matrix	Reference	Comments
Flame Atomic Absorption Spectroscopy (FAAS).	≥ 1.0	Any matrix	Perkin-Elmer (1982).	Not sensitive enough for biomonitoring without extensive sample digestion, metal chelation and organic solvent extraction.
Graphite Furnace Atomic Absorption Spectroscopy (GFAAS).	0.04 ≥ 0.20	Urine Blood	Pruszkowska et al. (1983). Stoeppler and Brandt (1980)	Methods of choice for routine cadmium analysis.
Inductively-Coupled Argon-Plasma Atomic Emission Spectroscopy (ICAP AES).	2.0	Any matrix	NIOSH (1984A).	Requires extensive sample preparation and concentration of metal with chelating resin. Advantage is simultaneous analyses for as many as 10 metals from 1 sample.
Neutron Activation Gamma Spectroscopy (NA).	1.5	In vivo (liver)	Ellis et al. (1983).	Only available in vivo method for direct determination of cadmium body tissue burdens; expensive; absolute determination of cadmium in reference materials.
Isotope Dilution Mass Spectroscopy (IDMS).	<1.0	Any matrix	Michiels and DeBievre (1986).	Suitable for absolute determination of cadmium in reference materials; expensive.
Differential Pulse Anodic Stripping Voltammetry (DPASV).	<1.0	Any matrix	Stoeppler and Brandt (1980).	Suitable for absolute determination of cadmium in reference materials; efficient method to check accuracy of analytical method.

To obtain a measurement using AAS, a light source (i.e., hollow cathode or lectrode-free discharge lamp) containing the element of interest as the cathode, is energized and the lamp emits a spectrum that is unique for that element. This light source is focused through a sample cell, and a selected wavelength is monitored by a monochrometer and photodetector cell. Any ground state atoms in the sample that match those of the lamp element and are in the path of the emitted light may absorb some of the light and decrease the amount of light that reaches the photodetector cell. The amount of light absorbed at each characteristic wavelength is proportional to the number of ground state atoms of the corresponding element that are in the pathway of the light between the source and detector.

To determine the amount of a specific metallic element in a sample using AAS, the sample is dissolved in a solvent and aspirated into a high-temperature flame as an aerosol. At high temperatures, the solvent is rapidly evaporated or decomposed and the solute is initially solidified; the majority of the sample elements then are transformed into an atomic vapor. Next, a light beam is focused above the flame and the amount of metal in the sample can be determined by measuring the degree of absorbance of the atoms of the target element released by the flame at a characteristic wavelength.

A more refined atomic absorption technique, flameless AAS, substitutes an electrothermal, graphite furnace for the flame. An aliquot (10–100 µl) of the sample is pipetted into the cold furnace, which is then heated rapidly to generate an atomic vapor of the element.

AAS is a sensitive and specific method for the elemental analysis of metals; its main drawback is nonspecific background absorbtion and scattering of the light beam by particles of the sample as it decomposes at high temperatures; nonspecific absorbance reduces the sensitivity of the analytical method. The problem of nonspecific absorbance and scattering can be reduced by extensive sample pretreatment, such as ashing and/or acid digestion of the sample to reduce its organic content.

Current AAS instruments employ background correction devices to adjust electronically for background absorbtion and scattering. A common method to correct for background effects is to use a deuterium arc lamp as a second light source. A continuum light source, such as the deuterium lamp, emits a broad spectrum of wavelengths instead of specific wavelengths characteristic of a particular element, as with the hollow cathode tube. With this system, light from the primary source and the continuum source are passed alternately through the sample cell. The target element effectively absorbs light only from the primary source (which is much brighter than the continuum source at the characteristic wavelengths), while the background matrix absorbs and scatters light from both sources equally. Therefore, when the ratio of the two beams is measured electronically, the effect of nonspecific background absorption and scattering is eliminated. A less common, but more sophisticated, background correction system is based on the Zeeman effect, which uses a magnetically-activated light polarizer to compensate electronically for nonspecific absorbtion and scattering.

Atomic emission spectroscopy with inductively-coupled argon plasma (AES-ICAP) is widely used to analyze for metals. With this instrument, the sample is aspirated into an extremely hot argon plasma flame, which excites the metal atoms; emission spectra specific for the sample element then are generated. The quanta of emitted light passing through a monochrometer are amplified by photomultiplier tubes and measured by a photodetector to determine the amount of metal in the sample. An advantage of AES-ICAP over AAS is that multi-elemental analyses of a sample can be performed by simultaneously measuring specific elemental emission energies. However, AES-ICAP lacks the sensitivity of AAS, exhibiting a limit of detection which is higher than the limit of detection for graphite-furnace AAS (Table 3).

Neutron activation (NA) analysis and isotope dilution mass spectrometry (IDMS) are 2 additional, but highly specialized, methods that have been used for cadmium determinations. These methods are expensive because they require elaborate and sophisticated instrumentation.

NA analysis has the distinct advantage over other analytical methods of being able to determine cadmium body burdens in specific organs (e.g., liver, kidney) *in vivo* (Ellis et al. 1983). Neutron bombardment of the target transforms cadmium-113 to cadmium-114, which promptly decays ($<10^{-14}$ sec) to its ground state, emitting gamma rays that are measured using large gamma detectors; appropriate shielding and instrumentation are required when using this method.

IDMS analysis, a definitive but laborious method, is based on the change in the ratio of 2 isotopes of cadmium (cadmium 111 and 112) that occurs when a known amount of the element (with an artificially altered ratio of the same isotopes [i.e., a cadmium 111 "spike"] is added to a weighed aliquot of the sample (Michiels and De Bievre 1986).

5.1.2 Methods Developed for CDB Determinations

A variety of methods have been used for preparing and analyzing CDB samples; most of these methods rely on one of the analytical techniques described above. Among the earliest reports, Princi (1947) and Smith et al. (1955) employed a colorimetric procedure to analyze for CDB and CDU. Samples were dried and digested through several cycles with concentrated mineral acids (HNO_3 and H_2SO_4) and hydrogen peroxide (H_2O_2). The digest was neutralized, and the cadmium was complexed with diphenylthiocarbazone and extracted with chloroform. The dithizone-cadmium complex then was quantified using a spectrometer.

Colorimetric procedures for cadmium analyses were replaced by methods based on atomic absorption spectroscopy (AAS) in the early 1960s, but many of the complex sample preparation procedures were retained. Kjellstrom (1979) reports that in Japanese, American and Swedish laboratories during the early 1970s, blood samples were wet ashed with mineral acids or ashed at high temperature and wetted with nitric acid. The cadmium in the digest was complexed with metal chelators including diethyl dithiocarbamate (DDTC), ammonium pyrrolidine dithiocarbamate (APDC) or diphenylthiocarbazone (dithizone) in ammonia-citrate buffer and extracted with methyl isobutyl ketone (MIBK). The resulting solution then was analyzed by flame AAS or graphite-furnace AAS forcadmium determinations using deuterium-lamp background correction.

In the late 1970s, researchers began developing simpler preparation procedures. Roels et al. (1978) and Roberts and Clark (1986) developed simplified digestion procedures. Using the Roberts and Clark method, a 0.5 ml aliquot of blood is collected and transferred to a digestion tube containing 1 ml concentrated HNO_3. The blood is then digested at 110 °C for 4 hours. The sample is reduced in volume by continued heating, and 0.5 ml 30% H_2O_2 is added as the sample dries. The residue is dissolved in 5 ml dilute (1%) HNO_3, and 20 µl of sample is then analyzed by graphite-furnace AAS with deuterium-background correction.

The current trend in the preparation of blood samples is to dilute the sample and add matrix modifiers to reduce background interference, rather than digesting the sample to reduce organic content. The method of Stoeppler and Brandt (1980), and the abbreviated procedure published in the American Public Health Association's (APHA) *Methods for Biological Monitoring* (1988), are straightforward and are nearly identical. For the APHA method, a small aliquot (50–300 µl) of whole blood that has been stabilized with ethylenediaminetetraacetate (EDTA) is added to 1.0 ml 1M HNO_3, vigorously shaken and centrifuged. Aliquots (10–25 µl) of the supernatant then are then analyzed by graphite-furnace AAS with appropriate background correction.

Using the method of Stoeppler and Brandt (1980), aliquots (50–200 µl) of whole blood that have been stabilized with EDTA are pipetted into clean polystyrene tubes and mixed with 150–600 µl of 1 M HNO_3. After vigorous shaking, the solution is centrifuged and a 10–25 µl aliquot of the supernatant then is analyzed by graphite-furnace AAS with appropriate background correction.

Claeys-Thoreau (1982) and DeBenzo et al. (1990) diluted blood samples at a ratio of 1:10 with a matrix modifier (0.2% Triton X-100, a wetting agent) for direct determinations of CDB. DeBenzo et al. also demonstrated that aqueous standards of cadmium, instead of spiked, whole-blood samples, could be used to establish calibration curves if standards and samples are treated with additional small volumes of matrix modifiers (i.e., 1% HNO_3, 0.2% ammonium hydrogenphosphate and 1 mg/ml magnesium salts).

These direct dilution procedures for CDB analysis are simple and rapid. Laboratories can process more than 100 samples a day using a dedicated graphite-furnace AAS, an auto-sampler, and either a Zeeman- or a deuterium-background correction system. Several authors emphasize using optimum

settings for graphite-furnace temperatures during the drying, charring, and atomization processes associated with the flameless AAS method, and the need to run frequent QC samples when performing automated analysis.

5.1.3 Sample Collection and Handling

Sample collection procedures are addressed primarily to identify ways to minimize the degree of variability that may be introduced by sample collection during medical monitoring. It is unclear at this point the extent to which collection procedures contribute to variability among CDB samples. Sources of variation that may result from sampling procedures include time-of-day effects and introduction of external contamination during the collection process. To minimize these sources, strict adherence to a sample collection protocol is recommended. Such a protocol must include provisions for thorough cleaning of the site from which blood will be extracted; also, every effort should be made to collect samples near the same time of day. It is also important to recognize that under the recent OSHA bloodborne pathogens standard (29 CFR 1910.1030), blood samples and certain body fluids must be handled and treated as if they are infectious.

5.1.4 Best Achievable Performance

The best achievable performance using a particular method for CDB determinations is assumed to be equivalent to the performance reported by research laboratories in which the method was developed.

For their method, Roberts and Clark (1986) demonstrated a limit of detection of 0.4 µg Cd/l in whole blood, with a linear response curve from 0.4 to 16.0 µg Cd/l. They report a coefficient of variation (CV) of 6.7% at 8.0 µg/l.

The APHA (1988) reports a range of 1.0–25 µg/l, with a CV of 7.3% (concentration not stated). Insufficient documentation was available to critique this method.

Stoeppler and Brandt (1980) achieved a detection limit of 0.2 µg Cd/l whole blood, with a linear range of 0.4–12.0 µg Cd/l, and a CV of 15–30%, for samples at < 1.0 µg/l. Improved precision (CV of 3.8%) was reported for CDB concentrations at 9.3 µg/l.

5.1.5 General Method Performance

For any particular method, the performance expected from commercial laboratories may be somewhat lower than that reported by the research laboratory in which the method was developed. With participation in appropriate proficiency programs and use of a proper in-house QA/QC program incorporating provisions for regular corrective actions, the performance of commercial laboratories is expected to approach that reported by research laboratories. Also, the results reported for existing proficiency programs serve as a gauge of the likely level of performance that currently can be expected from commercial laboratories offering these analyses.

Weber (1988) reports on the results of the proficiency program run by the Centre de Toxicologie du Quebec (CTQ). As indicated previously, participants in that program receive 18 blood samples per year having cadmium concentrations ranging from 0.2–20 µg/l. Currently, 76 laboratories are participating in this program. The program is established for several analytes in addition to cadmium, and not all of these laboratories participate in the cadmium proficiency-testing program.

Under the CTQ program, cadmium results from individual laboratories are compared against the consensus mean derived for each sample. Results indicate that after receiving 60 samples (i.e., after participation for approximately three years), 60% of the laboratories in the program are able to report results that fall within ± µg/l or 15% of the mean, whichever is greater. (For this procedure, the 15% criterion was applied to concentrations exceeding 7 µg/l.) On any single sample of the last 20 samples, the percentage of laboratories falling within the specified range is between 55 and 80%.

The CTQ also evaluates the performance of participating laboratories against a less severe standard: ± µg/l or 15% of the mean, whichever is greater (Weber 1988); 90% of participating laboratories are able to satisfy this standard after approximately 3 years in the program. (The 15% criterion is used for concentrations in excess of 13 µg/l.) On any single sample of the last 15 samples, the percentage of laboratories falling within the specified range is between 80 and 95% (except for a single test for which only 60% of the laboratories achieved the desired performance).

Based on the data presented in Weber (1988), the CV for analysis of CDB is nearly constant at 20% for cadmium concentrations exceeding 5 µg/l, and increases for cadmium concentrations below 5 µg/l. At 2 µg/l, the reported CV rises to approximately 40%. At 1 µg/l, the reported CV is approximately 60%.

Participating laboratories also tend to overestimate concentrations for samples exhibiting concentrations less than 2 µg/l (see Figure 11 of Weber 1988). This problem is due in part to the proficiency evaluation criterion that allows reporting a minimum ±2.0 µg/l for evaluated CDB samples. There is currently little economic or regulatory incentive for laboratories participating in the CTQ program to achieve greater accuracy for CDB samples containing cadmium at concentrations less than 2.0 µg/l, even if the laboratory has the experience and competency to distinguish among lower concentrations in the samples obtained from the CTQ.

The collective experience of international agencies and investigators demonstrate the need for a vigorous QC program to ensure that CDB values reported by participating laboratories are indeed reasonably accurate. As Friberg (1988) stated:

Information about the quality of published data has often been lacking. This is of concern as assessment of metals in trace concentrations in biological media are fraught with difficulties from the collection, handling, and storage of samples to the chemical analyses. This has been proven over and over again from the results of interlaboratory testing and quality control exercises. Large variations in results were reported even from "experienced" laboratories.

The UNEP/WHO global study of cadmium biological monitoring set a limit for CDB accuracy using the maximum allowable deviation method at Y=X± (0.1X+1) for a targeted concentration of 10 µg Cd/l (Friberg and Vahter 1983). The performance of participating laboratories over a concentration range of 1.5–12 µg/l was reported by Lind et al. (1987). Of the 3 QC runs conducted during 1982 and 1983, 1 or 2 of the 6 laboratories failed each run. For the years 1983 and 1985, between zero and 2 laboratories failed each of the consecutive QC runs.

In another study (Vahter and Friberg 1988), QC samples consisting of both external (unknown) and internal (stated) concentrations were distributed to laboratories participating in the epidemiology research. In this study, the maximum acceptable deviation between the regression analysis of reported results and reference values was set at Y=X± (0.05X+0.2) for a concentration range of 0.3–5.0 µg Cd/l. It is reported that only 2 of 5 laboratories had acceptable data after the first QC set, and only 1 of 5 laboratories had acceptable data after the second QC set. By the fourth QC set, however, all 5 laboratories were judged proficient.

The need for high quality CDB monitoring is apparent when the toxicological and biological characteristics of this metal are considered; an increase in CDB from 2 to 4 µg/l could cause a doubling of the cadmium accumulation in the kidney, a critical target tissue for selective cadmium accumulation (Nordberg and Nordberg 1988).

Historically, the CDC's internal QC program for CDB cadmium monitoring program has found achievable accuracy to be ± 10% of the true value at CDB concentrations ≥ 5.0 µg/l (Paschal 1990). Data on the performance of laboratories participating in this program currently are not available.

5.1.6 Observed CDB Concentrations

As stated in Section 4.3, CDB concentrations are representative of ongoing levels of exposure to cadmium. Among those who have been exposed chronically to cadmium for extended periods, however, CDB may contain a component attributable to the general cadmium body burden.

5.1.6.1 CDB concentrations among unexposed samples

Numerous studies have been conducted examining CDB concentrations in the general population, and in control groups used for comparison with cadmium-exposed workers. A number of reports have been published that present erroneously high values of CDB (Nordberg and Nordberg 1988). This problem was due to contamination of samples during sampling and analysis, and to errors in analysis. Early AAS methods were not sufficiently sensitive to accurately estimate CDB concentrations.

Table 4 presents results of recent studies reporting CDB levels for the general U.S. population not exposed occupationally to cadmium. Other surveys of tissue cadmium using U.S. samples and conducted as part of a cooperative effort among Japan, Sweden and the U.S., did not collect CDB data

because standard analytical methodologies were unavailable, and because of analytic problems (Kjellstrom 1979; SWRI 1978).

Arithmetic and/or geometric means and standard deviations are provided in Table 4 for measurements among the populations defined in each study listed. The range of reported measurements and/or the 95% upper and lower confidence intervals for the means are presented when this information was reported in a study. For studies reporting either an arithmetic or geometric standard deviation along with a mean, the lower and upper 95th percentile for the distribution also were derived and reported in the table.

TABLE 4.—BLOOD CADMIUM CONCENTRATIONS OF U.S. POPULATION NOT OCCUPATIONALLY EXPOSED TO CADMIUM [a]

Study No.	Number in study (n)	Sex	Age	Smoking habits [b]	Arithmetic mean (±S.D.) [c]	Absolute range or (95% CI) [d]	Geometric mean (±GSD) [e]	Lower 95th percentile of distribution [f]	Upper 95th percentile of distribution [f]	Reference
1	80	M	4–69	NS, S	1.13	0.35–3.3	0.98±1.71	0.4	2.4	Kowal et al. (1979).
	88	F	4–69	NS, S	1.03	0.21–3.3	0.91±1.63	0.4	2.0	
	115	M/F	4–69	NS	0.95	0.21–3.3	0.85±1.59	0.4	1.8	
	31	M/F	4–69	S	1.54	0.4–3.3	1.37±1.65	0.6	3.2	
2	10	M	Adults	7	2.0±2.1	(0.5–5.0)		[g] (0)	[g] (5.8)	Ellis et al. (1983).
3	24	M	Adults	NS			0.6±1/87	0.2	1.8	Frieberg and Vahter (1983).
	20	M	Adults	S			1.2±2.13	0.3	4.4	
	64	F	Adults	NS			0.5±1.85	0.2	1.4	
	39	F	Adults	S			0.8±2.22)	0.2	3.1	
4	32	M	Adults	S, NS			1.2±2.0	0.4	3.9	Thun et al. (1989).
5	35	M	Adults	?	2.1±2.1	(0.5–7.3)		[g] (0)	[g] (5.6)	Mueller et al. (1989).

a—Concentrations reported n µg Cd/l blood unless otherwise stated
b—NS never smoked; S-current cigarette smoker
c—S.D.—Arithmetic Standard Deviation
d—C.I.—Confidence interval
e—GSD—Geometric Standard Deviation
f—Based on an assumed lognormal distribution
g—Based on an assumed normal distribution

The data provided in table 4 from Kowal et al. (1979) are from studies conducted between 1974 and 1976 evaluating CDB levels for the general population in Chicago, and are considered to be representative of the U.S. population. These studies indicate that the average CDB concentration among those not occupationally exposed to cadmium is approximately 1 µg/l.

In several other studies presented in Table 4, measurements are reported separately for males and females, and for smokers and nonsmokers. The data in this table indicate that similar CDB levels are observed among males and females in the general population, but that smokers tend to exhibit higher CDB levels than nonsmokers. Based on the Kowal et al. (1979) study, smokers not occupationally exposed to cadmium exhibit an average CDB level of 1.4 µg/l.

In general, nonsmokers tend to exhibit levels ranging to 2 µg/l, while levels observed among smokers range to 5 µg/l. Based on the data presented in Table 4, 95% of those not occupationally exposed to cadmium exhibit CDB levels less than 5 µg/l.

5.1.6.2 *CDB concentrations among exposed workers*

Table 5 is a summary of results from studies reporting CDB levels among workers exposed to cadmium in the work place. As in Table 4, arithmetic and/or geometric means and standard deviations are provided if reported in the listed studies. The absolute range, or the 95% confidence interval around the mean, of the data in each study are provided when reported. In addition, the lower and upper 95th percentile of the distribution are presented for each study i which a mean and corresponding standard deviation were reported.

TABLE 5—BLOOD CADMIUM IN WORKERS EXPOSED TO CADMIUM IN THE WORK PLACE

[Concentrations of Cadmium in Blood[a]]

Study number	Work environment (worker population monitored)	Number in study	Employment in years (mean)	Mean concentration of cadmium in air (µg/mg³)	Arithmetic mean (±S.D.) [b]	Absolute range or (95% C.I.) [c]	Geometric mean (±GSD) [d]	Lower 95th percentile of range [e] ( ) [f]	Upper 95th percentile of range [e] P ( ) [f]	Reference
1	Ni-Cd Battery Plant and Cd Production.		3–40	≥90						Lauwerye et al.
	Plant	96			21.4±1.9			(18)	(25)	1976.
	(Workers without Kidney Lesions).	25			38.8±3.8			(32)	(45)	
	(Workers with Kidney Lesions).									
2	Ni-Cd Battery Plant									Adamsson et al.
	(Smokers)	7	(5)	10.1	22.7	7.3–67.2				(1979).
	(Nonsmokers)	8	(9)	7.0	7.0	4.9–10.5				

TABLE 5—BLOOD CADMIUM IN WORKERS EXPOSED TO CADMIUM IN THE WORK PLACE—Continued

[Concentrations of Cadmium in Blood[a]]

Study number	Work environment (worker population monitored)	Number in study	Employment in years (mean)	Mean concentration of cadmium in air (µg/mg³)	Arithmetic mean (±S.D.)[b]	Absolute range or (95% C.I.)[c]	Geometric mean (±GSD)[d]	Lower 95th percentile of range[e] ( )[f]	Upper 95th percentile of range[e] P ( )[f]	Reference
3	Cadmium Alloy Plant.									Sukuri et al. 198.
	(High Exposure Group).	7	(10.6)	[1,000–	20.8±7.1			(7.3)	(34)	
	(Low Exposure Group).	9	(7.3)	5 yrs; 40–5 yrs].	7.1±1.1			(5.1	(9.1)	
4	Retrospective Study of Workers with Renal Problems.	19	15–41							Roels et al. 1982.
	(Before Removal).		(27.2)		39.9±3.7	11–179		(34)	(46)	
	(After Removal)		(4.2)[g]		14.1±5.6	5.7–27.4		(4.4)	(24)	
5	Cadmium Production Plant.									Ellis et al. 1983.
	(Workers without Renal Dysfunction).	33	1–34		15.±5.7	7–31		(5.4)	(25)	
	(Workers with Renal Dysfunction).	18	10–34		24±8.5	10–34		(9.3)	(39)	
6	Cd-Cu Alloy Plant	75	Up to 39				8.8±1.1	7.5	10	Mason et al. 1988.
7	Cadmium Recovery Operation.	45	(19.0)				7.9±2.0	2.5	25	Thun et al. 1989.
	(Current [19] and Former [26] Workers.									
8	Cadmium Recovery Operation.	40			10.2±5.3	2.2–18.8		(1.3)	(19)	Mueller et al. 1989.

[a] Concentrations reported in µg Cd/1 blood unless otherwise stated
[b] S.D.—Standard Deviation
[c] C.I.—Confidence Interval
[d] GDS—Geometric Standard Deviation
[e] Based on an assumed lognormal distribution
[f] Based on an assumed normal distribution
[g] Years following removal.

Table 5 also provides estimates of the duration, and level, of exposure to cadmium in the work place if these data were reported in the listed studies. The data presented in table 5 suggest that CDB levels are dose related. Sukuri et al. (1983) show that higher CDB levels are observed among workers experiencing higher work place exposure. This trend appears to be true of the studies listed in the table.

CDB levels reported in table 5 are higher among those showing signs of cadmium-related kidney damage than those showing no such damage. Lauwerys et al. (1976) report CDB levels among workers with kidney lesions that generally are above the levels reported for workers without kidney lesions. Ellis et al. (1983) report a similar observation comparing workers with and without renal dysfunction, although they found more overlap between the 2 groups than Lauwerys et al.

The data in table 5 also indicate that CDB levels are higher among those experiencing current occupational exposure than those who have been removed from such exposure. Roels et al. (1982) indicate that CDB levels observed among workers experiencing ongoing exposure in the work place are almost entirely above levels observed among workers removed from such exposure. This finding suggests that CDB levels decrease once cadmium exposure has ceased.

A comparison of the data presented in tables 4 and 5 indicates that CDB levels observed among cadmium-exposed workers is significantly higher than levels observed among the unexposed groups. With the exception of 2 studies presented in table 5 (1 of which includes former workers in the sample group tested), the lower 95th percentile for CDB levels among exposed workers are greater than 5 µg/l, which is the value of the upper 95th percentile for CDB levels observed among those who are not occupationally exposed. Therefore, a CDB level of 5 µg/l represents a threshold above which significant work place exposure to cadmium may be occurring.

5.1.7 Conclusions and Recommendations for CDB

Based on the above evaluation, the following recommendations are made for a CDB proficiency program.

5.1.7.1 Recommended method

The method of Stoeppler and Brandt (1980) should be adopted for analyzing CDB. This method was selected over other methods for its straightforward sample-preparation procedures, and because limitations of the method were described adequately. It also is the method used by a plurality of laboratories currently participating in the CTQ proficiency program. In a recent CTQ interlaboratory comparison report (CTQ 1991), analysis of the methods used by laboratories to measure CDB indicates that 46% (11 of 24) of the participating laboratories used the Stoeppler and Brandt methodology (HNO_3 deproteinization of blood followed by analysis of the supernatant by GF-AAS). Other CDB methods employed by participating laboratories identified in the

CTQ report include dilution of blood (29%), acid digestion (12%) and miscellaneous methods (12%).

Laboratories may adopt alternate methods, but it is the responsibility of the laboratory to demonstrate that the alternate methods meet the data quality objectives defined for the Stoeppler and Brandt method (see Section 5.1.7.2 below).

5.1.7.2 Data quality objectives

Based on the above evaluation, the following data quality objectives (DQOs) should facilitate interpretation of analytical results.

Limit of Detection. 0.5 µg/l should be achievable using the Stoeppler and Brandt method. Stoeppler and Brandt (1980) report a limit of detection equivalent to ≤0.2 µg/l in whole blood using 25 µl aliquots of deproteinized, diluted blood samples.

Accuracy. Initially, some of the laboratories performing CDB measurements may be expected to satisfy criteria similar to the less severe criteria specified by the CTQ program, i.e., measurements within 2 µg/l or 15% (whichever is greater) of the target value. About 60% of the laboratories enrolled in the CTQ program could meet this criterion on the first proficiency test (Weber 1988).

Currently, approximately 12 laboratories in the CTQ program are achieving an accuracy for CDB analysis within the more severe constraints of ±1 µg/l or 15% (whichever is greater). Later, as laboratories gain experience, they should achieve the level of accuracy exhibited by these 12 laboratories. The experience in the CTQ program has shown that, even without incentives, laboratories benefit from the feedback of the program; after they have analyzed 40–50 control samples from the program, performance improves to the point where about 60% of the laboratories can meet the stricter criterion of ±1 µg/l or 15% (Weber 1988). Thus, this stricter target accuracy is a reasonable DQO.

Precision. Although Stoeppler and Brandt (1980) suggest that a coefficient of variation (CV) near 1.3% (for a 10 µg/l concentration) is achievable for within-run reproducibility, it is recognized that other factors affecting within- and between-run comparability will increase the achievable CV. Stoeppler and Brandt (1980) observed CVs that were as high as 30% for low concentrations (0.4 µg/l), and CVs of less than 5% for higher concentrations.

For internal QC samples (see Section 3.3.1), laboratories should attain an overall precision near 25%. For CDB samples with concentrations less than 2 µg/l, a target precision of 40% is reasonable, while precisions of 20% should be achievable for concentrations greater than 2 µg/l. Although these values are more strict than values observed in the CTQ interlaboratory program reported by Webber (1988), they are within the achievable limits reported by Stoeppler and Brandt (1980).

5.1.7.3 Quality assurance/quality control

Commercial laboratories providing measurement of CDB should adopt an internal QA/QC program that incorporates the following components: Strict adherence to the selected method, including all calibration requirements; regular incorporation of QC samples during actual runs; a protocol for corrective actions, and documentation of these actions; and, participation in an interlaboratory proficiency program. Note that the nonmandatory QA/QC program presented in Attachment 1 is based on the Stoeppler and Brandt method for CDB analysis. Should an alternate method be adopted, the laboratory should develop a QA/QC program satisfying the provisions of Section 3.3.1.

5.2 Measuring Cadmium in Urine (CDU)

As in the case of CDB measurement, proper determination of CDU requires strict analytical discipline regarding collection and handling of samples. Because cadmium is both ubiquitous in the environment and employed widely in coloring agents for industrial products that may be used during sample collection, preparation and analysis, care should be exercised to ensure that samples are not contaminated during the sampling procedure.

Methods for CDU determination share many of the same features as those employed for the determination of CDB. Thus, changes and improvements to methods for measuring CDU over the past 40 years parallel those used to monitor CDB. The direction of development has largely been toward the simplification of sample preparation techniques made possible because of improvements in analytic techniques.

5.2.1 Units of CDU Measurement

Procedures adopted for reporting CDU concentrations are not uniform. In fact, the situation for reporting CDU is more complicated than for CDB, where concentrations are normalized against a unit volume of whole blood.

Concentrations of solutes in urine vary with several biological factors (including the time since last voiding and the volume of liquid consumed over the last few hours); as a result, solute concentrations should be normalized against another characteristic of urine that represents changes in solute concentrations. The 2 most common techniques are either to standardize solute concentrations against the concentration of creatinine, or to standardize solute concentrations against the specific gravity of the urine. Thus, CDU concentrations have been reported in the literature as "uncorrected" concentrations of cadmium per volume of urine (i.e., µg Cd/l urine), "corrected" concentrations of cadmium per volume of urine at a standard specific gravity (i.e., µg Cd/l urine at a specific gravity of 1.020), or "corrected" mass concentration per unit mass of creatinine (i.e., µg Cd/g creatinine). (CDU concentrations [whether uncorrected or corrected for specific gravity, or normalized to creatinine] occasionally are reported in nanomoles [i.e., nmoles] of cadmium per unit mass or volume. In this protocol, these values are converted to µg of cadmium per unit mass or volume using 89 nmoles of cadmium=10 µg.)

While it is agreed generally that urine values of analytes should be normalized for reporting purposes, some debate exists over what correction method should be used. The medical community has long favored normalization based on creatinine concentration, a common urinary constituent. Creatinine is a normal product of tissue catabolism, is excreted at a uniform rate, and the total amount excreted per day is constant on a day-to-day basis (NIOSH 1984b). While this correction method is accepted widely in Europe, and within some occupational health circles, Kowals (1983) argues that the use of specific gravity (i.e., total solids per unit volume) is more straightforward and practical (than creatinine) in adjusting CDU values for populations that vary by age or gender.

Kowals (1983) found that urinary creatinine (CRTU) is lower in females than males, and also varies with age. Creatinine excretion is highest in younger males (20–30 years old), decreases at middle age (50–60 years), and may rise slightly in later years. Thus, cadmium concentrations may be underestimated for some workers with high CRTU levels.

Within a single void urine collection, urine concentration of any analyte will be affected by recent consumption of large volumes of liquids, and by heavy physical labor in hot environments. The absolute amount of analyte excreted may be identical, but concentrations will vary widely so that urine must be corrected for specific gravity (i.e., to normalize concentrations to the quantity of total solute) using a fixed value (e.g., 1.020 or 1.024). However, since heavy-metal exposure may increase urinary protein excretion, there is a tendency to underestimate cadmium concentrations in samples with high specific gravities when specific-gravity corrections are applied.

Despite some shortcomings, reporting solute concentrations as a function of creatinine concentration is accepted generally; OSHA therefore recommends that CDU levels be reported as the mass of cadmium per unit mass of creatinine (µg/g CTRU).

Reporting CDU as µg/g CRTU requires an additional analytical process beyond the analysis of cadmium: Samples must be analyzed independently for creatinine so that results may be reported as the ratio of cadmium to creatinine concentrations found in the urine sample. Consequently, the overall quality of the analysis depends on the combined performance by a laboratory on these 2 determinations. The analysis used for CDU determinations is addressed below in terms of µg Cd/l, with analysis of creatinine addressed separately. Techniques for assessing creatinine are discussed in Section 5.4.

Techniques for deriving cadmium as a ratio of CRTU, and the confidence limits for independent measurements of cadmium and CRTU, are provided in Section 3.3.3.

5.2.2 Analytical Techniques Used to Monitor CDU

Analytical techniques used for CDU determinations are similar to those employed for CDB determinations; these techniques are summarized in Table 3. As with CDB monitoring, the technique most suitable for CDU determinations is atomic absorption spectroscopy (AAS). AAS methods used for CDU determinations typically employ a graphite furnace, with background correction

made using either the deuterium-lamp or Zeeman techniques; Section 5.1.1 provides a detailed description of AAS methods.

5.2.3 Methods Developed for CDU Determinations

Princi (1947), Smith et al. (1955), Smith and Kench (1957), and Tsuchiya (1967) used colorimetric procedures similar to those described in the CDB section above to estimate CDU concentrations. In these methods, urine (50 ml) is reduced to dryness by heating in a sand bath and digested (wet ashed) with mineral acids. Cadmium then is complexed with dithiazone, extracted with chloroform and quantified by spectrophotometry. These early studies typically report reagent blank values equivalent to 0.3 µg Cd/l, and CDU concentrations among nonexposed control groups at maximum levels of 10 µg Cd/l—erroneously high values when compared to more recent surveys of cadmium concentrations in the general population.

By the mid-1970s, most analytical procedures for CDU analysis used either wet ashing (mineral acid) or high temperatures (>400°C) to digest the organic matrix of urine, followed by cadmium chelation with APDC or DDTC solutions and extraction with MIBK. The resulting aliquots were analyzed by flame or graphite-furnace AAS (Kjellstrom 1979). Improvements in control over temperature parameters with electrothermal heating devices used in conjunction with flameless AAS techniques, and optimization of temperature programs for controlling the drying, charring, and atomization processes in sample analyses, led to improved analytical detection of diluted urine samples without the need for sample digestion or ashing. Roels et al. (1978) successfully used a simple sample preparation, dilution of 1.0 ml aliquots of urine with 0.1 N HNO_3, to achieve accurate low-level determinations of CDU.

In the method described by Pruszkowska et al. (1983), which has become the preferred method for CDU analysis, urine samples were diluted at a ratio of 1:5 with water; diammonium hydrogenphosphate in dilute HNO_3 was used as a matrix modifier. The matrix modifier allows for a higher charring temperature without loss of cadmium through volatilization during preatomization. This procedure also employs a stabilized temperature platform in a graphite furnace, while nonspecific background absorbtion is corrected using the Zeeman technique. This method allows for an absolute detection limit of approximately 0.04 µg Cd/l urine.

5.2.4 Sample Collection and Handling

Sample collection procedures for CDU may contribute to variability observed among CDU measurements. Sources of variation attendant to sampling include time-of-day, the interval since ingestion of liquids, and the introduction of external contamination during the collection process. Therefore, to minimize contributions from these variables, strict adherence to a sample-collection protocol is recommended. This protocol should include provisions for normalizing the conditions under which urine is collected. Every effort also should be made to collect samples during the same time of day.

Collection of urine samples from an industrial work force for biological monitoring purposes usually is performed using "spot" (i.e., single-void) urine with the pH of the sample determined immediately. Logistic and sample-integrity problems arise when efforts are made to collect urine over long periods (e.g., 24 hrs). Unless single-void urines are used, there are numerous opportunities for measurement error because of poor control over sample collection, storage and environmental contamination.

To minimize the interval during which sample urine resides in the bladder, the following adaption to the "spot" collection procedure is recommended: The bladder should first be emptied, and then a large glass of water should be consumed; the sample may be collected within an hour after the water is consumed.

5.2.5 Best Achievable Performance

Performance using a particular method for CDU determinations is assumed to be equivalent to the performance reported by the research laboratories in which the method was developed. Pruszkowska et al. (1983) report a detection limit of 0.04 µg/l CDU, with a CV of <4% between 0–5 µg/l. The CDC reports a minimum CDU detection limit of 0.07 µg/l using a modified method based on Pruszkowska et al. (1983). No CV is stated in this protocol; the protocol contains only rejection criteria for internal QC parameters used during accuracy determinations with known standards (Attachment 8 of exhibit 106 of OSHA docket H057A). Stoeppler and Brandt (1980) report a CDU detection limit of 0.2 µ/l for their methodology.

5.2.6 General Method Performance

For any particular method, the expected initial performance from commercial laboratories may be somewhat lower than that reported by the research laboratory in which the method was developed. With participation in appropriate proficiency programs, and use of a proper in-house QA/QC program incorporating provisions for regular corrective actions, the performance of commercial laboratories may be expected to improve and approach that reported by a research laboratories. The results reported for existing proficiency programs serve to specify the initial level of performance that likely can be expected from commercial laboratories offering analysis using a particular method.

Weber (1988) reports on the results of the CTQ proficiency program, which includes CDU results for laboratories participating in the program. Results indicate that after receiving 60 samples (i.e., after participating in the program for approximately 3 years), approximately 80% of the participating laboratories report CDU results ranging between ±2 µg/l or 15% of the consensus mean, whichever is greater. On any single sample of the last 15 samples, the proportion of laboratories falling within the specified range is between 75 and 95%, except for a single test for which only 60% of the laboratories reported acceptable results. For each of the last 15 samples, approximately 60% of the laboratories reported results within ±1 µg or 15% of the mean, whichever is greater. The range of concentrations included in this set of samples was not reported.

Another report from the CTQ (1991) summarizes preliminary CDU results from their 1991 interlaboratory program. According to the report, for 3 CDU samples with values of 9.0, 16.8, 31.5 µg/l, acceptable results (target of ±2 µg/l or 15 % of the consensus mean, whichever is greater) were achieved by only 44–52% of the 34 laboratories participating in the CDU program. The overall CVs for these 3 CDU samples among the 34 participating laboratories were 31%, 25%, and 49%, respectively. The reason for this poor performance has not been determined.

A more recent report from the CTQ (Weber, private communication) indicates that 36% of the laboratories in the program have been able to achieve the target of ±1 µg/l or 15% for more than 75% of the samples analyzed over the last 5 years, while 45% of participating laboratories achieved a target of ±2 µg/l or 15% for more than 75% of the samples analyzed over the same period.

Note that results reported in the interlaboratory programs are in terms of µg Cd/l of urine, unadjusted for creatinine. The performance indicated, therefore, is a measure of the performance of the cadmium portion of the analyses, and does not include variation that may be introduced during the analysis of CRTU.

5.2.7 Observed CDU Concentrations

Prior to the onset of renal dysfunction, CDU concentrations provide a general indication of the exposure history (i.e., body burden) (see Section 4.3). Once renal dysfunction occurs, CDU levels appear to increase and are no longer indicative solely of cadmium body burden (Friberg and Elinder 1988).

5.2.7.1 *Range of CDU concentrations observed among unexposed samples*

Surveys of CDU concentrations in the general population were first reported from cooperative studies among industrial countries (i.e., Japan, U.S. and Sweden) conducted in the mid-1970s. In summarizing these data, Kjellstrom (1979) reported that CDU concentrations among Dallas, Texas men (age range: <9–59 years; smokers and nonsmokers) varied from 0.11–1.12 µg/l (uncorrected for creatinine or specific gravity). These CDU concentrations are intermediate between population values found in Sweden (range: 0.11–0.80 µg/l) and Japan (range: 0.14–2.32 µg/l).

Kowal and Zirkes (1983) reported CDU concentrations for almost 1,000 samples collected during 1978–79 from the general U.S. adult population (i.e., nine states; both genders; ages 20–74 years). They report that CDU concentrations are lognormally distributed; low levels predominated, but a small proportion of the population exhibited high levels. These investigators transformed the CDU concentrations values, and reported the same data 3 different ways: µg/l urine (unadjusted), µg/l (specific gravity adjusted to 1.020), and µg/g CRTU. These data are summarized in Tables 6 and 7.

Based on further statistical examination of these data, including the lifestyle

characteristics of this group, Kowal (1988) suggested increased cadmium absorption (i.e., body burden) was correlated with low dietary intakes of calcium and iron, as well as cigarette smoking.

CDU levels presented in Table 6 are adjusted for age and gender. Results suggest that CDU levels may be slightly different among men and women (i.e., higher among men when values are unadjusted, but lower among men when the values are adjusted, for specific gravity or CRTU). Mean differences among men and women are small compared to the standard deviations, and therefore may not be significant. Levels of CDU also appear to increase with age. The data in Table 6 suggest as well that reporting CDU levels adjusted for specific gravity or as a function of CRTU results in reduced variability.

TABLE 6.—URINE CADMIUM CONCENTRATIONS IN THE U.S. ADULT POPULATION: NORMAL AND CONCENTRATION-ADJUSTED VALUES BY AGE AND SEX [1]

	Geometric means (and geometric standard deviations)		
	Unadjusted (µg/l)	SG-adjusted [2] µg/l at 1.020)	Creatine-adjusted (µg/g)
Sex:			
Male (n=484)	0.55 (2.9)	0.73 (2.6)	0.55 (2.7)
Female (n=498)	0.49 (3.0)	0.86 (2.7)	0.78 (2.7)
Age:			
20–29 (n=222)	0.32 (3.0)	0.43 (2.7)	0.32 (2.7)
30–39 (n=141)	0.46 (3.2)	0.70 (2.8)	0.54 (2.7)
40–49 (n=142)	0.50 (3.0)	0.81 (2.6)	0.70 (2.7)
50–59 (n=117)	0.61 (2.9)	0.99 (2.4)	0.90 (2.3)
60–69 (n=272)	0.76 (2.6)	1.16 (2.3)	1.03 (2.3)

[1] From Kowal and Zirkes 1983.
[2] SC-adjusted is adjusted for specific gravity.

TABLE 7.—URINE CADMIUM CONCENTRATIONS IN THE U.S. ADULT POPULATION: CUMULATIVE FREQUENCY DISTRIBUTION OF URINARY CADMIUM (N=982)[1]

Range of concentrations	Unadjusted (µg/l) percent	SG-adjusted (µg/l at 1.020) percent	Creatine-adjusted (µg/g) percent
<0.5	43.9	28.0	35.8
0.6–1.0	71.7	56.4	65.6
1.1–1.5	84.4	74.9	81.4
1.6–2.0	91.3	84.7	88.9
2.1–3.0	97.3	94.4	95.8
3.1–4.0	98.8	97.4	97.2
4.1–5.0	99.4	98.2	97.9
5.1–10.0	99.6	99.4	99.3
10.0–20.0	99.8	99.6	99.6

[1] Source: Kowal and Zirkes (1983).

The data in the Table 6 indicate the geometric mean of CDU levels observed among the general population is 0.52 µ/g Cd/l urine (unadjusted), with a geometric standard deviation of 3.0. Normalized for creatinine, the geometric mean for the population is 0.66 µ/g CRTU, with a geometric standard deviation of 2.7. Table 7 provides the distributions of CDU concentrations for the general population studied by Kowal and Zirkes. The data in this table indicate that 95% of the CDU levels observed among those not occupationally exposed to cadmium are below 3 µ/g CRTU.

5.2.7.2 *Range of CDU concentrations observed among exposed workers*

Table 8 is a summary of results from available studies of CDU concentrations observed among cadmium-exposed workers. In this table, arithmetic and/or geometric means and standard deviations are provided if reported in these studies. The absolute range for the data in each study, or the 95% confidence interval around the mean of each study, also are provided when reported. The lower and upper 95th percentile of the distribution are presented for each study in which a mean and corresponding standard deviation were reported. Table 8 also provides estimates of the years of exposure, and the levels of exposure, to cadmium in the work place if reported in these studies. Concentrations reported in this table are in µ/g CRTU, unless otherwise stated.

TABLE 8—URINE CADMIUM CONCENTRATIONS IN WORKERS EXPOSED TO CADMIUM IN THE WORKPLACE

Study number and work environment (worker population monitored)	Number in study (n)	Employment in years (mean)	Mean concentration of cadmium in air (µg/m³)	Concentration of cadmium in urine[a]					
				Arithmetic mean (±S.D.)[b]	Absolute range or (95 percent C.I.)[c]	Geometric mean (±GSD)[d]	Lower 95th percentile of range[e] ( )	Upper 95th percentile of range[e] ( )	Reference
1. Ni-Cd Battery Plant and Cd Production Plant.	.....	3–40	≤90	.....	.....	.....	.....	.....	Lauwerys et al. 1976.
(Workers without Kidney Lesions).	96	.....	.....	16.3±16.7	.....	.....	(0)	(44)	
(Workers with Kidney Lesions).	25	.....	.....	48.2±42.6	.....	.....	(0)	(120)	
2. Ni-Cd Battery Plant.	.....	.....	.....	.....	.....	.....	.....	.....	Adamsson et al. (1979).
(Smokers) ..	7	(5)	10.1	5.5	1.0–14.7	.....	.....	.....	
(Non-smokers).	8	(9)	7.0	3.6	0.5–9.3	.....	.....	.....	
3. Cadmium Salts Production Facility.	148	(15.4)	.....	15.8	2–150	.....	.....	.....	Butchet et al. 1980.
4. Retrospective Study of Workers with Renal Problems.	19	15–41	.....	.....	.....	.....	.....	.....	Roels et al. 1982.
(Before Removal).	.....	(27.2)	.....	39.4∓28.1	10.8–117	.....	(0)	(88)	
(After Removal).	.....	(4.2)[g]	.....	16.4±9.0	80–42.3	.....	(1.0)	(32)	
5. Cadmium Production Plant.	.....	.....	.....	.....	.....	.....	.....	.....	Ellis et al. 1983.
(Workers without Renal Dysfunction).	33	1–34	.....	9.4±6.9	2–27	.....	(0)	(21)	
(Workers with Renal Dysfunction).	18	10–34	.....	22.8±12.7	8–55	.....	(1)	(45)	
6. Cd-Cu Alloy Plant.	75	Up to 39 ...	Note (h) .	6.9±9.4	.....	.....	(0)	(23)	Mason et al. 1988.
7. Cadmium Recovery Operation.	45	(19)	87	9.3±6.9	.....	.....	(0)	(21)	Thun et al. 1989.
8. Pigment Manufacturing Plant.	29	(12.8)	0.18–3.0	.....	0.2–9.5	1.1	.....	.....	Mueller et al. 1989.
9. Pigment Manufacturing Plant.	26	(12.1)	≤3.0	.....	.....	1.25±2.45	0.3	6	Kawada et al. 1990.

a—Concentrations are reported in µg/g Cr
b—S.D.—Standard Deviation
c—C.I.—Confidence Interval
d—GSD—Geometric Standard Deviation
e—Based on an assumed lognormal distribution
f—Based on an assumed normal distribution
g—Years following removal
h—Equivalent to 50 for 20–22 yrs

Data in Table 8 from Lauwerys et al. (1976) and Ellis et al. (1983) indicate that CDU concentrations are higher among those exhibiting kidney lesions or dysfunction than among those lacking these symptoms. Data from the study by Roels et al. (1982) indicate that CDU levels decrease among workers removed from occupational exposure to cadmium in comparison to workers

experiencing ongoing exposure. In both cases, however, the distinction between the 2 groups is not as clear as with CDB; there is more overlap in CDU levels observed among each of the paired populations than is true for corresponding CDB levels. As with CDB levels, the data in Table 8 suggest increased CDU concentrations among workers who experienced increased overall exposure.

Although a few occupationally-exposed workers in the studies presented in Table 8 exhibit CDU levels below 3 µg/g CRTU, most of those workers exposed to cadmium levels in excess of the PEL defined in the final cadmium rule exhibit CDU levels above 3 µg/g CRTU; this level represents the upper 95th percentile of the CDU distribution observed among those who are not occupationally exposed to cadmium (Table 7).

The mean CDU levels reported in Table 8 among occupationally-exposed groups studied (except 2) exceed 3 µg/g CRTU. Correspondingly, the level of exposure reported in these studies (with 1 exception) are significantly higher than what workers will experience under the final cadmium rule. The 2 exceptions are from the studies by Mueller et al. (1989) and Kawada et al. (1990); these studies indicate that workers exposed to cadmium during pigment manufacture do not exhibit CDU levels as high as those levels observed among workers exposed to cadmium in other occupations. Exposure levels, however, were lower in the pigment manufacturing plants studied. Significantly, workers removed from occupational cadmium exposure for an average of 4 years still exhibited CDU levels in excess of 3 µg/g CRTU (Roels et al. 1982). In the single-exception study with a reported level of cadmium exposure lower than levels proposed in the final rule (i.e., the study of a pigment manufacturing plant by Kawada et al. 1990), most of the workers exhibited CDU levels less than 3 µg/g CRTU (i.e., the mean value was only 1.3 µg/g CRTU). CDU levels among workers with such limited cadmium exposure are expected to be significantly lower than levels of other studies reported in Table 8.

Based on the above data, a CDU level of 3 µg/g CRTU appear to represent a threshold above which significant work place exposure to cadmium occurs over the work span of those being monitored. Note that this threshold is not as distinct as the corresponding threshold described for CDB. In general, the variability associated with CDU measurements among exposed workers appears to be higher than the variability associated with CDB measurements among similar workers.

5.2.8 Conclusions and Recommendations for CDU

The above evaluation supports the following recommendations for a CDU proficiency program. These recommendations address only sampling and analysis procedures for CDU determinations specifically, which are to be reported as an unadjusted µg Cd/l urine. Normalizing this result to creatinine requires a second analysis for CRTU so that the ratio of the 2 measurements can be obtained. Creatinine analysis is addressed in Section 5.4.

Formal procedures for combining the 2 measurements to derive a value and a confidence limit for CDU in µg/g CRTU are provided in Section 3.3.3.

5.2.8.1 *Recommended method*

The method of Pruszkowska et al. (1983) should be adopted for CDU analysis. This method is recommended because it is simple, straightforward and reliable (i.e., small variations in experimental conditions do not affect the analytical results).

A synopsis of the methods used by laboratories to determine CDU under the interlaboratory program administered by the CTQ (1991) indicates that more than 78% (24 of 31) of the participating laboratories use a dilution method to prepare urine samples for CDU analysis. Laboratories may adopt alternate methods, but it is the responsibility of the laboratory to demonstrate that the alternate methods provide results of comparable quality to the Pruszkowska method.

5.2.8.2 *Data quality objectives*

The following data quality objectives should facilitate interpretation of analytical results, and are achievable based on the above evaluation.

Limit of Detection. A level of 0.5 µg/l (i.e., corresponding to a detection limit of 0.5 µg/g CRTU, assuming 1 g CRT/l urine) should be achievable. Pruszkowska et al. (1983) achieved a limit of detection of 0.04 µg/l for CDU based on the slope of the curve for their working standards (0.35 pg Cd/0.0044, A signal=1% absorbance using GF-AAS).

The CDC reports a minimum detection limit for CDU of 0.07 µg/l using a modified Pruszkowska method. This limit of detection was defined as 3 times the standard deviation calculated from 10 repeated measurements of a "low level" CDU test sample (Attachment 8 of exhibit 106 of OSHA docket H057A).

Stoeppler and Brandt (1980) report a limit of detection for CDU of 0.2 µg/l using an aqueous dilution (1:2) of the urine samples.

Accuracy. A recent report from the CTQ (Weber, private communication) indicates that 36% of the laboratories in the program achieve the target of ±1 µg/l or 15% for more than 75% of the samples analyzed over the last 5 years, while 45% of participating laboratories achieve a target of ±2 µg/l or 15% for more than 75% of the samples analyzed over the same period. With time and a strong incentive for improvement, it is expected that the proportion of laboratories successfully achieving the stricter level of accuracy should increase. It should be noted, however, these indices of performance do not include variations resulting from the ancillary measurement of CRTU (which is recommended for the proper recording of results). The low cadmium levels expected to be measured indicate that the analysis of creatinine will contribute relatively little to the overall variability observed among creatinine-normalized CDU levels (see Section 5.4). The initial target value for reporting CDU under this program, therefore, is set at ±1 µg/g CRTU or 15% (whichever is greater).

Precision. For internal QC samples (which are recommended as part of an internal QA/QC program, Section 3.3.1), laboratories should attain an overall precision of 25%. For CDB samples with concentrations less than 2 µg/l, a target precision of 40% is acceptable, while precisions of 20% should be achievable for CDU concentrations greater than 2 µg/l. Although these values are more stringent than those observed in the CTQ interlaboratory program reported by Webber (1988), they are well within limits expected to be achievable for the method as reported by Stoeppler and Brandt (1980).

5.2.8.3 *Quality assurance/quality control*

Commercial laboratories providing CDU determinations should adopt an internal QA/QC program that incorporates the following components: Strict adherence to the selected method, including calibration requirements; regular incorporation of QC samples during actual runs; a protocol for corrective actions, and documentation of such actions; and, participation in an interlaboratory proficiency program. Note that the nonmandatory program presented in Attachment 1 as an example of an acceptable QA/QC program, is based on using the Pruszkowska method for CDU analysis. Should an alternate method be adopted by a laboratory, the laboratory should develop a QA/QC program equivalent to the nonmandatory program, and which satisfies the provisions of Section 3.3.1.

5.3 Monitoring β-2–Microglobulin in Urine (B2MU)

As indicated in Section 4.3, B2MU appears to be the best of several small proteins that may be monitored as early indicators of cadmium-induced renal damage. Several analytic techniques are available for measuring B2M.

5.3.1 Units of B2MU Measurement

Procedures adopted for reporting B2MU levels are not uniform. In these guidelines, OSHA recommends that B2MU levels be reported as µg/g CRTU, similar to reporting CDU concentrations. Reporting B2MU normalized to the concentration of CRTU requires an additional analytical process beyond the analysis of B2M: Independent analysis for creatinine so that results may be reported as a ratio of the B2M and creatinine concentrations found in the urine sample. Consequently, the overall quality of the analysis depends on the combined performance on these 2 analyses. The analysis used for B2MU determinations is described in terms of µg B2M/l urine, with analysis of creatinine addressed separately. Techniques used to measure creatinine are provided in Section 5.4. Note that Section 3.3.3 provides techniques for deriving the value of B2M as function of CRTU, and the confidence limits for independent measurements of B2M and CRTU.

5.3.2 Analytical Techniques Used to Monitor B2MU

One of the earliest tests used to measure B2MU was the radial immunodiffusion technique. This technique is a simple and specific method for identification and quantitation of a number of proteins found in human serum and other body fluids when the protein is not readily differentiated by standard electrophoretic procedures. A quantitative relationship exists between the

concentration of a protein deposited in a well that is cut into a thin agarose layer containing the corresponding monospecific antiserum, and the distance that the resultant complex diffuses.

The wells are filled with an unknown serum and the standard (or control), and incubated in a moist environment at room temperature. After the optimal point of diffusion has been reached, the diameters of the resulting precipition rings are measured. The diameter of a ring is related to the concentration of the constituent substance. For B2MU determinations required in the medical monitoring program, this method requires a process that may be insufficient to concentrate the protein to levels that are required for detection.

Radioimmunoassay (RIA) techniques are used widely in immunologic assays to measure the concentration of antigen or antibody in body-fluid samples. RIA procedures are based on competitive-binding techniques. If antigen concentration is being measured, the principle underlying the procedure is that radioactive-labeled antigen competes with the sample's unlabeled antigen for binding sites on a known amount of immobile antibody. When these 3 components are present in the system, an equilibrium exists. This equilibrium is followed by a separation of the free and bound forms of the antigen. Either free or bound radioactive-labeled antigen can be assessed to determine the amount of antigen in the sample. The analysis is performed by measuring the level of radiation emitted either by the bound complex following removal of the solution containing the free antigen, or by the isolated solution containing the residual-free antigen. The main advantage of the RIA method is the extreme sensitivity of detection for emitted radiation and the corresponding ability to detect trace amounts of antigen. Additionally, large numbers of tests can be performed rapidly.

The enzyme-linked immunosorbent assay (ELISA) techniques are similar to RIA techniques except that nonradioactive labels are employed. This technique is safe, specific and rapid, and is nearly as sensitive as RIA techniques. An enzyme-labeled antigen is used in the immunologic assay; the labeled antigen detects the presence and quantity of unlabeled antigen in the sample. In a representative ELISA test, a plastic plate is coated with antibody (e.g., antibody to B2M). The antibody reacts with antigen (B2M) in the urine and forms an antigen-antibody complex on the plate. A second anti-B2M antibody (i.e., labeled with an enzyme) is added to the mixture and forms an antibody-antigen-antibody complex. Enzyme activity is measured spectrophotometrically after the addition of a specific chromogenic substrate which is activated by the bound enzyme. The results of a typical test are calculated by comparing the spectrophotometric reading of a serum sample to that of a control or reference serum. In general, these procedures are faster and require less laboratory work than other methods.

In a fluorescent ELISA technique (such as the one employed in the Pharmacia Delphia test for B2M), the labeled enzyme is bound to a strong fluorescent dye. In the Pharmacia Delphia test, an antigen bound to a fluorescent dye competes with unlabeled antigen in the sample for a predetermined amount of specific, immobile antibody. Once equilibrium is reached, the immobile phase is removed from the labeled antigen in the sample solution and washed; an enhancement solution then is added that liberates the fluorescent dye from the bound antigen-antibody complex. The enhancement solution also contains a chelate that complexes with the fluorescent dye in solution; this complex increases the fluorescent properties of the dye so that it is easier to detect.

To determine the quantity of B2M in a sample using the Pharmacia Delphia test, the intensity of the fluorescence of the enhancement solution is measured. This intensity is proportional to the concentration of labeled antigen that bound to the immobile antibody phase during the initial competition with unlabeled antigen from the sample. Consequently, the intensity of the fluorescence is an inverse function of the concentration of antigen (B2M) in the original sample. The relationship between the fluorescence level and the B2M concentration in the sample is determined using a series of graded standards, and extrapolating these standards to find the concentration of the unknown sample.

5.3.3 Methods Developed for B2MU Determinations

B2MU usually is measured by radioimmunoassay (RIA) or enzyme-linked immunosorbent assay (ELISA); however, other methods (including gel electrophoresis, radial immunodiffusion, and nephelometric assays) also have been described (Schardun and van Epps 1987). RIA and ELISA methods are preferred because they are sensitive at concentrations as low as micrograms per liter, require no concentration processes, are highly reliable and use only a small sample volume.

Based on a survey of the literature, the ELISA technique is recommended for monitoring B2MU. While RIAs provide greater sensitivity (typically about 1 µg/l, Evrin et al. 1971), they depend on the use of radioisotopes; use of radioisotopes requires adherence to rules and regulations established by the Atomic Energy Commission, and necessitates an expensive radioactivity counter for testing. Radioisotopes also have a relatively short half-life, which corresponds to a reduced shelf life, thereby increasing the cost and complexity of testing. In contrast, ELISA testing can be performed on routine laboratory spectrophotometers, do *not* necessitate adherence to additional rules and regulations governing the handling of radioactive substances, and the test kits have long shelf lives. Further, the range of sensitivity commonly achieved by the recommended ELISA test (i.e., the Pharmacia Delphia test) is approximately 100 µg/l (Pharmacia 1990), which is sufficient for monitoring B2MU levels resulting from cadmium exposure. Based on the studies listed in Table 9 (Section 5.3.7), the average range of B2M concentrations among the general, nonexposed population falls between 60 and 300 µg/g CRTU. The upper 95th percentile of distributions, derived from studies in Table 9 which reported standard deviations, range between 180 and 1,140 µg/g CRTU. Also, the Pharmacia Delphia test currently is the most widely used test for assessing B2MU.

5.3.4 Sample Collection and Handling

As with CDB or CDU, sample collection procedures are addressed primarily to identify ways to minimize the degree of variability introduced by sample collection during medical monitoring. It is unclear the extent to which sample collection contributes to B2MU variability. Sources of variation include time-of-day effects, the interval since consuming liquids and the quantity of liquids consumed, and the introduction of external contamination during the collection process. A special problem unique to B2M sampling is the sensitivity of this protein to degradation under acid conditions commonly found in the bladder. To minimize this problem, strict adherence to a sampling protocol is recommended. The protocol should include provisions for normalizing the conditions under which the urine is collected. Clearly, it is important to minimize the interval urine spends in the bladder. It also is recommended that every effort be made to collect samples during the same time of day.

Collection of urine samples for biological monitoring usually is performed using "spot" (i.e., single-void) urine. Logistics and sample integrity become problems when efforts are made to collect urine over extended periods (e.g., 24 hrs). Unless single-void urines are used, numerous opportunities exist for measurement error because of poor control over sample collection, storage and environmental contamination.

To minimize the interval that sample urine resides in the bladder, the following adaption to the "spot" collection procedure is recommended: The bladder should be emptied and then a large glass of water should be consumed; the sample then should be collected within an hour after the water is consumed.

5.3.5 Best Achievable Performance

The best achievable performance is assumed to be equivalent to the performance reported by the manufacturers of the Pharmacia Delphia test kits (Pharmacia 1990). According to the insert that comes with these kits, QC results should be within ±2 SDs of the mean for each control sample tested; a CV of less than or equal to 5.2% should be maintained. The total CV reported for test kits is less than or equal to 7.2%.

5.3.6 General Method Performance

Unlike analyses for CDB and CDU, the Pharmacia Delphia test is standardized in a commercial kit that controls for many sources of variation. In the absence of data to the contrary, it is assumed that the achievable performance reported by the manufacturer of this test kit will serve as an achievable performance objective. The CTQ proficiency testing program for B2MU analysis is expected to use the performance parameters defined by the test kit manufacturer as the basis of the B2MU proficiency testing program.

Note that results reported for the test kit are expressed in terms of µg B2M/l of urine, and have not been adjusted for creatinine. The indicated performance, therefore, is a measure of the performance of the B2M portion of the analyses only, and does not include variation that may have been introduced during the analysis of creatinine.

5.3.7 Observed B2MU Concentrations

As indicated in Section 4.3, the concentration of B2MU may serve as an early indicator of the onset of kidney damage associated with cadmium exposure.

5.3.7.1 Range of B2MU Concentrations Among Unexposed Samples

Most of the studies listed in Table 9 report B2MU levels for those who were not occupationally exposed to cadmium. Studies noted in the second column of this table (which contain the footnote "d") reported B2MU concentrations among cadmium-exposed workers who, nonetheless, showed *no* signs of proteinuria. These latter studies are included in this table because, as indicated in Section 4.3, monitoring B2MU is intended to provide advanced warning of the onset of kidney dysfunction associated with cadmium exposure, rather than to distinguish relative exposure. This table, therefore, indicates the range of B2MU levels observed among those who had no symptoms of renal dysfunction (including cadmium-exposed workers with none of these symptoms).

To the extent possible, the studies listed in Table 9 provide geometric means and geometric standard deviations for measurements among the groups defined in each study. For studies reporting a geometric standard deviation along with a mean, the lower and upper 95th percentile for these distributions were derived and reported in the table.

The data provided from 15 of the 19 studies listed in Table 9 indicate that the geometric mean concentration of B2M observed among those who were not occupationally exposed to cadmium is 70–170 µg/g CRTU. Data from the 4 remaining studies indicate that exposed workers who exhibit no signs of proteinuria show mean B2MU levels of 60–300 µg/g CRTU. B2MU values in the study by Thun et al. (1989), however, appear high in comparison to the other 3 studies.

TABLE 9.—B-2-MICROGLOBULIN CONCENTRATIONS OBSERVED IN URINE AMONG THOSE NOT OCCUPATIONALLY EXPOSED TO CADMIUM

Study No.	No. in study	Geometric mean	Geometric standard deviation	Lower 95th percentile of distribution[a]	Upper 95th percentile of distribution[a]	Reference
1	133 m[b]	115 µg/g[c]	4.03	12	1,140 µg/g[c]	Ishizaki et al. 1989.
2	161 f[b]	146 µg/g[c]	3.11	23	940 µg/g[c]	Ishizaki et al. 1989.
3	10	84 µg/g				Ellis et al. 1983.
4	203	76 µg/l				Stewart and Hughes 1981.
5	9	103 µg/g				Chia et al. 1989.
6	47[d]	86 µg/L	1.9	30 µg/1	250 µg/L	Kjellstrom et al. 1977.
7	1,000[e]	68.1 µg/gr Cr[f]	3.1 m & f	< 10 µg/gr Cr[h]	320 µg/gr Cr[h]	Kowal 1983.
8	87	71 µg/g[i]		7[h]	200[h]	Buchet et al. 1980.
9	10	0.073 mg/24h				Evrin et al. 1971.
10	59	156 µg/g	1.1[j]	130	180	Mason et al. 1988.
11	8	118 µg/g				Iwao et al. 1980.
12	34	79 µg/g				Wibowo et al. 1982.
13	41 m				400 µg/gr Cr[k]	Falck et al. 1983.
14	35[n]	67				Roels et al. 1991.
15	31[d]	63				Roels et al. 1991.
16	36[d]	77[i]				Miksche et al. 1981.
17	18[n]	130				Kawada et al. 1989.
18	32[p]	122				Kawada et al. 1989.
19	18[d]	295	1.4	170	510	Thun et al. 1989.

a—Based on an assumed lognormal distribution.
b—m = males, f = females.
c—Aged general population from non-polluted area; 47.9% population aged 50–69; 52.1% ≥ 70 years of age; values reported in study.
d—Exposed workers without proteinuria.
e—492 females, 484 male.
f—Creatinine adjusted; males = 68.1 µg/g Cr, females = 64.3 µg/g Cr.
h—Reported in the study.
i—Arithmetic mean.
j—Geometric standard error.
k—Upper 95% tolerance limits: for Falck this is based on the 24 hour urine sample.
n—Controls.
p—Exposed synthetic resin and pigment workers without proteinuria; Cadmium in urine levels up to 10 µg/g Cr.

If this study is removed, B2MU levels for those who are not occupationally exposed to cadmium are similar to B2MU levels found among cadmium-exposed workers who exhibit no signs of kidney dysfunction. Although the mean is high in the study by Thun et al., the range of measurements reported in this study is within the ranges reported for the other studies.

Determining a reasonable upper limit from the range of B2M concentrations observed among those who do not exhibit signs of proteinuria is problematic. Elevated B2MU levels are among the signs used to define the onset of kidney dysfunction. Without access to the raw data from the studies listed in Table 9, it is necessary to rely on reported standard deviations to estimate an upper limit for normal B2MU concentrations (i.e., the upper 95th percentile for the distributions measured). For the 8 studies reporting a geometric standard deviation, the upper 95th percentiles for the distributions are 180–1140 µg/g CRTU. These values are in general agreement with the upper 95th percentile for the distribution (i.e., 631 µg/g CRTU) reported by Buchet et al. (1980). These upper limits also appear to be in general agreement with B2MU values (i.e., 100–690 µg/g CRTU) reported as the normal upper limit by Iwao et al. (1980), Kawada et al. (1989), Wibowo et al. (1982), and Schardun and van Epps (1987). These values must be compared to levels reported among those exhibiting kidney dysfunction to define a threshold level for kidney dysfunction related to cadmium exposure.

5.3.7.2 Range of B2MU Concentrations Among Exposed Workers

TABLE 10.—B-2-MICROGLOBULIN CONCENTRATIONS OBSERVED IN URINE AMONG OCCUPATIONALLY-EXPOSED WORKERS

Study No.	N	Concentration of B-2-Microglobulin in urine				Reference
		Geometric mean (µg/g) [a]	Geom std dev	L 95% of range [b]	U 95% of range [b]	
1	1,424	160	6.19	8.1	3,300	Ishizaki et al., 1989.
2	1,754	260	6.50	12	5,600	Ishizaki et al., 1989.
3	33	210	.....	.....	.....	Ellis et al., 1983.
4	65	210	.....	.....	.....	Chia et al., 1989.
5	[c]44	5,700	6.49	[d]300	[d]98,000	Kjellstrom et al., 1977.
6	148	[e]180	.....	[f]110	[f]280	Buchet et al., 1980.
7	37	160	3.90	17	1,500	Kenzaburo et al., 1979.
8	[c]45	3,300	8.7	[d]310	[d]89,000	Mason et al., 1988.
9	[c]10	6,100	5.99	[f]650	[f]57,000	Falck et al., 1983.
10	[c]11	3,900	2.96	[d]710	[d]15,000	Elinder et al., 1985.
11	[c]12	300	.....	.....	.....	Roels et al., 1991.
12	[g]8	7,400	.....	.....	.....	Roels et al., 1991.
13	[c]23	[h]1,800	.....	.....	.....	Roels et al., 1989.
14	10	690	.....	.....	.....	Iwao et al., 1980.
15	34	71	.....	.....	.....	Wibowo et al., 1982.
16	[c]15	4,700	6.49	[d]590	[d]93,000	Thun et al., 1989.

[a] Unless otherwise stated.
[b] Based on an assumed lognormal distribution.
[c] Among workers diagnosed as having renal dysfunction; for Elinder this means β 2 levels greater than 300 micrograms per gram creatinine (µg/gr Cr); for Roels, 1991, range = 31 − 35, 170 µgβ_2/gr Cr and geometric mean = 63 among healthy workers; for Mason β_2 > 300 µg/gr Cr.
[d] Based on a detailed review of the data by OSHA.
[e] Arthmetic mean.
[f] Reported in the study.
[g] Retired workers.
[h] 1,800 µgβ_2/gr Cr for first survey; second survey = 1,600; third survey = 2,600; fourth survey = 2,600; fifth survey = 2,600.

Table 10 presents results from studies reporting B2MU determinations among those occupationally exposed to cadmium in the work place; in some of these studies, kidney dysfunction was observed among exposed workers, while other studies did not make an effort to distinguish among exposed workers based on kidney dysfunction. As with Table 9, this table provides geometric means and geometric standard deviations for the groups defined in each study if available. For studies reporting a geometric standard deviation along with a mean, the lower and upper 95th percentiles for the distributions are derived and reported in the table.

The data provided in Table 10 indicate that the mean B2MU concentration observed among workers experiencing occupational exposure to cadmium (but with undefined levels of proteinuria) is 160–7400 µg/g CRTU. One of these studies reports geometric means lower than this range (i.e., as low as 71 µg/g CRTU); an explanation for this wide spread in average concentrations is not available.

Seven of the studies listed in Table 10 report a range of B2MU levels among those diagnosed as having renal dysfunction. As indicated in this table, renal dysfunction (proteinuria) is defined in several of these studies by B2MU levels in excess of 300 µg/g CRTU (see footnote "c" of Table 10); therefore, the range of B2MU levels observed in these studies is a function of the operational definition used to identify those with renal dysfunction. Nevertheless, a B2MU level of 300 µg/g CRTU appears to be a meaningful threshold for identifying those having early signs of kidney damage. While levels much higher than 300 µg/g CRTU have been observed among those with renal dysfunction, the vast majority of those not occupationally exposed to cadmium exhibit much lower B2MU concentrations (see Table 9). Similarly, the vast majority of workers *not* exhibiting renal dysfunction are found to have levels below 300 µg/g CRTU (Table 9).

The 300 µg/g CRTU level for B2MU proposed in the above paragraph has support among researchers as the threshold level that distinguishes between cadmium-exposed workers with and without kidney dysfunction. For example, in the guide for physicians who must evaluate cadmium-exposed workers written for the Cadmium Council by Dr. Lauwerys, levels of B2M greater than 200–300 µg/g CRTU are considered to require additional medical evaluation for kidney dysfunction (exhibit 8–447, OSHA docket H057A). The most widely used test for measuring B2M (i.e., the Pharmacia Delphia test) defines B2MU levels above 300 µg/l as abnormal (exhibit L–140–1, OSHA docket H057A).

Dr. Elinder, chairman of the Department of Nephrology at the Karolinska Institute, testified at the hearings on the proposed cadmium rule. According to Dr. Elinder (exhibit L–140–45, OSHA docket H057A), the normal concentration of B2MU has been well documented (Evrin and Wibell 1972; Kjellstrom et al. 1977a; Elinder et al. 1978, 1983; Buchet et al. 1980; Jawaid et al. 1983; Kowal and Zirkes, 1983). Elinder stated that the upper 95 or 97.5 percentiles for B2MU among those without tubular dysfunction is below 300 µg/g CRTU (Kjellstrom et al. 1977a; Buchet et al. 1980; Kowal and Zirkes, 1983). Elinder defined levels of B2M above 300 µg/g CRTU as "slight" proteinuria.

5.3.8 Conclusions and Recommendations for B2MU

Based on the above evaluation, the following recommendations are made for a B2MU proficiency testing program. Note that the following discussion addresses only sampling and analysis for B2MU determinations (i.e., to be reported as an unadjusted µg B2M/l urine). Normalizing this result to creatinine requires a second analysis for CRTU (see Section 5.4) so that the ratio of the 2 measurements can be obtained.

5.3.8.1 *Recommended method*

The Pharmacia Delphia method (Pharmacia 1990) should be adopted as the standard method for B2MU determinations. Laboratories may adopt alternate methods, but it is the responsibility of the laboratory to demonstrate that alternate methods provide results of comparable quality to the Pharmacia Delphia method.

5.3.8.2 *Data quality objectives*

The following data quality objectives should facilitate interpretation of analytical results, and should be achievable based on the above evaluation.

Limit of Detection. A limit of 100 µg/l urine should be achievable, although the insert to the test kit (Pharmacia 1990) cites a detection limit of 150 µg/l; private conversations with representatives of Pharmacia, however, indicate that the lower limit of 100 µg/l should be achievable provided an additional standard of 100 µg/l B2M is run with the other standards to derive the calibration

curve (Section 3.3.1.1). The lower detection limit is desirable due to the proximity of this detection limit to B2MU values defined for the cadmium medical monitoring program.

Accuracy. Because results from an interlaboratory proficiency testing program are not available currently, it is difficult to define an achievable level of accuracy. Given the general performance parameters defined by the insert to the test kits, however, an accuracy of ±15% of the target value appears achievable.

Due to the low levels of B2MU to be measured generally, it is anticipated that the analysis of creatinine will contribute relatively little to the overall variability observed among creatinine-normalized B2MU levels (see Section 5.4). The initial level of accuracy for reporting B2MU levels under this program should be set at ±15%.

Precision. Based on precision data reported by Pharmacia (1990), a precision value (i.e., CV) of 5% should be achievable over the defined range of the analyte. For internal QC samples (i.e., recommended as part of an internal QA/QC program, Section 3.3.1), laboratories should attain precision near 5% over the range of concentrations measured.

5.3.8.3 *Quality assurance/quality control*

Commercial laboratories providing measurement of B2MU should adopt an internal QA/QC program that incorporates the following components: Strict adherence to the Pharmacia Delphia method, including calibration requirements; regular use of QC samples during routine runs; a protocol for corrective actions, and documentation of these actions; and, participation in an interlaboratory proficiency program. Procedures that may be used to address internal QC requirements are presented in Attachment 1. Due to differences between analyses for B2MU and CDB/CDU, specific values presented in Attachment 1 may have to be modified. Other components of the program (including characterization runs), however, can be adapted to a program for B2MU.

5.4 Monitoring Creatinine in Urine (CRTU)

Because CDU and B2MU should be reported relative to concentrations of CRTU, these concentrations should be determined in addition CDU and B2MU determinations.

5.4.1 Units of CRTU Measurement

CDU should be reported as µg Cd/g CRTU, while B2MU should be reported as µg B2M/g CRTU. To derive the ratio of cadmium or B2M to creatinine, CRTU should be reported in units of g crtn/l of urine. Depending on the analytical method, it may be necessary to convert results of creatinine determinations accordingly.

5.4.2 Analytical Techniques Used to Monitor CRTU

Of the techniques available for CRTU determinations, an absorbance spectrophotometric technique and a high-performance liquid chromatography (HPLC) technique are identified as acceptable in this protocol.

5.4.3 Methods Developed for CRTU Determinations

CRTU analysise performed in support of either CDU or B2MU determinations should be performed using either of the following 2 methods:

1. The Du Pont method (i.e., Jaffe method), in which creatinine in a sample reacts with picrate under alkaline conditions, and the resulting red chromophore is monitored (at 510 nm) for a fixed interval to determine the rate of the reaction; this reaction rate is proportional to the concentration of creatinine present in the sample (a copy of this method is provided in Attachment 2 of this protocol); or,

2. The OSHA SLC Technical Center (OSLTC) method, in which creatinine in an aliquot of sample is separated using an HPLC column equipped with a UV detector; the resulting peak is quantified using an electrical integrator (a copy of this method is provided in Attachment 3 of this protocol).

5.4.4 Sample Collection and Handling

CRTU samples should be segregated from samples collected for CDU or B2MU analysis. Sample-collection techniques have been described under Section 5.2.4. Samples should be preserved either to stabilize CDU (with HNO_3) or B2MU (with NaOH). Neither of these procedures should adversely affect CRTU analysis (see Attachment 3).

5.4.5 General Method Performance

Data from the OSLTC indicate that a CV of 5% should be achievable using the OSLTC method (Septon, L private communication). The achievable accuracy of this method has not been determined.

Results reported in surveys conducted by the CAP (CAP 1991a, 1991b and 1992) indicate that a CV of 5% is achievable. The accuracy achievable for CRTU determinations has not been reported.

Laboratories performing creatinine analysis under this protocol should be CAP accredited and should be active participants in the CAP surveys.

5.4.6 Observed CRTU Concentrations

Published data suggest the range of CRTU concentrations is 1.0–1.6 g in 24-hour urine samples (Harrison 1987). These values are equivalent to about 1 g/l urine.

5.4.7 Conclusions and Recommendations for CRTU

5.4.7.1 Recommended method

Use either the Jaffe method (Attachment 2) or the OSLTC method (Attachment 3). Alternate methods may be acceptable provided adequate performance is demonstrated in the CAP program.

5.4.7.2 Data quality objectives

Limit of Detection. This value has not been formally defined; however, a value of 0.1 g/l urine should be readily achievable.

Accuracy. This value has not been defined formally; accuracy should be sufficient to retain accreditation from the CAP.

Precision. A CV of 5% should be achievable using the recommended methods.

6.0 References

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Attachment 1: Nonmandatory Protocol for an Internal Quality Assurance/Quality Control Program

The following is an example of the type of internal quality assurance/quality control program that assures adequate control to satisfy OSHA requirements under this protocol. However, other approaches may also be acceptable. As indicated in Section 3.3.1 of the protocol, the QA/QC program for CDB and CDU should address, at a minimum, the following:

- calibration;
- establishment of control limits;
- internal QC analyses and maintaining control; and
- corrective action protocols.

This illustrative program includes both initial characterization runs to establish the performance of the method and ongoing analysis of quality control samples intermixed with compliance samples to maintain control.

Calibration

Before any analytical runs are conducted, the analytic instrument must be calibrated. This is to be done at the beginning of each day on which quality control samples and/or compliance samples are run. Once calibration is established, quality control samples or compliance samples may be run. Regardless of the type of samples run, every fifth sample must be a standard to assure that the calibration is holding.

Calibration is defined as holding if every standard is within plus or minus (±) 15% of its theoretical value. If a standard is more than plus or minus 15% of its theoretical value, then the run is out of control due to calibration error and the entire set of samples must either be reanalyzed after recalibrating or results should be recalculated based on a statistical curve derived from the measurement of all standards.

It is essential that the highest standard run is higher than the highest sample run. To assure that this is the case, it may be necessary to run a high standard at the end of the run, which is selected based on the results obtained over the course of the run.

All standards should be kept fresh, and as they get old, they should be compared with new standards and replaced if they exceed the new standards by ± 15%.

Initial Characterization Runs and Establishing Control

A participating laboratory should establish four pools of quality control samples for each of the analytes for which determinations will be made. The concentrations of quality control samples within each pool are to be centered around each of the four target levels for the particular analyte identified in Section 4.4 of the protocol.

Within each pool, at least 4 quality control samples need to be established with varying concentrations ranging between plus or minus 50% of the target value of that pool. Thus for the medium-high cadmium in blood pool, the theoretical values of the quality control samples may range from 5 to 15 µg/l, (the target value is 10 µg/l). At least 4 unique theoretical values must be represented in this pool.

The range of theoretical values of plus or minus 50% of the target value of a pool means that there will be overlap of the pools. For example, the range of values for the medium-low pool for cadmium in blood is 3.5 to 10.5 µg/l while the range of values for the medium-high pool is 5 to 15 µg/l. Therefore, it is possible for a quality control sample from the medium-low pool to have a higher concentration of cadmium than a quality control sample from the medium-high pool.

Quality control samples may be obtained as commercially available reference materials, internally prepared, or both. Internally prepared samples should be well characterized and traced or compared to a reference material for which a consensus

value for concentration is available. Levels of analyte in the quality control samples must be concealed from the analyst prior to the reporting of analytical results. Potential sources of materials that may be used to construct quality control samples are listed in Section 3.3.1 of the protocol.

Before any compliance samples are analyzed, control limits must be established. Control limits should be calculated for every pool of each analyte for which determinations will be made, and control charts should be kept for each pool of each analyte. A separate set of control charts and control limits should be established for each analytical instrument in a laboratory that will be used for analysis of compliance samples.

At the beginning of this QA/QC program, control limits should be based on the results of the analysis of 20 quality control samples from each pool of each analyte. For any given pool, the 20 quality control samples should be run on 20 different days. Although no more than one sample should be run from any single pool on a particular day, a laboratory may run quality control samples from different pools on the same day. This constitutes a set of initial characterization runs.

For each quality control sample analyzed, the value F/T (defined in the glossary) should be calculated. To calculate the control limits for a pool of an analyte, it is first necessary to calculate the mean, $\bar{X}$, of the F/T values for each quality control sample in a pool and then to calculate its standard deviation σ.Thus, for the control limit for a pool, $\bar{X}$ is calculated as:

$$\frac{\left(\sum \frac{F}{T}\right)}{N}$$

and σ is calculated as

$$\left[\frac{\sum\left(\frac{F}{T}-\bar{X}\right)^2}{(N-1)}\right]^{\frac{1}{2}}$$

Where N is the number of quality control samples run for a pool.

The control limit for a particular pool is then given by the mean plus or minus 3 standard deviations ($\bar{X} \pm 3\sigma$).

The control limits may be no greater than 40% of the mean F/T value. If three standard deviations are greater than 40% of the mean F/T value, then analysis of compliance samples may not begin.[1] Instead, an investigation into the causes of the large standard deviation should begin, and the inadequacies must be remedied. Then, control limits must be reestablished which will mean repeating the running 20 quality control samples from each pool over 20 days.

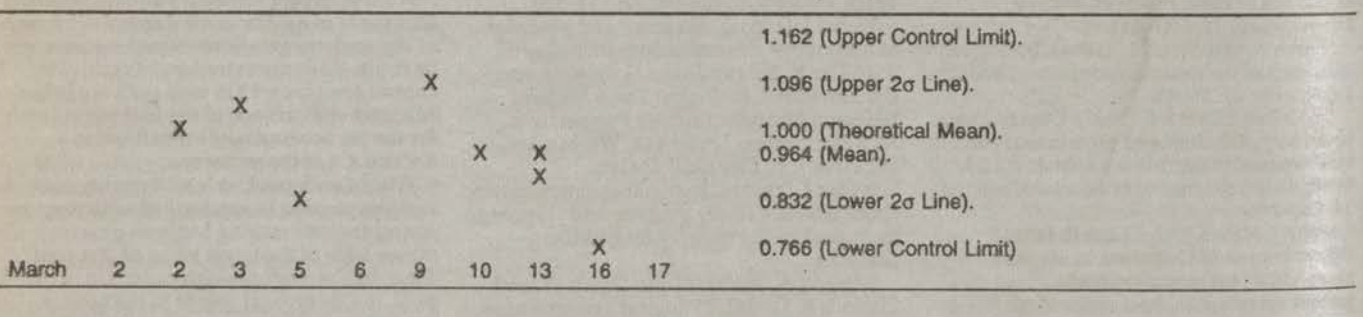
Internal Quality Control Analyses and Maintaining Control

Once control limits have been established for each pool of an analyte, analysis of compliance samples may begin. During any run of compliance samples, quality control samples are to be interspersed at a rate of no less than 5% of the compliance sample workload. When quality control samples are run, however, they should be run in sets consisting of one quality control sample from each pool. Therefore, it may be necessary, at times, to intersperse quality control samples at a rate greater than 5%.

There should be at least one set of quality control samples run with any analysis of compliance samples. At a minimum, for example, 4 quality control samples should be run even if only 1 compliance sample is run. Generally, the number of quality control samples that should be run are a multiple of four with the minimum equal to the smallest multiple of four that is greater than 5% of the total number of samples to be run. For example, if 300 compliance samples of an analyte are run, then at least 16 quality control samples should be run (16 is the smallest multiple of four that is greater than 15, which is 5% of 300).

Control charts for each pool of an analyte (and for each instrument in the laboratory to be used for analysis of compliance samples) should be established by plotting F/T versus date as the quality control sample results are reported. On the graph there should be lines representing the control limits for the pool, the mean F/T limits for the pool, and the theoretical F/T of 1.000. Lines representing plus or minus (±) 2σ should also be represented on the charts. A theoretical example of a control chart is presented in Figure 1.

FIGURE 1.—THEORETICAL EXAMPLE OF A CONTROL CHART FOR A POOL OF AN ANALYTE



All quality control samples should be plotted on the chart, and the charts should be checked for visual trends. If a quality control sample falls above or below the control limits for its pool, then corrective steps must be taken (see the section on corrective actions below). Once a laboratory's program has been established, control limits should be updated every two months.

The updated control limits should be calculated from the results of the last 100 quality control samples run for each pool. If 100 quality control samples from a pool have not been run at the time of the update, then the limits should be based on as many as have been run provided at least 20 quality control samples from each pool have been run over 20 different days.

The trends that should be looked for on the control charts are:

1. 10 consecutive quality control samples falling above or below the mean;

2. 3 consecutive quality control samples falling more than 2σ from the mean (above or below the 2σ lines of the chart); or

3. the mean calculated to update the control limits falls more than 10% above or below the theoretical mean of 1.000.

If any of these trends is observed, then all analysis must be stopped, and an investigation into the causes of the errors must begin. Before the analysis of compliance samples may resume, the inadequacies must be remedied and the control limits must be reestablished for that pool of an analyte. Reestablishment of control limits will entail running 20 sets of quality control samples over 20 days.

Note that alternative procedures for defining internal quality control limits may also be acceptable. Limits may be based, for example, on proficiency testing, such as ±1 μg or 15% of the mean (whichever is greater). These should be clearly defined.

Corrective actions

Corrective action is the term used to describe the identification and remediation of errors occurring within an analysis. Corrective action is necessary whenever the result of the analysis of any quality control sample falls outside of the established control limits. The steps involved may include simple things like checking

[1] Note that the value, "40%" may change over time as experience is gained with the program.

calculations of basic instrument maintenance, or it may involve more complicated actions like major instrument repair. Whatever the source of error, it must be identified and corrected (and a Corrective Action Report (CAR) must be completed. CARs should be kept on file by the laboratory.

Attachment 2—Creatinine in Urine (JAFFE PROCEDURE)

Intended use: The CREA pack is used in the Du Pont ACA® discrete clinical analyzer to quantitatively measure creatinine in serum and urine.

Summary: The CREA method employs a modification of the kinetic Jaffe reaction reported by Larsen. This method has been reported to be less susceptible than conventional methods to interference from non-creatinine, Jaffe-positive compounds.[1]

A split sample comparison between the CREA method and a conventional Jaffe procedure on Autoanalyzer® showed a good correlation. (See SPECIFIC PERFORMANCE CHARACTERISTICS).

* Note: Numbered subscripts refer to the bibliography and lettered subscripts refer to footnotes.

Autoanalyzer,® is a registered trademark of Technicon Corp., Tarrytown, NY.

Principles of Procedure: In the presence of a strong base such as NaOH, picrate reacts with creatinine to form a red chromophore. The rate of increasing absorbance at 510 nm due to the formation of this chromophore during a 17.07-second measurement period is directly proportional to the creatinine concentration in the sample.

$$\text{Creatinine} + \text{Picrate} \xrightarrow{\text{NaOH}} \text{Red chromophore (absorbs at 510 nm)}$$

Reagents:

Compartment[a]	Form	Ingredient	Quantity[b]
No. 2, 3, & 4.	Liquid	Picrate ..	0.11 mmol.
6	Liquid	NaOH (for pH adjustment)[c].	

a. Compartments are numbered 1–7, with compartment #7 located closest to pack fill position #2.

b. Nominal value at manufacture.

c. See PRECAUTIONS.

Precautions: Compartment #6 contains 75µL of 10 N NaOH; avoid contact; skin irritant; rinse contacted area with water. Comply with OSHA'S Bloodborne Pathogens Standard while handling biological samples (29 CFR 1910.1039).

Used packs contain human body fluids; handle with appropriate care.

FOR IN VITRO DIAGNOSTIC USE

MIXING & DILUTING

Mixing and diluting are automatically performed by the ACA® discrete clinical analyzer. The sample cup must contain sufficient quantity to accommodate the sample volume plus the "dead volume"; precise cup filling is not required.

SAMPLE CUP VOLUMES (µL)

Analyzer	Standard		Microsystem	
	Dead	Total	Dead	Total
II, III	120	3000	10	500
IV, SX	120	3000	30	500
V	90	3000	10	500

Storage of Unprocessed Packs: Store at 2–8°C. Do not freeze. Do not expose to temperatures above 35°C or to direct sunlight.

Expiration: Refer to EXPIRATION DATE on the tray label.

Specimen Collection: Serum or urine can be collected and stored by normal procedures.[2]

Known Interfering Substances[3]

• Serum Protein Influence—Serum protein levels exert a direct influence on the CREA assay. The following should be taken into account when this method is used for urine samples and when it is calibrated:

Aqueous creatinine standards or urine specimens will give CREA results depressed by approximately 0.7 mg/dL [62 µmol/L][d] and will be less precise than samples containing more than 3 g/dL [30 g/L] protein.

All urine specimens should be diluted with an albumin solution to give a final protein concentration of at least 3 g/dL [30 g/L]. Du Pont Enzyme Diluent (Cat. #790035–901) may be used for this purpose.

• High concentration of endrogenous bilirubin (>20 mg/dL [>342 µmol/L]) will give depressed CREA results (average depression 0.8 mg/dL [71 µmol/L]).[4]

• Grossly hemolyzed (hemoglobin >100 mg/dL [>62 µmol/L]) or visibly lipemic specimens may cause falsely elevated CREA results.[5,6]

• The following cephalosporin antibiotics do not interfere with the CREA method when present at the concentrations indicated. Systematic inaccuracies (bias) due to these substances are less than or equal to 0.1 mg/dL [8.84 µmol/L] at CREA concentrations of approximately 1 mg/dL [88 µmol/L].

Antibiotic	Peak serum level[7,8,9]		Drug concentration	
	mg/dL	[mmol/L]	mg/dL	[mmol/L]
Cephaloridine	1.4	0.3	25	6.0
Cephalexin	0.6–2.0	0.2–0.6	25	7.2
Cephamandole	1.3–2.5	0.3–0.5	25	4.9
Cephapirin	2.0	D0.4	25	5.6
Cephradine	1.5–2.0	0.4–0.6	25	7.1
Cefazolin	2.5–5.0	0.55–1.1	50	11.0

• The following cephalosporin antibiotics have been shown to affect CREA results when present at the indicated concentrations. System inaccuracies (bias) due to these substances are greater that 0.1 mg/dL [8.84 µmol/L] at CREA concentrations of:

Antibiotic	Peak serum level[8,10]		Drug concentration		
	mg/dL	[mmol/L]	mg/dL	[mmol/L]	Effect
Cephalothin	1–6	0.2–1.5	100	25.2	↓20–25%
Cephoxitin	2.0	0.5	5.0	1.2	↑35–40%

• The single wavelength measurement used in this method eliminates interference from chromophores whose 510 nm absorbance is constant throughout the measurement period.

• Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot to lot.

d. Systeme International d'unites (S.I. Units) are in brackets.

Procedure:

TEST MATERIALS

Item	II, III Du Pont Cat. No.	IV, SX Du Pont Cat. No.	V Du Pont Cat. No.
ACA® CREA Analytical Test Pack	701976901	701976901	701976901
Sample System Kit or	710642901	710642901	713697901
Micro Sample System Kit and	702694901	710356901	NA
Micro Sample System Holders	702785000	NA	NA
DYLUX® Photosensitive	.....	.....	.....
Printer Paper	700036000	NA	NA
Thermal Printer Paper	NA	710639901	713645901
Du Pont Purified Water	704209901	710615901	710815901
Cell Wash Solution	701864901	710664901	710864901

Test Steps

The operator need only load the sample kit and appropriate test pack(s) into a properly prepared ACA® discrete clinical analyzer. It automatically advances the pack(s) through the test steps and prints a result(s). See the Instrument Manual of the ACA® analyzer for details of mechanical travel of the test pack(s).

Preset Creatinine (CREA)—Test Conditions

- Sample Volume: 200 µL
- Diluent: Purified Water
- Temperature: 37.0 ± 0.1°C
- Reaction Period: 29 seconds
- Type of Measurement: Rate
- Measurement Period: 17.07 seconds
- Wavelength: 510 nm
- Units: mg/dL [µmol/L]

CALIBRATION

The general calibration procedure is described in the Calibration/Verification chapter of the Manuals.

The following information should be considered when calibrating the CREA method.

- Assay Range: 0–20 mg/mL [0–1768 µmol/L][c].
- Reference Material: Protein containing primary standards[f] or secondary calibrators such as Du Pont Elevated Chemistry Control (Cat. #790035903) and Normal Chemistry Control (Cat.•#790035905)[g].
- Suggested Calibration Levels: 1,5,20, mg/mL [88, 442, 1768 µmol/L].
- Calibration Scheme: 3 levels, 3 packs per level.
- Frequency: Each new pack lot. Every 3 months for any one pack lot.

e. For the results in S.I. units [µmol/L] the conversion factory is 88.4.

f. Refer to the Creatinine Standard Preparation and Calibration Procedure available on request from a Du Pont Representative.

g. If the Du Pont Chemistry Controls are being used, prepare them according to the instructions on the product insert sheets.

PRESET CREATININE (CREA) TEST CONDITIONS

Item	ACA® II analyzer	ACA® III, IV, SX, V analyzer
Count by	One (1) [Five (5)]	NA
Decimal Point.	0.0 mg/dL	000.0 mg/dL
Location	[000.0 µmol/L].	[000 µmol/L]
Assigned Starting.	999.8	−1.000 E1
Point or Offset C_o.	[9823.]	[−8.840 E2]
Scale Factor or Assigned.	0.2000 mg/dL/count[h]	2.004 E-1[h]
Linear Term C_1[h].	[0.3536 µmol/L/count].	[1.772E1]

h. The preset scale factor (linear term) was derived from the molar absorptivity of the indicator and is based on an absorbance to activity relationship (sensitivity) of 0.596 (mA/min)/(U/L). Due to small differences in filters and electronic components between instruments, the actual scale factor (linear term) may differ slightly from that given above.

Quality Control

Two types of quality control procedures are recommended:

• General Instrument Check. Refer to the Filter Balance Procedure and the Absorbance Test Method described in the ACA Analyzerinstrument Manual. Refer also to the ABS Test Methodology literature.

Creatinine Method Check. At least once daily run a CREA test on a solution of known creatinine activity such as an assayed control or calibration standard other than that used to calibrate the CREA method. For further details review the Quality Assurance Section of the Chemistry Manual. The result obtained should fall within acceptable limits defined by the day-to-day variability of the system as measured in the user's laboratory. (See SPECIFIC PERFORMANCE CHARACTERISTICS for guidance.) If the result falls outside the laboratory's acceptable limits, follow the procedure outlined in the Chemistry Troubleshooting Section of the Chemistry Manual.

A possible system malfunction is indicated when analysis of a sample with five

consecutive test packs gives the following results:

Level	SD
1 mg/dL [88 µmol/L]	>0.15 mg/dL [>13 µmol/L]
20 mg/dL [1768 µmol/L]	>0.68 mg/dL [>60 µmol/L]

Refer to the procedure outlined in the Trouble Shooting Section of the Manual.

Results

The ACA® analyzer automatically calculates and prints the CREA result in mg/dL [µmol/L].

Limitation of Procedure

Results >20 mg/dL [1768 µmol/L]:

• Dilute with suitable protein base diluent. Reassay. Correct for diluting before reporting.

The reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing a letter code or word immediately following the numerical value should not be reported. Refer to the Manual for the definition of error codes.

Reference Interval

SERUM:[11]

Males	0.8–1.3 md/dL [71–115 µmol/L]
Females	0.6–1.0 md/dL [53–88 µmol/L]

URINE:[12]

Males	0.6–2.5 g/24 hr [53–221 mmol/24 hr]
Females	0.6–1.5 g/24 hr [53–133 mmol/24 hr]

Each laboratory should establish its own reference intervals for CREA as performed on the analyzer.

i. Reference interval data obtained from 200 apparently healthy individuals (71 males, 129 females) between the ages of 19 and 72.

Specific Performance Characteristics[j]

REPRODUCIBILITY[k]

Material	Mean	Standard deviation (% CV)	
		Within-run	Between-day
Lyophilized Control	1.3 [115]	0.05 (3.7) [4.4]	0.05 (3.7) [4.4]
Lyophilized Control	20.6 [1821]	0.12 (0.6) [10.6]	0.37 (1.8) [32.7]

CORRELATION—REGRESSION STATISTICS[l]

Comparative method	Slope	Intercept	Correlation coefficient	n
Autoanalyzer®	1.03	0.03[2.7]	0.997	260

j. All specific performance characteristics tests were run after normal recommended equipment quality control checks were performed (see Instrument Manual).

k. Specimens at each level were analyzed in duplicate for twenty days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

l. Model equation for regression statistics is:

$$\text{Result of ACA}^{®}\text{ Analyzer} = \text{Slope (Comparative method result)} + \text{intercept}$$

Assay Range[m]

0.0–20.0 mg/dl
[0–1768 µmol]

m. See REPRODUCIBILITY for method performance within the assay range.

Analytical Specificity

See KNOWN INTERFERING SUBSTANCES section for details.

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[12] Dicht, JJ, Reference Intervals for Serum Amylase and Urinary Creatinine on the Du Pont ACA® Discrete Clinical Analyzer, Du Pont Company, Wilmington, DE (November 1984).

Attachment 3—Analysis of Creatinine for the Normalization of Cadmium and Beta-2-Microglobulin Concentrations in Urine

Matrix: Urine.

Target concentration: 1.1 g/L (this amount is representative of creatinine concentrations found in urine).

Procedure: A 1.0 mL aliquot of urine is passed through a C18 SEP-PAK® (Waters Associates). Approximately 30 mL of HPLC (high performance liquid chromatography) grade water is then run through the SEP-PAK. The resulting solution is diluted to volume in a 100-mL volumetric flask and analyzed by HPLC using an ultraviolet (UV) detector.

Special requirements: After collection, samples should be appropriately stabilized

for cadmium (Cd) analysis by using 10% high purity (with low Cd background levels) nitric acid (exactly 1.0 mL of 10% nitric acid per 10 mL of urine) or stabilized for Beta-2-Microglobulin (B2M) by taking to pH 7 with dilute NaOH (exactly 1.0 mL of 0.11 N NaOH per 10 mL of urine). If not immediately analyzed, the samples should be frozen and shipped by overnight mail in an insulated container.

Dated: January 1992.

David B. Armitage,

Duane Lee,

Chemists.

Organic Service Branch II, OSHA Technical Center, Salt Lake City, Utah

1. General Discussion

1.1 Background

1.1.1. History of procedure

Creatinine has been analyzed by several methods in the past. The earliest methods were of the wet chemical type. As an example, creatinine reacts with sodium picrate in basic solution to form a red complex, which is then analyzed colorimetrically (Refs. 5.1. and 5.2.).

Since industrial hygiene laboratories will be analyzing for Cd and B2M in urine, they will be normalizing those concentrations to the concentration of creatinine in urine. A literature search revealed several HPLC methods (Refs. 5.3., 5.4., 5.5. and 5.6.) for creatinine in urine and because many industrial hygiene laboratories have HPLC equipment, it was desirable to develop an industrial hygiene HPLC method for creatinine in urine. The method of Hausen, Fuchs, and Wachter was chosen as the starting point for method development. SEP-PAKs were used for sample clarification and cleanup in this method to protect the analytical column. The urine aliquot which has been passed through the SEP-PAK is then analyzed by reverse-phase HPLC using ion-pair techniques.

This method is very similar to that of Ogata and Taguchi (Ref. 5.6.), except they used centrifugation for sample clean-up. It is also of note that they did a comparison of their HPLC results to those of the Jaffe method (a picric acid method commonly used in the health care industry) and found a linear relationship of close to 1:1. This indicates that either HPLC or colorimetric methods may be used to measure creatinine concentrations in urine.

1.1.2. Physical properties (Ref. 5.7.)

Molecular weight: 113.12

Molecular formula: C_4–H_7–N_3–0

Chemical name: 2-amino-1,5-dihydro-1-methyl-4H-imidazol-4-one

CAS No.: 60–27–5

Melting point: 300 °C (decomposes)

Appearance: white powder

Solubility: soluble in water; slightly soluble in alcohol; practically insoluble in acetone, ether, and chloroform

Synonyms: 1-methylglycocyamidine, 1-methylhydantoin-2-imide

Structure: see Figure #1

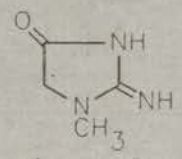


Figure #1

1.2. Advantages

1.2.1. This method offers a simple, straightforward, and specific alternative method to the Jaffe method.

1.2.2. HPLC instrumentation is commonly found in many industrial hygiene laboratories.

2. Sample stabilization procedure

2.1. Apparatus

Metal-free plastic container for urine sample.

2.2. Reagents

2.2.1. Stabilizing Solution—

(1) Nitric acid (10%, high purity with low Cd background levels) for stabilizing urine for Cd analysis or

(2) NaOH, 0.11 N, for stabilizing urine for B2M analysis.

2.2.2. HPLC grade water

2.3. Technique

2.3.1. Stabilizing solution is added to the urine sample (see section 2.2.1.). The stabilizing solution should be such that for each 10 mL of urine, add exactly 1.0 mL of stabilizer solution. (Never add water or urine to acid or base. Always add acid or base to water or urine.) Exactly 1.0 mL of 0.11 N NaOH added to 10 mL of urine should result in a pH of 7. Or add 1.0 mL of 10% nitric acid to 10 mL of urine.

2.3.2. After sample collection seal the plastic bottle securely and wrap it with an appropriate seal. Urine samples should be frozen and then shipped by overnight mail (if shipping is necessary) in an insulated container. (Do not fill plastic bottle too full. This will allow for expansion of contents during the freezing process.)

2.4. The Effect of Preparation and Stabilization Techniques on Creatinine Concentrations

Three urine samples were prepared by making one sample acidic, not treating a second sample, and adjusting a third sample to pH 7. The samples were analyzed in duplicate by two different procedures. For the first procedure a 1.0 mL aliquot of urine was put in a 100-mL volumetric flask, diluted to volume with HPLC grade water, and then analyzed directly on an HPLC. The other procedure used SEP-PAKs. The SEP-PAK was rinsed with approximately 5 mL of methanol followed by approximately 10 mL of HPLC grade water and both rinses were discarded. Then, 1.0 mL of the urine sample was put through the SEP-PAK, followed by 30 mL of HPLC grade water. The urine and water were transferred to a 100-mL volumetric flask, diluted to volume with HPLC grade water, and analyzed by HPLC. These three urine samples were analyzed on the day they were obtained and then frozen. The results show that whether the urine is acidic, untreated or adjusted to pH 7, the resulting answer for creatinine is essentially unchanged. The purpose of stabilizing the urine by making it acidic or neutral is for the analysis of Cd or B2M respectively.

COMPARISON OF PREPARATION & STABILIZATION TECHNIQUES

Sample	w/o SEP-PAK g/L creatinine	with SEP-PAK g/L creatinine
Acid	1.10	1.10
Acid	1.11	1.10
Untreated	1.12	1.11
Untreated	1.11	1.12
pH 7	1.08	1.02
pH 7	1.11	1.08

2.5. Storage

After 4 days and 54 days of storage in a freezer, the samples were thawed, brought to room temperature and analyzed using the same procedures as in section 2.4. The results of several days of storage show that the resulting answer of creatinine is essentially unchanged.

STORAGE DATA

Sample	4 days		54 days	
	w/o SEP-PAK g/L creatinine	with SEP-PAK g/L creatinine	w/o SEP-PAK g/L creatinine	with SEP-PAK g/L creatinine
Acid	1.09	1.09	1.08	1.09
Acid	1.10	1.10	1.09	1.10
Acid	.....	.....	1.09	1.09
Untreated	1.13	1.14	1.09	1.11
Untreated	1.15	1.14	1.10	1.10

STORAGE DATA—Continued

Sample	4 days		54 days	
	w/o SEP-PAK g/L creatinine	with SEP-PAK g/L creatinine	w/o SEP-PAK g/L creatinine	with SEP-PAK g/L creatinine
Untreated	.....	.....	1.09	1.10
pH 7	1.14	1.13	1.12	1.12
pH 7	1.14	1.13	1.12	1.12
pH 7	.....	.....	1.12	1.12

2.6. Interferences

None.

2.7. Safety precautions

2.7.1. Make sure samples are properly sealed and frozen before shipment to avoid leakage.

2.7.2. Follow the appropriate shipping procedures.

The following modified special safety precautions are based on those recommended by the Centers for Disease Control (CDC) (Ref. 5.8.). and OSHA's Bloodborne Pathogens standard (29 CFR 1910.1039)."

2.7.3. Wear gloves, lab coat, and safety glasses while handling all human urine products. Disposable plastic, glass, and paper (pipet tips, gloves, etc.) that contact urine should be placed in a biohazard autoclave bag.

These bags should be kept in appropriate containers until sealed and autoclaved. Wipe down all work surfaces with 10% sodium hypochlorite solution when work is finished.

2.7.4. Dispose of all biological samples and diluted specimens in a biohazard autoclave bag at the end of the analytical run.

2.7.5. Special care should be taken when handling and dispensing nitric acid. Always remember to add acid to water (or urine). Nitric acid is a corrosive chemical capable of severe eye and skin damage. Wear metal-free gloves, a lab coat, and safety glasses. If the nitric acid comes in contact with any part of the body, quickly wash with copious quantities of water for at least 15 minutes.

2.7.6. Special care should be taken when handling and dispensing NaOH. Always remember to add base to water (or urine). NaOH can cause severe eye and skin damage. Always wear the appropriate gloves, a lab coat, and safety glasses. If the NaOH comes in contact with any part of the body, quickly wash with copious quantities of water for at least 15 minutes.

3. Analytical procedure

3.1. Apparatus

3.1.1. A high performance liquid chromatograph equipped with pump, sample injector and UV detector.

3.1.2. A C18 HPLC column; 25 cm x 4.6 mm I.D.

3.1.3. An electronic integrator, or some other suitable means of determining analyte response.

3.1.4. Stripchart recorder.

3.1.5. C18 SEP-PAKs (Waters Associates) or equivalent.

3.1.6. Luer-lock syringe for sample preparation (5 mL or 10 mL).

3.1.7. Volumetric pipettes and flasks for standard and sample preparation.

3.1.8. Vacuum system to aid sample preparation (optional).

3.2. Reagents

3.2.1. Water, HPLC grade.

3.2.2. Methanol, HPLC grade.

3.2.3. PIC B–7® (Waters Associates) in small vials.

3.2.4. Creatinine, anhydrous, Sigma Chemical Corp., purity not listed.

3.2.5. 1–Heptanesulfonic acid, sodium salt monohydrate.

3.2.6. Phosphoric acid.

3.2.7. Mobile phase. It can be prepared by mixing one vial of PIC B–7 into a 1 L solution of 50% methanol and 50% water. The mobile phase can also be made by preparing a solution that is 50% methanol and 50% water with 0.005M heptanesulfonic acid and adjusting the pH of the solution to 3.5 with phosphoric acid.

3.3. Standard preparation

3.3.1. Stock standards are prepared by weighing 10 to 15 mg of creatinine. This is transferred to a 25-mL volumetric flask and diluted to volume with HPLC grade water.

3.3.2. Dilutions to a working range of 3 to 35 µg/mL are made in either HPLC grade water or HPLC mobile phase (standards give the same detector response in either solution).

3.4. Sample preparation

3.4.1. The C18 SEP-PAK is connected to a Luer-lock syringe. It is rinsed with 5 mL HPLC grade methanol and then 10 mL of HPLC grade water. These rinses are discarded.

3.4.2. Exactly 1.0 mL of urine is pipetted into the syringe. The urine is put through the SEP-PAK into a suitable container using a vacuum system.

3.4.3. The walls of the syringe are rinsed in several stages with a total of approximately 30 mL of HPLC grade water. These rinses are put through the SEP-PAK into the same container. The resulting solution is transferred to a 100-mL volumetric flask and then brought to volume with HPLC grade water.

3.5. Analysis (conditions and hardware are those used in this evaluation.)

3.5.1. Instrument conditions

Column: Zorbax® ODS, 5–6 µm particle size; 25 cm x 4.6 mm I.D.

Mobile phase: See Section 3.2.7.

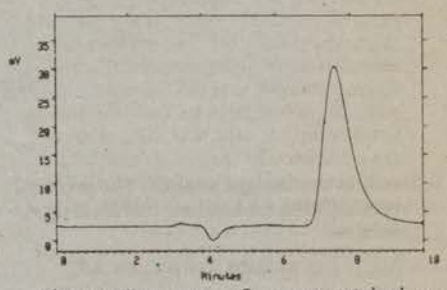
Detector: Dual wavelength UV; 229 nm (primary) 254 nm (secondary)

Flow rate: 0.7 mL/ minute

Retention time: 7.2 minutes

Sensitivity: 0.05 AUFS

Injection volume: 20µl



Chromatogram of a creatinine standard

Figure #2

3.6. Interferences

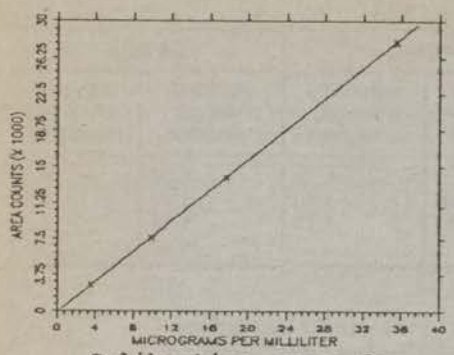
3.6.1. Any compound that has the same retention time as creatinine and absorbs at 229 nm is an interference.

3.6.2. HPLC conditions may be varied to circumvent interferences. In addition, analysis at another UV wavelength (i.e. 254 nm) would allow a comparison of the ratio of response of a standard to that of a sample. Any deviations would indicate an interference.

3.7. Calculations

3.7.1. A calibration curve is constructed by plotting detector response versus standard concentration (See Figure #3).

3.7.2. The concentration of creatinine in a sample is determined by finding the concentration corresponding to its detector response. (See Figure #3).



Calibration curve for creatinine
Figure #3

3.7.3. The µg/mL creatinine from section 3.7.2. is then multiplied by 100 (the dilution factor). This value is equivalent to the micrograms of creatinine in the 1.0 mL stabilized urine aliquot or the milligrams of creatinine per liter of urine. The desired units, g/L, is determined by the following relationship:

$$g/L = \frac{\mu g/mL}{1000} = \frac{mg/L}{1000}$$

3.7.4. The resulting value for creatinine is used to normalize the urinary concentration of the desired analyte (A) (Cd or B2M) by using the following formula.

$$\mu g\ A/g\ creatinine = \frac{\mu g\ A/L\ (experimental)}{g/L\ creatinine}$$

Where A is the desired analyte. The protocol of reporting such normalized results is µg A/g creatinine.

3.8. Safety precautions See section 2.7.

4. Conclusions

The determination of creatinine in urine by HPLC is a good alternative to the Jaffe method for industrial hygiene laboratories. Sample clarification with SEP–PAKs did not change the amount of creatinine found in urine samples. However, it does protect the analytical column. The results of this creatinine in urine procedure are unaffected by the pH of the urine sample under the conditions tested by this procedure. Therefore, no special measures are required for creatinine analysis whether the urine sample has been stabilized with 10% nitric acid for the Cd analysis or brought to a pH of 7 with 0.11 N NaOH for the B2M analysis.

5. References

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Signed at Washington, DC, this 13th day of April, 1993.

David Zeigler,

Acting Assistant Secretary of Labor.

[FR Doc. 93–9035 Filed 4–22–93; 8:45 am]

BILLING CODE 4510–26–P

federal register

Friday
April 23, 1993

Part III

Department of Agriculture

Cooperative State Research Service

7 CFR Part 3401

Rangeland Research Grants Program; Administrative Provisions; Rule

DEPARTMENT OF AGRICULTURE

Cooperative State Research Service

7 CFR Part 3401

Rangeland Research Grants Program; Administrative Provisions

AGENCY: Cooperative State Research Service, USDA.

ACTION: Final rule; amendment.

SUMMARY: This final rule amends the Cooperative State Research Service (CSRS) regulations relating to the administration of the Rangeland Research Grants Program, which prescribe the procedures to be followed annually in the solicitation of rangeland research grant proposals, the evaluation of such proposals, and the award of rangeland research grants under this program. This rule sets out formally provisions of the Special Research Grants administrative provisions, that, formerly, were only referenced in the Rangeland Research Grants Program regulations. This rule also includes changes similar to those made to the Special Research Grants Program regulations published on November 15, 1991. In this regard, this rule amends the regulations by indicating that the proposal evaluation criteria contained in these regulations apply unless otherwise stated in the annual program solicitation, by providing for an increased avenue for publication of requests for grant proposals, by providing for the grant document to state the conditions under which a grantee may approve changes to an approved budget, by indicating that the format for research grant proposals applies unless otherwise stated in the program solicitation, by adding references to applicable regulations pertaining to lobbying, debarment and suspension (nonprocurement), debt collection, CSRS implementation of the National Environmental Policy Act, and drug-free workplace, and by making a few additional changes.

EFFECTIVE DATE: April 23, 1993.

FOR FURTHER INFORMATION CONTACT: Terry J. Pacovsky, Director, Awards Management Division, Office of Grants and Program Systems, Cooperative State Research Service, United States Department of Agriculture, room 322, Aerospace Center, Washington, DC 20250–2200. (Telephone (202) 401–5024).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction

The Office of Management and Budget has previously approved the information collection requirements contained in the current regulations at 7 CFR part 3401 under the provisions of 44 U.S.C. chapter 35 and OMB Document No. 0524–0022 has been assigned. Public reporting burden for the information collections contained in these regulations is estimated to vary from ½ hour to 3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, room 404–W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB Document No. 0524–0022), Washington, DC 20503.

Classification

This rule has been reviewed under Executive Order 12291, and it has been determined that it is not a major rule because it does not involve a substantial or major impact on the Nation's economy or on large numbers of individuals or businesses. There will be no major increase in cost or prices for consumers, individual industries, Federal, State, or local governmental agencies, or on geographical regions. It will not have a significant economic impact on competitive employment, investment, productivity, innovation, or on the ability of United States enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, it will not have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Public Law 96–534 (5 U.S.C. 601 *et seq.*).

Regulatory Analysis

Not required for this rulemaking.

Environmental Impact Statement

This regulation does not significantly affect the environment.

Therefore, an environmental impact statement is not required under the National Environmental Policy Act of 1969, as amended. (42 U.S.C. 4321 *et seq.*)

Catalog of Federal Domestic Assistance

The Rangeland Research Grant Program is listed in the Catalog of Federal Domestic Assistance under No. 10.200. For reasons set forth in the Final Rule-related Notice to 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1993), this program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Background and Purpose

Under the authority of section 1480 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended, the Secretary of Agriculture is authorized to make grants to land-grant colleges and universities, State agricultural experiment stations, and colleges, universities, and Federal laboratories having a demonstrable capacity in rangeland research, as determined by the Secretary, to carry out rangeland research. 7 CFR 2.107(a)(28) delegates this authority to the Administrator of CSRS. In the past, the Rangeland Research Program regulations, 7 CFR part 3401, to a substantial extent, referenced provisions from the Special Research Grant Program regulations, 7 CFR part 3400. 7 CFR part 3400 was amended on November 15, 1991 (56 FR 58146). CSRS now amends the administrative regulations governing the Rangeland Research Grant Program authorized by section 1480 through the formulation of separate regulations for this program. CSRS accomplishes this by replacing § 3401.2 and adding §§ 3401.6 through 3401.17. In addition to setting out fully the provisions of 7 CFR part 3400 that formerly were referenced, the changes herein also reflect changes similar to those made to 7 CFR part 3400 on November 15, 1991.

On November 4, 1992, the Department published a Notice in the **Federal Register** (57 FR 52688–52695) proposing the amendment of this Rule and inviting comments from interested individuals and organizations. Written comments were requested by December 4, 1992. No comments were received. CSRS has made additional minor changes to the proposed rule published in the **Federal Register** on November 4, 1992. These additional changes are of a clarifying or clerical nature.

List of Subjects in 7 CFR Part 3401

Agricultural research, Grant programs—agriculture, Grants administration, Range management, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, title 7, subtitle B, chapter XXXIV, part 3401 of the Code of Federal Regulations, is revised to read as follows:

PART 3401—RANGELAND RESEARCH GRANTS PROGRAM

Subpart A—General

Sec.
3401.1 Applicability of regulations of this part.
3401.2 Definitions.
3401.3 Eligibility requirements.
3401.4 Matching funds requirement.
3401.5 Indirect costs and tuition remission costs.
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3401.8 Grant awards.
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Subpart B—Scientific Peer Review of Research Applications for Funding

3401.12 Establishment and operation of peer review groups.
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3401.15 Availability of information.
3401.16 Proposal review.
3401.17 Review criteria.

Authority: 7 U.S.C. 3316.

Subpart A—General

§3401.1 Applicability of regulations of this part.

(a) The regulations of this part apply to rangeland research grants awarded under the authority of section 1480 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3333) to land-grant colleges and universities, State agricultural experiment stations, and colleges, universities, and Federal laboratories having a demonstrable capacity in rangeland research, as determined by the Secretary, to carry out rangeland research. The Administrator of the Cooperative State Research Service (CSRS) shall determine and announce, through publication each year of a Notice in the Federal Register, professional trade journals, agency or program handbooks, the Catalog of Federal Domestic Assistance or any other appropriate means, research program areas for which proposals will be solicited, to the extent that funds are available.

(b) The regulations of this Part do not apply to research grants awarded by the Department of Agriculture under any other authority.

§3401.2 Definitions.

As used in this part:

(a) *Administrator* means the Administrator of CSRS and any other officer or employee of the Department of Agriculture to whom the authority involved may be delegated.

(b) *Department* means the Department of Agriculture.

(c) *Principal investigator* means a single individual designated by the grantee in the grant application and approved by the Administrator who is responsible for the scientific and technical direction of the project.

(d) *Grantee* means the entity designated in the grant award document as the responsible legal entity to whom a grant is awarded under this Part.

(e) *Research project grant* means the award by the Administrator of funds to a grantee to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to establish, discover, elucidate, or confirm information or the underlying mechanisms relating to a research program area identified in the annual solicitation of applications.

(f) *Project* means the particular activity within the scope of one or more of the research program areas identified in the annual solicitation of applications, which is supported by a grant award under this Part.

(g) *Project period* means the total length of time that is approved by the Administrator for conducting the research project as outlined in an approved grant application.

(h) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(i) *Awarding official* means the Administrator and any other officer or employee of the Department to whom the authority to issue or modify research project grant instruments has been delegated.

(j) *Peer review group* means an assembled group of experts or consultants qualified by training or experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this Part, on the scientific and technical merit of grant applications in those fields.

(k) *Ad hoc reviewers* means experts or consultants qualified by training or experience in particular scientific or technical fields to render special expert advice, whose written evaluations of grant applications are designed to complement the expertise of the peer review group, in accordance with the provisions of this Part, on the scientific or technical merit of grant applications in those fields.

(l) *Research* means any systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(m) *Methodology* means the project approach to be followed and the resources needed to carry out the project.

§3401.3 Eligibility requirements.

(a) Except where otherwise prohibited by law, any land-grant college or university, State agricultural experiment station, and any college, university, or Federal laboratory having a demonstrable capacity in rangeland research, as determined by the Secretary, shall be eligible to apply for and to receive a project grant under this Part, provided that the applicant qualifies as a responsible grantee under the criteria set forth in paragraph (b) of this section.

(b) To qualify as responsible, an applicant must meet the following standards as they relate to a particular project:

(1) Have adequate financial resources for performance, the necessary experience, organizational and technical qualifications, and facilities, or a firm commitment, arrangement, or ability to obtain such (including proposed subagreements);

(2) Be able to comply with the proposed or required completion schedule for the project;

(3) Have a satisfactory record of integrity, judgment, and performance, including, in particular, any prior performance under grants and contracts from the Federal government;

(4) Have an adequate financial management system and audit procedure which provides efficient and effective accountability and control of all property, funds, and other assets; and

(5) Be otherwise qualified and eligible to receive a research project grant under applicable laws and regulations.

(c) Any applicant who is determined to be not responsible will be notified in writing of such findings and the basis therefor.

§3401.4 Matching funds requirement.

In accordance with section 1480 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3333), except in the case of Federal laboratories, each grant recipient must match the Federal funds expended on a research project based on a formula of 50 percent Federal and 50 percent non-Federal funding.

§3401.5 Indirect costs and tuition remission costs.

Pursuant to section 1473 of the National Agricultural Research, Extension, and Teaching Policy Act of

1977, as amended (7 U.S.C. 3319), funds made available under this program to recipients other than Federal laboratories shall not be subject to reduction for indirect costs or tuition remission costs. Since indirect costs and tuition remission costs, except in the case of Federal laboratories, are not allowable costs for purposes of this program, such costs may not be used to satisfy the matching requirement set forth in § 3401.4.

§ 3401.6 How to apply for a grant.

(a) *General.* After consultation with the Rangeland Research Advisory Board, established pursuant to section 1482 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (7 U.S.C. 3335), a request for proposals will be prepared and announced through publications such as the **Federal Register**, professional trade journals, agency or program handbooks, the Catalog of Federal Domestic Assistance, or any other appropriate means of solicitation, as early as practicable each fiscal year. It will contain information sufficient to enable all eligible applicants to prepare rangeland research grant proposals and will be as complete as possible with respect to:

(1) Descriptions of specific research program areas which the Department proposes to support during the fiscal year involved, including anticipated funds to be awarded;

(2) Deadline dates for having proposal packages postmarked;

(3) Name and address where proposals should be mailed;

(4) Number of copies to be submitted;

(5) Forms required to be used when submitting proposals; and

(6) Special requirements.

(b) *Application kit.* An Application Kit will be made available to any potential grant applicant who requests a copy. This kit contains required forms, certifications, and instructions applicable to the submission of grant proposals.

(c) *Format for research grant proposals.* Unless otherwise stated in the specific program solicitation, the following format applies:

(1) *Application for funding.* All research grant proposals submitted by eligible applicants should contain an Application for Funding form, which must be signed by the proposing principal investigator(s) and endorsed by the cognizant authorized organizational representative who possesses the necessary authority to commit the applicant's time and other relevant resources.

(2) *Title of project.* The title of the project must be brief (80-character maximum), yet represent the major thrust of the research. This title will be used to provide information to the Congress and other interested parties who may be unfamiliar with scientific terms; therefore, highly technical words or phraseology should be avoided where possible. In addition, phrases such as "investigation of" or "research on" should not be used.

(3) *Objectives.* Clear, concise, complete, enumerated, and logically arranged statement(s) of the specific aims of the research must be included in all proposals.

(4) *Procedures.* The procedures or methodology to be applied to the proposed research plan should be stated explicitly. This section of the grant proposal should include but not necessarily be limited to:

(i) A description of the proposed investigations and/or experiments in the sequence in which it is planned to carry them out;

(ii) Techniques to be employed, including their feasibility;

(iii) Kinds of results expected;

(iv) Means by which data will be analyzed or interpreted;

(v) Pitfalls which might be encountered; and

(vi) Limitations to proposed procedures.

(5) *Justification.* This section of the grant proposal should describe:

(i) The importance of the problem to the needs of the Department and to the Nation, including estimates of the magnitude of the problem;

(ii) The importance of starting the work during the current fiscal year; and

(iii) Reasons for having the work performed by the proposing organization.

(6) *Literature review.* A summary of pertinent publications with emphasis on their relationship to the research should be provided and should include all important and recent publications. The citations should be accurate, complete, written in acceptable journal format, and be appended to the proposal.

(7) *Current research.* The relevancy of the proposed research to ongoing and, as yet, unpublished research of both the applicant and any other institutions should be described.

(8) *Facilities and equipment.* All facilities, including laboratories, that are available for use or assignment to the proposed research project during the requested period of support, should be reported and described. Any materials, procedures, situations, or activities, whether or not directly related to a particular phase of the proposed research, and which may be hazardous to personnel, must be explained fully, along with an outline of precautions to be exercised. All items of major instrumentation available for use or assignment to the proposed research project during the requested period of support should be itemized. In addition, items of nonexpendable equipment needed to conduct and bring the proposed project to a successful conclusion should be listed.

(9) *Collaborative arrangements.* If the proposed project requires collaboration with other research scientists, corporations, organizations, agencies, or entities, such collaboration must be explained fully and justified. Evidence should be provided to assure peer reviewers that the collaborators involved agree with the arrangements. It should be specifically indicated whether or not such collaborative arrangements have the potential for any conflict(s) of interest. Proposals which indicate collaborative involvement must state which applicant is to receive any resulting grant award, since only one eligible applicant, as provided in § 3401.3, may be the recipient of a research project grant under one proposal.

(10) *Research timetable.* The applicant should outline all important research phases as a function of time, year by year.

(11) *Personnel support.* All personnel who will be involved in the research effort must be identified clearly. For each scientist involved, the following should be included:

(i) An estimate of the time commitments necessary;

(ii) Vitae of the principal investigator(s), senior associate(s), and other professional personnel to assist reviewers in evaluating the competence and experience of the project staff. This section should include curricula vitae of *all* key persons who will work on the proposed research project, whether or not Federal funds are sought for their support. The vitae are to be no more than two pages each in length, excluding publication listings; and

(iii) A chronological listing of the most representative publications during the past five years shall be provided for each professional project member for whom a curriculum vitae appears under this section. Authors should be listed in the same order as they appear on each paper cited, along with the title and complete reference as these usually appear in journals.

(12) *Budget.* A detailed budget is required for each year of requested support. In addition, a summary budget is required detailing requested support

for the overall project period. A copy of the form which must be used for this purpose, along with instructions for completion, is included in the Application Kit identified under § 3401.6(b) and may be reproduced as needed by applicants. Funds may be requested under any of the categories listed, provided that the item or service for which support is requested is allowable under applicable Federal cost principles and can be identified as necessary for successful conduct of the proposed research project. As stated in § 3401.4 each grant recipient must match the Federal funds expended on a research project based on a formula of 50 percent Federal and 50 percent non-Federal funding. As stated in § 3401.5, indirect costs and tuition remission costs are not allowable costs for purposes of this program and, thus, may not be used to satisfy the matching requirement set forth in § 3401.4.

(13) *Research involving special considerations.* A number of situations encountered in the conduct of research require special information and supporting documentation before funding can be approved for the project. If such situations are anticipated, the proposal must so indicate. It is expected that a significant number of rangeland research grant proposals will involve the following:

(i) *Recombinant DNA molecules.* All key personnel identified in a proposal and all endorsing officials of a proposed performing entity are required to comply with the guidelines established by the National Institutes of Health entitled, "Guidelines for Research Involving Recombinant DNA Molecules," as revised. The Application Kit, identified in § 3401.6(b), contains forms which are suitable for such certification of compliance.

(ii) *Human subjects at risk.* Responsibility for safeguarding the rights and welfare of human subjects used in any research project supported with grant funds provided by the Department rests with the performing entity. Regulations have been issued by the Department under 7 CFR part 1c, Protection of Human Subjects. In the event that a project involving human subjects at risk is recommended for award, the applicant will be required to submit a statement certifying that the research plan has been reviewed and approved by the Institutional Review Board at the proposing organization or institution. The Application Kit, identified in § 3401.6(b), contains forms which are suitable for such certification.

(iii) *Laboratory animal care.* The responsibility for the humane care and treatment of any laboratory animal, which has the same meaning as "animal" in section 2(g) of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2132(g)), used in any research project supported with Rangeland Research Grant Program funds rests with the performing organization. In this regard, all key personnel identified in a proposal and all endorsing officials of the proposed performing entity are required to comply with the applicable provisions of the Animal Welfare Act of 1966, as amended (7 U.S.C. 2131 *et seq.*) and the regulations promulgated thereunder by the Secretary of Agriculture in 9 CFR parts 1, 2, 3, and 4. In the event that a project involving the use of a laboratory animal is recommended for award, the applicant will be required to submit a statement certifying such compliance. The Application Kit, identified in § 3401.6(b), contains forms which are suitable for such certification.

(14) *Current and pending support.* All proposals must list any other current public or private research support, in addition to the proposed project, to which key personnel listed in the proposal under consideration have committed portions of their time, whether or not salary support for the person(s) involved is included in the budgets of the various projects. This section must also contain analogous information for all projects underway and for pending research proposals which are currently being considered by, or which will be submitted in the near future to, other possible sponsors, including other Departmental programs or agencies. Concurrent submission of identical or similar projects to other possible sponsors will not prejudice its review or evaluation by the Administrator or experts or consultants engaged by the Administrator for this purpose. The Application Kit, identified in § 3401.6(b), contains a form which is suitable for listing current and pending support.

(15) *Additions to project description.* Each project description is expected by the Administrator, members of peer review groups, and the relevant program staff to be complete in itself. However, in those instances in which the inclusion of additional information is necessary, the number of copies submitted should match the number of copies of the application requested in the annual solicitation of proposals as indicated in § 3401.6(a)(4). Each set of such materials must be identified with the title of the research project as it appears in the Application for Funding and the name(s) of the principal investigator(s). Examples of additional materials may include photographs which do not reproduce well, reprints, and other pertinent materials which are deemed to be unsuitable for inclusion in the proposal.

(16) *Organizational management information.* Specific management information relating to an applicant shall be submitted on a *one-time basis prior to the award of a research project grant* identified under this part if such information has not been provided previously under this or another program for which the sponsoring agency is responsible. Copies of forms recommended for use in fulfilling the requirements contained in this section will be provided by the agency specified in this part once a research project grant has been recommended for funding.

§ 3401.7 Evaluation and disposition of applications.

(a) *Evaluation.* All proposals received from eligible applicants in accordance with eligible research problem or program areas and deadlines established in the applicable request for proposals shall be evaluated by the Administrator through such officers, employees, and others as the Administrator determines are particularly qualified in the areas of research represented by particular projects. To assist in equitably and objectively evaluating proposals and to obtain the best possible balance of viewpoints, the Administrator may solicit the advice of peer scientists, *ad hoc* reviewers, or others who are recognized specialists in the research program areas covered by the applications received. Specific evaluations will be based upon the criteria established in subpart B of this part, § 3401.17, unless CSRS determines that different criteria are necessary for the proper evaluation of proposals in one or more specific program areas, and announces such criteria and their relative importance in the annual program solicitation. The overriding purpose of such evaluations is to provide information upon which the Administrator can make informed judgments in selecting proposals for ultimate support. Incomplete, unclear, or poorly organized applications will work to the detriment of applicants during the peer evaluation process. To ensure a comprehensive evaluation, all applications should be written with the care and thoroughness accorded papers for publication.

(b) *Disposition.* On the basis of the Administrator's evaluation of an application in accordance with paragraph (a) of this section, the Administrator will: Approve support using currently available funds; defer support due to lack of funds or a need

for further evaluations; or disapprove support for the proposed project in whole or in part. With respect to approved projects, the Administrator will determine the project period (subject to extension as provided in § 3401.9(c)) during which the project may be supported. Any deferral or disapproval of an application will not preclude its reconsideration or a reapplication during subsequent fiscal years.

§ 3401.8 Grant awards.

(a) *General.* Within the limit of funds available for such purpose, the awarding official shall make research project grants to those responsible, eligible applicants whose proposals are judged most meritorious in the announced program areas under the evaluation criteria and procedures set forth in this part. The date specified by the Administrator as the beginning of the project period shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. All funds granted under this part shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations of this Part, the terms and conditions of the award, the applicable Federal cost principles, and the Department's "Uniform Federal Assistance Regulations" (part 3015 of this title).

(b) *Grant award document and notice of grant award*—(1) *Grant award document.* The grant award document shall include at a minimum the following:

(i) Legal name and address of performing organization or institution to whom the Administrator has awarded a rangeland research project grant under the terms of this part;

(ii) Title of project;

(iii) Name(s) and address(es) of principal investigator(s) chosen to direct and control approved activities;

(iv) Identifying grant number assigned by the Department;

(v) Project period, which specifies how long the Department intends to support the effort without requiring recompetition for funds;

(vi) Total amount of Departmental financial assistance approved by the Administrator during the project period;

(vii) Legal authority(ies) under which the research project grant is awarded to accomplish the purpose of the law;

(viii) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the research project grant award; and

(ix) Other information or provisions deemed necessary by the Department to carry out its granting activities or to accomplish the purpose of a particular research project grant.

(2) *Notice of grant award.* The notice of grant award, in the form of a letter, will be prepared and will provide pertinent instructions or information to the grantee that is not included in the grant award document.

(c) *Categories of grant instruments.* The major categories of grant instruments by which the Department may provide support are as follows:

(1) *Standard grant.* This is a grant instrument by which the Department agrees to support a specified level of research effort for a predetermined project period without the announced intention of providing additional support at a future date. This type of research project grant is approved on the basis of peer review and recommendation and is funded for the entire project period at the time of award.

(2) *Renewal grant.* This is a document by which the Department agrees to provide additional funding under a standard grant as specified in paragraph (c)(1) of this section for a project period beyond that approved in an original or amended award, provided that the cumulative period does not exceed the statutory limitation. When a renewal application is submitted, it should include a summary of progress to date under the previous grant instrument. Such a renewal shall be based upon new application, *de novo* peer review and staff evaluation, new recommendation and approval, and a new award instrument.

(3) *Continuation grant.* This is a grant instrument by which the Department agrees to support a specified level of effort for a predetermined period of time with a statement of intention to provide additional support at a future date, provided that performance has been satisfactory, appropriations are available for this purpose, and continued support would be in the best interests of the Federal government and the public. It involves a long-term research project that is considered by peer reviewers and Departmental officers to have an unusually high degree of scientific merit, the results of which are expected to have a significant impact on the productivity of the Nation's rangelands, and its supports the efforts of experienced scientists with records of outstanding research accomplishments. This kind of document normally will be awarded for an initial one-year period and any subsequent continuation research project grants also will be awarded in one-year increments, but in no case may the cumulative period of the project exceed the statutory limit. The award of a continuation research project grant to fund an initial or succeeding budget period does not constitute an obligation to fund any subsequent budget period. A grantee must submit a separate application for continued support for each subsequent fiscal year. Requests for such continued support must be submitted in duplicate at least three months prior to the expiration date of the budget period currently being funded. Such requests must include: an interim progress report detailing all work performed to date; an Application for Funding; a proposed budget for the ensuing period, including an estimate of funds anticipated to remain unobligated at the end of the current budget period; and current information regarding other extramural support for senior personnel. Decisions regarding continued support and the actual funding levels of such support in future years usually will be made administratively after consideration of such factors as the grantee's progress and management practices and within the context of available funds. Since initial peer reviews were based upon the full term and scope of the original rangeland research grant application, additional evaluations of this type generally are not required prior to successive years' support. However, in unusual cases (e.g., when the nature of the project or key personnel change or when the amount of future support requested substantially exceeds the grant application originally reviewed and approved), additional reviews may be required prior to approval of continued funding.

(4) *Supplemental grant.* This is an instrument by which the Department agrees to provide small amounts of additional funding under a standard, renewal, or continuation grant as specified in paragraphs (c)(1), (c)(2), and (c)(3) of this section and may involve a short-term (usually six months or less) extension of the project period beyond that approved in an original or amended award, but in no case may the cumulative period of the project, including short term extensions, exceed the statutory time limitation. A supplement is awarded only if required to assure adequate completion of the original scope of work and if there is sufficient justification of need to warrant such action. A request of this nature normally does not require additional peer review.

(d) *Obligation of the Federal government.* Neither the approval of any application nor the award of any research project grant shall commit or obligate the United States in any way to make any renewal, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 3401.9 Use of funds; changes.

(a) *Delegation of fiscal responsibility.* The grantee may not delegate or transfer in whole or in part, to another person, institution, or organization the responsibility for use or expenditure of grant funds.

(b) *Change in project plans.* (1) The permissible changes by the grantee, principal investigator(s), or other key project personnel in the approved research project grant shall be limited to changes in methodology, techniques, or other aspects of the project to expedite achievement of the projects' approved goals. If the grantee or the principal investigator(s) is uncertain as to whether a change complies with this provision, the question shall be referred to the Administrator for a final determination.

(2) Changes in approved goals, or objectives, shall be requested by the grantee and approved in writing by the Department *prior to effecting such changes.* In no event shall requests for such changes be approved which are outside the scope of the original approved project.

(3) Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and approved in writing by the Department *prior to effecting such changes.*

(4) Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the grantee and approved in writing by the Department *prior to effecting such changes,* except as may be allowed in the terms and conditions of a grant award.

(c) *Changes in project period.* The project period determined pursuant to § 3401.7(b) may be extended by the Administrator without additional financial support, for such additional period(s) as the Administrator determines may be necessary to complete, or fulfill the purposes of, an approved project. Any extension, when combined with the originally approved or amended project period, shall be conditioned upon prior request by the grantee and approval in writing by the Department, unless prescribed otherwise in the terms and conditions of a grant award.

(d) *Changes in approved budget.* The terms and conditions of a grant will prescribe circumstances under which written Departmental approval will be requested and obtained prior to instituting changes in an approved budget.

§ 3401.10 Other Federal statutes and regulations that apply.

Several other Federal statutes and/or regulations apply to grant proposals considered for review or to research project grants awarded under this part. These include but are not limited to:

7 CFR Part 1c—USDA implementation of the Federal Policy for the Protection of Human Subjects;

7 CFR Part 1.1—USDA implementation of Freedom of Information Act;

7 CFR Part 3—USDA implementation of OMB Circular A-129 regarding debt collection;

7 CFR Part 15, Subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964;

7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., Circular Nos. A-110, A-21, and A-122) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly, the Federal Grant and Cooperative Agreement Act of 1977), as well as general policy requirements applicable to recipients of Departmental financial assistance;

7 CFR Part 3017—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants);

7 CFR Part 3018—USDA implementation of New Restrictions on Lobbying. Imposes new prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans;

7 CFR Part 3407—CSRS procedures to implement the National Environmental Policy Act;

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15b (USDA implementation of statute)—prohibiting discrimination based upon physical or mental handicap in Federally assisted programs; and

35 U.S.C. 200 *et seq.*—Bayh-Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR part 401).

§ 3401.11 Other conditions.

The Administrator may, with respect to any research project grant or to any class of awards, impose additional conditions prior to or at the time of any award when, in the Administrator's judgment, such conditions are necessary to assure or protect advancement of the approved project, the interests of the public, or the conservation of grant funds.

Subpart B—Scientific Peer Review of Research Applications for Funding

§ 3401.12 Establishment and operation of peer review groups.

Subject to § 3401.7, the Administrator will adopt procedures for the conduct of peer reviews and the formulation of recommendations under § 3401.16.

§ 3401.13 Composition of peer review groups.

Peer review group members will be selected based upon their training or experience in relevant scientific or technical fields, taking into account the following factors:

(a) The level of formal scientific or technical education by the individual;

(b) The extent to which the individual has engaged in relevant research, the capacities in which the individual has done so (e.g., principal investigator, assistant), and the quality of such research;

(c) Professional recognition as reflected by awards and other honors received from scientific and professional organizations outside of the Department;

(d) The need of the group to include within its membership experts from various areas of specialization within relevant scientific or technical fields;

(e) The need of the group to include within its membership experts from a variety of organizational types (e.g., universities, industry, private consultant(s)) and geographic locations; and

(f) The need of the group to maintain a balanced membership, e.g., minority and female representation and an equitable age distribution.

§ 3401.14 Conflicts of interest.

Members of peer review groups covered by this part are subject to relevant provisions contained in title 18 of the United States Code relating to criminal activity, Department regulations governing employee responsibilities and conduct (part O of this title), and Executive Order 11222 (3 CFR, 1964-1965 Comp., p. 306), as amended.

§ 3401.15 Availability of information.

Information regarding the peer review process will be made available to the extent permitted under the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a.), and implementing Departmental regulations (part 1 of this title).

§ 3401.16 Proposal review.

(a) All research Applications for Funding will be acknowledged. Prior to technical examination, a preliminary review will be made for responsiveness to the request for proposals (e.g., relationship of application to research program area). Proposals that do not fall within the guidelines as stated in the annual request for proposals will be eliminated from competition and will be returned to the applicant. Proposals whose budgets exceed the maximum allowable amount for a particular program area as announced in the request for proposals may be considered as lying outside the guidelines.

(b) All applications will be reviewed carefully by the Administrator, qualified officers or employees of the Department, the respective peer review panel, and *ad hoc* reviewers, as required. Written comments will be solicited from *ad hoc* reviewers when required, and individual written comments and in-depth discussions will be provided by peer review group members prior to recommending applications for funding. Applications will be ranked and support levels recommended within the limitation of total available funding for each research program area as announced in the applicable request for proposals.

(c) Except to the extent otherwise provided by law, such recommendations are advisory only and are not binding on program officers or on the awarding official.

§ 3401.17 Review criteria.

(a) Federally funded research supported under these provisions shall be designed to, among other things, accomplish one or more of the following purposes:

(1) Improve management of rangelands and agricultural land as integrated systems for more efficient utilization of crops and waste products in the production of food and fiber;

(2) Improve methods of managing rangeland watersheds to maximize efficient use of water, improve water quality, and water conservation, to protect against onsite and offsite damage to rangeland resources from floods, erosion, and other detrimental influences, and to remedy unsatisfactory and unstable rangeland conditions;

(3) Increase revegetation and rehabilitation of rangelands, including the control of undesirable species of plants;

(4) Continue to satisfy human food and fiber needs;

(5) Enhance the long-term viability and competitiveness of food production and agricultural system of the United States within the global economy;

(6) Expand economic opportunities in rural America and enhance the quality of life for farmers, ranchers, rural citizens, and society as a whole;

(7) Improve the productivity of the American agricultural system and develop new agricultural crops and new uses for agricultural commodities;

(8) Develop information and systems to enhance the environment and the natural resource base upon which a sustainable agricultural economy depends; or

(9) Enhance human health.

(b) In carrying out its review under § 3401.16, the peer review panel will use the following form upon which the evaluation criteria to be used are enumerated, unless, pursuant to § 3401.7(a), different evaluation criteria are specified in the annual solicitation of proposals for a particular program:

Peer Panel Scoring Form

Proposal Identification No. _____

Institution and Project Title _____

I. Basic Requirement:

Proposal falls within guidelines?

_____Yes_____No. If no, explain why proposal does not meet guidelines under comment section of this form.

II. Selection Criteria:

	Score 1–10	Weight factor	Score X weight factor	Comments
1. Overall scientific and technical quality of proposal		10		
2. Scientific and technical quality of the approach		10		
3. Relevance and importance of proposed research to solution of specific areas of inquiry		6		
4. Feasibility of attaining objectives; adequacy of professional training and experience, facilities and equipment		5		

Score_____

Summary Comments_____

(c) Proposals satisfactorily meeting the guidelines will be evaluated and scored by the peer review panel for each criterion utilizing a scale of 1 through 10. A score of one (1) will be considered low and a score of ten (10) will be considered high for each selection criterion. A weighted factor is used for each criterion.

Done at Washington, DC, this 15th day of April, 1993.

R. Dean Plowman,

Acting Assistant Secretary, Science and Education.

[FR Doc. 93–9257 Filed 4–22–93; 8:45 am]

BILLING CODE 3410-22-M

federal register

Friday
April 23, 1993

Part IV

Department of Education

34 CFR Parts 674 et al.

Federal Perkins Loan, Federal Work-Study, Federal Supplemental Educational Opportunity Grant, et al.; Rule

DEPARTMENT OF EDUCATION

34 CFR Parts 674, 675, 676, 682, and 690

Federal Perkins Loan, Federal Work-Study, Federal Supplemental Educational Opportunity Grant, Federal Family Education Loan Programs and Federal Pell Grant Program

AGENCY: Department of Education.

ACTION: Notice of waivers of specific statutory and regulatory provisions.

SUMMARY: The Secretary of Education announces specific waivers of statutory and regulatory provisions governing the Federal Pell Grant, Federal Perkins Loan, Federal Work-Study (FWS), Federal Supplemental Educational Opportunity Grant (FSEOG), and Federal Family Education Loan (FFEL) programs to assist individual applicants and recipients who suffer financial harm from natural disasters such as Hurricane Andrew, Hurricane Iniki, or Typhoon Omar.

ADDRESSES: The Secretary is interested in receiving public comment as to whether additional waivers or modifications should be granted to assist these individuals. Comments should be sent to Harold McCullough, Grants Branch, Policy Development Division, Policy, Training, and Analysis Service, U.S. Department of Education, 400 Maryland Avenue SW., (Regional Office Building 3, room 4018), Washington, DC 20202-5447.

FOR FURTHER INFORMATION CONTACT: Kathy S. Gause, Grants Branch, Policy Development Division, Policy, Service, U.S. Department of Education, 400 Maryland Avenue, SW., (Regional Office Building 3, room 4018), Washington, DC 20202–5447. Telephone (202) 708-4690. Hearing-impaired individuals may call the Federal Dual Party Relay Service at 1–800–7–8339 (in the Washington, DC 202 area code, telephone 708-9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: Many student financial aid applicants and recipients have been adversely affected by recent natural disasters. The Secretary has been granted authority by the Dire Emergency Supplemental Appropriations Act of 1992 (Pub. L. 102–368) to waive or modify any statutory or regulatory provisions applicable to the student financial aid programs under Title IV of the Higher Education Act of 1965, as amended (HEA) to assist these individuals.

The Title IV student financial aid programs affected by this notice are the FFEL Program (consisting of the Federal Stafford Loan Program, the Federal Supplemental Loans for Students [SLS] Program, the Federal PLUS Program, and the Federal Consolidated Loan Program); the Federal Pell Grant Program; and the Federal Perkins Loan, Federal Work-Study, and Federal Supplemental Educational Opportunity Grant programs (known collectively as the campus-based programs).

After Hurricane Andrew, which devastated south Florida and sections of Louisiana, the Department of Education was asked to waive certain due-diligence requirements for loan collection in the Federal Perkins Loan and FFEL programs for debtors residing in the affected areas. In response, the Secretary notified program participants that he would waive the telephone contact requirements in §§ 682.410 and 682.411 of the FFEL Program regulations and in § 674.43 of the Perkins Loan Program regulations. Lenders, guaranty agencies, and institutions of higher education were excused from making any effort at telephone contact with a delinquent or defaulted debtor who resided in areas codes 305 and 813 in Florida and area codes 504 and 318 in Louisiana who was subject to a regulatory due-diligence deadline falling between August 24 and October 15, 1992, inclusive. The Secretary also urged loan collectors to wait until after October 1 to attempt calls to debtors for whom a due-diligence deadline was October 16 or later.

This notice of waivers of statutory and regulatory provisions includes a reference to a requirement that loan proceeds be delivered to a borrower within 45 days from the school's receipt of an FFEL Program check. This has been a programmatic requirement for several years.

Covered Individuals

This notice is intended to assist individuals who suffer financial harm from natural disasters such as Hurricane Andrew, Hurricane Iniki, and Typhoon Omar. In regard to Hurricane Andrew, Hurricane Iniki, and Typhoon Omar, these waivers apply only to individuals who, at the time the disaster struck, were residing, attending an institution of higher education, or employed in south Florida or Louisiana, on the Island of Kauai in Hawaii, or in the Territory of Guam on the date on which the President declared the existence of a major disaster (or, in the case of an individual who is a dependent student, whose parent or stepparent suffered financial harm from such disaster and who resided or was employed in such an area at that time). For these individuals, this notice only affects awards made and collection activities conducted during the 1992–93 award year (the period from July 1, 1992—June 30, 1993). These waivers also will be applicable, during the 1992–93 award year, to any other individuals who, at the time a disaster strikes, reside, attend an institution of higher education, or are employed within the affected areas on the date on which the President declares the existence of a major disaster (or, in the case of an individual who is a dependent student, whose parent or stepparent suffers financial harm from such disaster and who resides or is employed in such an area at that time).

The Secretary believes that the following waivers of the statutes and regulations governing the student financial aid programs under Title IV of the HEA are necessary to carry out the purposes of Public Law 102–368:

I. 34 CFR Part 668—Student Assistance General Provisions

A. 34 CFR 668.19 Financial Aid Transcript

Under current regulations, before a student who previously attended another eligible institution may receive any Title IV, HEA program funds, the institution to which the student is transferring must make an effort to obtain the student's financial aid transcript. However, the Secretary has decided that to best achieve the purposes of Public Law 102–368, the requirement to obtain financial aid transcripts before disbursing funds is being waived for individuals covered by the law. If the financial aid transcript is not available as a result of damage caused by Hurricane Andrew, Hurricane Iniki, Typhoon Omar, or other natural disasters during the 1992–93 award year, the institution may disburse Title IV funds. The institution must document in the student's file that the financial aid transcript is unavailable due to damage stemming from the natural disaster.

B. 34 CFR 668.51—668.61 Selection of Applicants for Verification

The Secretary has decided to waive verification requirements under 34 CFR 668.51—668.61 during the 1992–93 award year for those applicants who are selected for verification and whose records were lost or destroyed because of Hurricane Andrew, Hurricane Iniki, Typhoon Omar, or other natural disasters. The institution must document in the student's file that the records are unavailable due to damage stemming from the natural disaster.

II. 34 CFR parts 674, 675, and 676—Federal Perkins Loan, FWS, and FSEOG Programs

A. Sections 462, 442, and 413D of the HEA—Allocation of Funds and 34 CFR 674.4, 675.4, and 676.4 Allocation and Reallocation

The Secretary has decided that to best achieve the purposes of Public Law 102-368, the Department will waive the applicable statutory and regulatory requirements and reallocate Federal Perkins Loans, FSEOG, and FWS program funds to institutions that are enrolling students who demonstrate additional financial need as a result of Hurricane Andrew, Hurricane Iniki, Typhoon Omar, or other natural disasters so designated in the future. Institutions have the authority to determine a student's cost of attendance under these three programs. If, in the judgment of the financial aid administrator, a student's financial need has been increased by a natural disaster, the financial aid administrator can make the necessary adjustments to reflect that need. The financial aid administrator must document in the student's file that the adjustment has been made and cite the reasons for making the adjustment.

B. 34 CFR 674.34, 674.35, and 674.36 Deferment of Repayment

Many Federal Perkins Loan, National Direct Student Loan, and National Defense Student Loan borrowers who suffered financial harm from Hurricane Andrew, Hurricane Iniki, or Typhoon Omar or suffer financial harm from another natural disaster can neither receive nor submit deferment forms. Therefore, to assist these borrowers, the Secretary has decided to permit institutions to grant administrative hardship deferments to any borrower who, at the time the disaster struck, was residing, attending an institution of higher education, or employed in south Florida or Louisiana, on the Island of Kauai in Hawaii, or in the Territory of Guam. These deferments also will be applicable, during the 1992–93 award year, to any other individuals who, at the time a natural disaster occurs, reside, attend an institution of higher education, or are employed within the affected areas on the date on which the President declares the existence of a major disaster. The administrative hardship deferment may be granted for a period of time not to exceed the earlier of either the date on which the institution is able to resume normal due-diligence activities or June 30, 1993. During the period of the administrative hardship deferment interest continues to accrue. Documentation must be maintained according to the governing regulations.

III. 34 CFR Part 682—Federal Family Education Loan (FFEL) Program

A. 34 CFR 682.604 Processing the Borrower's Loan Proceeds and Counseling Borrowers

To assist affected individuals, the Secretary has decided that the requirement that loan proceeds be delivered to the borrower within 45 days of the school's receipt of the check will be revised to permit the school up to 100 days from the school's receipt of the check. Documentation must be maintained according to the governing regulations. The Department still expects delivery of a borrower's loan proceeds as soon as possible.

B. 34 CFR 682.210 Deferment

In cases where a borrower continues to be unemployed because of devastation caused by the disasters, the Secretary will extend the three (3)-year maximum unemployment deferment period by six (6) months. Documentation must be maintained according to the governing regulations.

C. 34 CFR 682.211 Forbearance

Many FFEL Program Loan borrowers who suffered financial harm from Hurricane Andrew, Hurricane Iniki, or Typhoon Omar or who suffer financial harm from natural disasters in the future can neither receive nor submit forbearance forms. Therefore, to assist these borrowers, the Secretary has decided to permit lenders to grant administrative forbearance to any borrower who, at the time the disaster occurred, was residing, attending an institution of higher education, or employed in south Florida or Louisiana, on the Island of Kauai in Hawaii, or in the Territory of Guam. The administrative forbearance also will be applicable, during the 1992-93 award year to any other individuals who, at the time a disaster occurs, reside, attend an institution of higher education, or are employed within the areas affected on the date on which the President declares the existence of a major disaster. The administrative forbearance may be granted for a period of time not to exceed the earlier of either the date on which the lender is able to resume normal loan servicing activities or June 30, 1993. Documentation must be maintained according to the governing regulations.

IV. 34 CFR Part 690—Pell Grant Program

Sections 411A–411F of the HEA—Need Analysis and 34 CFR 690.31 and 690.32 Special Conditions

The Secretary has decided that, to best achieve the purposes of Public Law 102-368, students who suffered financial harm from Hurricane Andrew, Hurricane Iniki, or Typhoon Omar or who suffer financial harm from another natural disaster during the 1992-93 award year, need not wait ten (10) weeks to file under the "special condition" provision of the Pell Grant Program, but may instead project that this loss of income will occur and file a correction application immediately on the basis of this projection.

Students meeting a special condition criterion must provide the data needed for the special calculation on either the Correction Application for Federal Student Assistance (Correction AFSA) or the Student Aid Report (SAR). In either case, the student forwards the document to the processor indicated on the form. At that time, a computation based on the expected year data will be made and a new SAR generated.

Dated: April 19, 1993.

Richard W. Riley,

Secretary of Education.

(Catalog of Federal Domestic Assistance Numbers: 84.032 Federal Family Education Loan Program; 84.038 Federal Perkins Loan Program; 84.007 Federal Supplemental Educational Opportunity Grant Program; 84.033 Federal Work-Study Program; 84.063 Federal Pell Grant Program)

[FR Doc. 93–9484 Filed 4–22–93; 8:45 am]

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federal register

Friday
April 23, 1993

Part V

Department of Education

Direct Grant Programs and Fellowship Programs; Notice

DEPARTMENT OF EDUCATION

Direct Grant Programs and Fellowship Programs

AGENCY: Department of Education.

ACTION: Notice of direct grant programs and fellowship programs under which the Secretary is making new awards for fiscal year 1993.

SUMMARY: The Secretary updates the list of the Department's direct grant programs and fellowship programs under which the Secretary is making new awards for fiscal year (FY) 1993 and estimates the deadline dates for the transmittal of applications for those programs for which application notices have not yet been published. The Secretary also revises the list of State Single Points of Contact (SPOCs) for programs subject to the requirements of Executive Order 12372 (Intergovernmental Review of Federal Programs). The notice is intended to help potential applicants in planning for the remainder of this fiscal year.

DATES: The actual or estimated deadline dates for transmitting applications under these programs are listed in column four of the chart contained in this notice. If a program will be announced at a later date, the actual deadline date will appear in the application notice published in the **Federal Register**.

For previously announced programs that are subject to Executive Order 12372, the deadline dates for the transmittal of State Process Recommendations by SPOCs and comments by other interested parties are listed in the application notices for those programs (see column three of the chart for the respective publication dates of—and **Federal Register** volume and page references to—those notices). The deadline date will also appear in the respective application notices for those programs yet to be announced (see column three).

The date on which applications will be available for any given program are in the application notice for that program.

ADDRESSES: The address and telephone number for obtaining applications for, or further information about, an individual program are in the application notice for that program.

Persons who use a telecommunications device for the deaf (TDD) may call the TDD number, if any, listed in the individual application notices. If a TDD number is not listed for a given program, persons who use a TDD may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

The address for transmitting recommendations and comments under Executive Order 12372 is in the appendix to this notice. The appendix also contains the addresses of individual SPOCs.

SUPPLEMENTARY INFORMATION: On September 21, 1992, the Secretary published in the **Federal Register** (57 FR 43498) the Department's annual combined application notice (CAN). That notice listed almost all of the direct grant and fellowship programs under which the Secretary planned to make new awards in FY 1993 and included the application notices for many of those programs. The list included some programs for which application notices had not yet been published. On November 18, 1992, the Secretary published in the **Federal Register** (57 FR 54064) a notice making certain corrections to the CAN of September 21.

Since publication of the CAN and the correction notice, additional application notices have been published. Also, some new programs have been added, and some other programs have been withdrawn or replaced. The Secretary determined that publication of an update would be useful to the educational community.

This notice, therefore, lists all FY 1993 programs previously announced in the **Federal Register**, including those for which the deadline dates have already passed, as well as FY 1993 programs to be announced at a later date. As is the case with the CAN, this notice is designed to assist potential applicants in planning projects and activities. However, to expedite publication of this update, the Secretary has decided not to include any individual application notices. Application notices are published separately in the **Federal Register**. If additional competitions are carried out in FY 1993 because of events not known at this time, the Secretary will announce those competitions in future issues of the **Federal Register**.

As an appendix to the CAN of September 21, 1992, the Secretary published a list of State Single Points of Contact (SPOCs) for programs subject to Executive Order 12372 and the regulations in 34 CFR part 79. Since publication of that list, the names or addresses of SPOCs in a few States have changed.

Therefore, as an appendix to this update, the Secretary is publishing a revised listing of SPOCs.

Organization of Notice

The chart lists all direct grant programs and certain fellowship programs under which the Secretary is making new awards in FY 1993. The listings are organized under the following principal program offices of the Department:

Office of Bilingual Education and Minority Languages Affairs

Office of Educational Research and Improvement

Office of Elementary and Secondary Education

Office of Postsecondary Education

Office of Special Education and Rehabilitative Services

Office of Vocational and Adult Education

The listing for each principal office includes application notices already published and those to be published at a later date. The latter are referenced with estimated dates (est.) in columns three and four of the chart. The programs are listed in order of their Catalog of Federal Domestic Assistance (CFDA) number irrespective of category. An asterisk (*) preceding a CFDA number indicates a program announced or listed since publication of the CAN and not included or referenced in that earlier combined notice.

The listing for each office contains the following information:

The CFDA number of each program.

The name of that program.

A reference to the application notice; that is, either (1) the publication date of the application notice, with a reference to the volume and page number of the **Federal Register** in which the announcement appeared, or (2) an estimated date for publication of the application notice.

The deadline date or estimated deadline date for the transmission of applications.

Programs To Be Announced at a Future Date

For FY 1993 a number of programs will be governed by new regulations or funding priorities. This notice references these types of programs with an asterisk following the respective estimated date (est.*) in column three of the chart. For further information regarding three of these programs, readers are referred to the following notices of proposed rulemaking and notice of proposed priority that have been published in the **Federal Register**:

Drug Prevention Programs in Higher Education—Notice of Proposed Rulemaking ..... 57 FR 44350 (9/25/92)
Patricia Roberts Harris Fellowship Program—Notice of Proposed Rulemaking ..... 58 FR 11928 (3/1/93)
Fund for Innovation in Education (FIE): Innovation in Education Program—Field-Testing and Demonstrations of New or Improved Assessments of K–12 Student Academic Performance—Notice of Proposed Priority for Fiscal Years 1993 and 1994. 58 FR 14274 (3/16/93)

National Education Goals

In 1990 the President and the Nation's Governors announced six National Education Goals for the year 2000:

Goal 1: All children in America will start school ready to learn.

Goal 2: The high school graduation rate will increase to at least 90 percent.

Goal 3: American students will leave grades 4, 8, and 12 having demonstrated competency in challenging subject matter, including English, mathematics, science, history, and geography; and every school in America will ensure that all students learn to use their minds well, so they may be prepared for responsible citizenship, further learning, and productive employment in our modern economy.

Goal 4: U.S. students will be first in the world in science and mathematics achievement.

Goal 5: Every adult American will be literate and will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Goal 6: Every school in America will be free of drugs and violence and will offer a disciplined environment conducive to learning.

In developing this combined application notice the Department has sought to ensure that programs awarding grants during FY 1993 will further achievement of the National Education Goals. The Secretary encourages applicants under these programs to consider the National Education Goals in developing their applications.

Applicability of Section 5301 of the Anti-Drug Abuse Act of 1988

A number of programs listed in the chart provide that a grant, fellowship, traineeship, or other monetary benefit may be awarded to an individual. This award may be made to the individual either directly by the Department or by a grantee that receives Federal funds for the purpose of providing, for example, fellowships, traineeships, or other awards to individuals.

Section 5301 of the Anti-Drug Abuse Act of 1988 (Pub. L. 100–690; 21 U.S.C. 862) provides that a sentencing court may deny eligibility for certain Federal benefits to an individual convicted of drug trafficking or possession. Thus, an individual who applies for a grant, fellowship, or other monetary benefit under a program covered by this notice should understand that, if convicted of drug trafficking or possession, he or she is subject to denial of eligibility for that benefit if the sentencing court imposes such a sanction.

This denial applies whether the Federal benefit is provided to the individual directly by the Department or is provided through a grant, fellowship, traineeship, or other award made available with Federal funds by a grantee.

Any persons determined to be ineligible for Federal benefits under the provisions of section 5301 are listed in the General Services Administration's "Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs."

Applicability of the Federal Debt Collection Procedures Act of 1990

The programs listed in the chart make discretionary awards subject to the eligibility requirements of the Federal Debt Collection Procedures Act of 1990 (Pub. L. 101–647; 28 U.S.C. 3201). The Act provides that if there is a judgment lien against a debtor's property for a debt to the United States, the debtor is not eligible to receive a Federal grant or loan, except direct payments to which the debtor is entitled as beneficiary, until the judgment is paid in full or otherwise satisfied.

LIST OF APPLICATION NOTICES

CFDA No.	Name of program	Application notice	Application deadline date
	Office of Bilingual Education and Minority Languages Affairs		
84.003D	Transitional Bilingual Education Program	9/21/92 (57 FR 43498)	1/15/93.
84.003G	Academic Excellence Program	9/21/92 (57 FR 43498)	1/22/93.
84.003J	Family English Literacy Program	9/21/92 (57 FR 43498)	11/16/92.
84.003K	Special Alternative Instructional Program	9/21/92 (57 FR 43498)	1/15/93.
84.003L	Special Populations Program	9/21/92 (57 FR 43498)	11/13/92.
*84.162	Emergency Immigrant Education Program	2/17/93 (58 FR 8744)	5/14/93.
84.194Q	State Educational Agency Program	9/21/92 (57 FR 43498)	1/22/93.
84.195P	Educational Personnel Training Program	10/1/92 (57 FR 45375)	1/27/93.
84.195T	Fellowship Program	9/21/92 (57 FR 43498)	1/15/93.
84.195V	Short-Term Training Program	9/21/92 (57 FR 43498); 10/30/92 (57 FR 49179)	Withdrawn.
	Office of Educational Research and Improvement		
	Library Programs		
*84.036A	Library Education and Human Resource Development.	12/11/92 (57 FR 58797)	2/24/93.
*84.036B	Library Career Training Program—Fellowship Awards	7/28/92 (57 FR 33410)	10/8/92.
*84.039C	Library Research and Demonstration—Online and Dial-in Access to a Statewide Multiple Library Database Demonstration Project.	3/3/93 (58 FR 12314)	5/28/93.
84.091A	Strengthening Research Library Resources Program	7/28/92 (57 FR 33410)	10/9/92 (1); 11/20/92 (2).

LIST OF APPLICATION NOTICES—Continued

CFDA No.	Name of program	Application notice	Application deadline date
84.163A	Library Services to Indian Tribes and Hawaiian Natives—Basic Grants.	7/28/92 (57 FR 33410)	10/5/92.
84.163B	Library Services to Indian Tribes and Hawaiian Natives—Special Projects.	7/28/92 (57 FR 33410)	4/5/93.
84.167A	Library Literacy Program	10/30/92 (57 FR 49270)	1/15/93.
84.197A–D	College Library Technology and Cooperation Grants Program.	7/28/92 (57 FR 33410)	1/15/93.
84.239A	Foreign Language Materials Acquisition Program	7/28/92 (57 FR 33410)	2/19/93.
	Fund for the Improvement and Reform of Schools and Teaching (First)		
84.117S	Educational Research Grant Program—State Systemic Educational Reforms.	Withdrawn	Withdrawn.
84.168C	Dwight D. Eisenhower National Program for Mathematics and Science—Professional Development for Teachers.	Withdrawn	Withdrawn.
84.211B	FIRST—Schools and Teachers Program—School-Level Projects.	Withdrawn	Withdrawn.
84.212A	FIRST—Family-School Partnership Program	9/21/92 (57 FR 43498); 11/23/92 (57 FR 54978)	12/14/92.
84.215	Secretary's Fund for Innovation in Education (FIE):		
*84.215A	FIE—Innovation in Education Program (General Competition).	1/27/93 (58 FR 6267)	4/30/93.
84.215B	FIE—Comprehensive School Health Education Program.	9/21/92 (57 FR 43498)	12/4/92.
*84.215D	Computer-Based Instruction Program	1/15/93 (58 FR 4660)	3/29/93.
84.215G	FIE—Innovation in Education Program—State Curriculum Frameworks for English, History, Geography, Civics and Arts Education.	12/1/92 (57 FR 56958)	2/26/93.
*84.215H	FIE—Innovation in Education Program—Field-Testing and Demonstrations of New or Improved Assessments of K–12 Student Academic Performance.	5/20/93 (est.*)	7/9/93 (est.).
	Office of Research		
84.117B	Educational Research Grant Program—Improved Assessments of K–12 Student Performance.	Withdrawn	Withdrawn.
84.117E	Educational Research Grant Program—Field-Initiated Studies.	9/21/92 (57 FR 43498)	1/8/93.
84.117J	Office of Educational Research and Improvement Fellows Program.	9/21/92 (57 FR 43498)	12/7/92.
	Programs for the Improvement of Practice		
84.073A	National Diffusion Network Program—New Developer Demonstrator Projects.	9/21/92 (57 FR 43498)	4/9/93.
84.073C	National Diffusion Network Program—New State Facilitator Projects.	9/21/92 (57 FR 43498)	3/8/93.
84.073E	National Diffusion Network Program—New Dissemination Process Projects.	9/21/92 (57 FR 43498)	5/21/93.
84.168A	Dwight D. Eisenhower National Program for Mathematics and Science—State Curriculum Frameworks for Mathematics and Science Competition.	11/25/92 (57 FR 55515)	2/19/93.
84.206A	Javits Gifted and Talented Students Education Grant Program.	9/21/92 (57 FR 43498)	2/5/93.
	National Center for Education Statistics		
84.999F	The National Assessment of Educational Progress (NAEP) Program (1994 Data Collection).	12/11/92 (57 FR 58798)	1/25/93.
84.999G	The National Assessment of Educational Progress (NAEP) Program (1994 Analysis).	12/11/92 (57 FR 58799)	1/25/93.
	Office of Elementary and Secondary Education		
84.004C	Desegregation of Public Education—State Educational Agency Desegregation Program.	9/21/92 (57 FR 43498)	11/6/92.
84.004D	Desegregation of Public Education—Desegregation Assistance Center Program Cooperative Agreement.	7/27/92 (57 FR 33190)	9/22/92.

LIST OF APPLICATION NOTICES—Continued

CFDA No.	Name of program	Application notice	Application deadline date
84.061A	Educational Services for Indian Children	9/21/92 (57 FR 43498)	2/26/93.
84.061C	Planning, Pilot, and Demonstration Projects for Indian Children (Planning Projects).	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	Withdrawn.
84.061D	Planning, Pilot, and Demonstration Projects for Indian Children (Pilot Projects).	9/21/92 (57 FR 43498)	2/26/93.
84.061E	Planning, Pilot, and Demonstration Projects for Indian Children (Demonstration Projects).	9/21/92 (57 FR 43498)	2/26/93.
84.061F	Indian Education—Educational Personnel Development.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	Withdrawn.
84.062A	Educational Services for Indian Adults	9/21/92 (57 FR 43498)	2/26/93.
84.072A	Indian-Controlled Schools—Enrichment Projects	9/21/92 (57 FR 43498)	2/26/93.
84.083A	Women's Educational Equity Act Program—General Significance Grants.	9/21/92 (57 FR 43498)	3/12/93.
84.083B	Women's Educational Equity Act Program—Challenge Grants.	9/21/92 (57 FR 43498)	3/12/93.
84.087A	Indian Fellowship Program	9/14/92 (57 FR 41928)	1/22/93.
84.123A	Law-Related Education Program	9/21/92 (57 FR 43498)	2/5/93.
84.141A	High School Equivalency Program	9/21/92 (57 FR 43498)	2/12/93.
84.144A	Chapter 1 Migrant Education Coordination Program	12/21/92 (57 FR 60710)	2/12/93.
84.149A	College Assistance Migrant Program	9/21/92 (57 FR 43498)	2/12/93.
84.165A	Magnet Schools Assistance Program	12/24/92 (57 FR 61514); 2/9/93 (58 FR 7771)	3/1/93.
84.184B	Drug-Free Schools and Communities Federal Activities Grants Program.	9/21/92 (57 FR 43498)	12/9/92.
84.207A	Drug-Free Schools and Communities School Personnel Training Grants Program.	9/21/92 (57 FR 43498)	2/8/93.
84.214A	Migrant Education Even Start Program	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	4/20/93.
84.233A	Drug-Free Schools and Communities Emergency Grants Program.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	1/12/93.
84.241A	Drug-Free Schools and Communities Counselor Training Grants Program.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	2/19/93.
84.256	Territories and Freely Associated States Educational Grants Program.	3/18/93 (58 FR 14565)	5/25/93.
84.258A	Even Start Program—Indian Tribes and Tribal Organizations.	9/21/92 (57 FR 43498); 2/19/93 (58 FR 9152)	4/27/93.
*84.266	Training In Early Childhood Education and Violence Counseling.	4/30/93 (est.)	6/18/93 (est.).
	Office of Postsecondary Education		
*84.015A	National Resource Centers and Fellowships—African Studies Center.	5/3/93 (est.)	6/21/93 (est.).
84.016A	Undergraduate International Studies and Foreign Language.	8/18/92 (57 FR 37152)	11/2/92.
84.017A	International Research and Studies	8/26/92 (57 FR 38678)	11/2/92.
84.019A	Fulbright-Hays Faculty Research Abroad	7/24/92 (57 FR 32970)	10/30/92.
84.021A	Fulbright-Hays Group Projects Abroad	8/18/92 (57 FR 37151)	10/23/92.
84.022A	Fulbright-Hays Doctoral Dissertation Research Abroad.	7/24/92 (57 FR 32979)	10/30/92.
*84.031A	Strengthening Institutions Program	3/11/93 (58 FR 13465)	4/26/93.
84.031G	Endowment Challenge Grant Program	9/21/92 (57 FR 43498)	6/14/93.
84.031H	Strengthening Institutions Program and Endowment Challenge Grant Program—Designation as an Eligible Institution.	10/1/92 (57 FR 45376)	11/30/92.
84.042A	Student Support Services	9/15/92 (57 FR 42559); 11/16/92 (57 FR 54064)	11/10/92.
*84.055A	Cooperative Education Program—Administration Projects.	6/7/93 (est.*)	7/19/93 (est.).
*84.055B	Cooperative Education Program—Demonstration Projects.	6/7/93 (est.*)	7/19/93 (est.).
*84.055C	Cooperative Education Program—Research Projects	6/7/93 (est.*)	7/19/93 (est.).
*84.055D	Cooperative Education Program—Training and Resource Center Projects.	6/7/93 (est.*)	7/19/93 (est.).
*84.094B	Patricia Roberts Harris Fellowship Program	6/1/93 (est.*)	7/9/93 (est.).
84.097A	Law School Clinical Experience Program	12/24/92 (57 FR 61402)	3/1/93.
84.120	Minority Science Improvement Program—Institutional, Design, Special, and Cooperative Projects.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	12/28/92.
84.153A	Business and International Education	8/18/92 (57 FR 37152)	11/9/92.
*84.170A	Jacob K. Javits Fellows Program	2/9/93 (58 FR 7771)	3/15/93.
*84.200A	Graduate Assistance in Areas of National Need Program.	Withdrawn	Withdrawn.

LIST OF APPLICATION NOTICES—Continued

CFDA No.	Name of program	Application notice	Application deadline date
84.202A	Grants to Institutions and Consortia to Encourage Women and Minority Participation in Graduate Education Program.	10/16/92 (57 FR 47536); 10/19/92 (57 FR 47688)	11/30/92.
84.219	Student Literacy Corps and Student Mentoring Corps Program.	3/16/93 (58 FR 14206)	5/3/93.
84.220A	Centers for International Business Education	9/21/92 (57 FR 43498)	2/19/93.
84.229A	Language Resource Centers Program	9/21/92 (57 FR 43498)	3/1/93.
*84.251	Foreign Periodicals	5/14/93 (est.)	7/16/93 (est.).
*84.252	Urban Community Service	6/10/93 (est.)	7/16/93 (est.).
*84.261	Dwight D. Eisenhower Leadership Program	6/2/93 (est.)	7/19/93 (est.).
*84.262	Minority Teacher Recruitment—Programs to Encourage Minority Students to Become Teachers.	5/10/93 (est.)	6/30/93 (est.).
	Fund for the Improvement of Postsecondary Education (FIPSE)		
84.116A	Comprehensive Program (Preapplications)	9/11/92 (57 FR 41736)	10/27/92.
84.116B	Comprehensive Program (Applications)[3]	9/11/92 (57 FR 41736)	3/5/93.
84.116F	Fund for the Improvement of Postsecondary Education—Innovative Projects for Student Community Service.	5/3/93 (est.)	6/18/93 (est.).
84.116J	Fund for the Improvement of Postsecondary Education—Special Focus Competition (Invitational Priority: Higher Education Cooperation and Exchange between the United States and the European Community).	4/30/93 (est.)	6/14/93 (est.).
84.183A	Drug Prevention Programs in Higher Education—Institution-Wide Program.	9/21/92 (57 FR 43498)	1/19/93.
84.183B	Drug Prevention Programs in Higher Education—Special Focus Program Competition: National College Student Organizational Network Program.	9/21/92 (57 FR 43498)	4/5/93.
84.183D	Drug Prevention Programs in Higher Education—Special Focus Program Competition: Specific Approaches to Prevention Projects (Invitational Priority: Higher Education Consortia for Drug Prevention).	9/21/92 (57 FR 43498)	2/17/93.
84.183E	Drug Prevention Programs in Higher Education—Analysis and Dissemination Program Competitions: Dissemination of Successful Projects.	9/21/92 (57 FR 43498)	1/19/93
84.183F	Drug Prevention Programs in Higher Education—Analysis and Dissemination Program Competitions: Analysis Projects.	9/21/92 (57 FR 43498); 1/25/93 (58 FR 5963)	3/22/93.
	Office of Special Education and Rehabilitative Services		
	Office of Special Education Programs		
84.023A	Advancing and Improving the Research Knowledge Base.	9/15/92 (57 FR 42560)	2/12/93.
84.023B	Student-Initiated Research Projects	9/15/92 (57 FR 42560)	11/13/92.
84.023C	Field-Initiated Research Projects	9/15/92 (57 FR 42560)	11/13/92.
84.023N	Initial Career Awards	9/15/92 (57 FR 42561)	1/8/93.
84.023P	Increasing Participation in General Education Development Programs among Youth with Disabilities.	1/15/93 (58 FR 4866); 2/22/93 (58 FR 9597–9999)	4/19/93.
84.023R	Including Children with Disabilities as Part of Systemic Efforts to Restructure Schools.	9/15/92 (57 FR 42561)	12/11/92.
84.023T	Enhancing Language Acquisition among Students Who Are Deaf or Hard of Hearing.	1/15/93 (58 FR 4866)	4/19/93.
84.024B	Early Childhood Demonstration Project	9/21/92 (57 FR 43444)	11/23/92.
84.024D	Outreach Projects	9/21/92 (57 FR 43444)	12/11/92.
84.024J	Statewide Data Systems Projects	9/17/92 (57 FR 42988)	3/8/93.
84.024P	Model Early Intervention and Preschool Training Projects.	10/6/92 (57 FR 46070)	1/11/93.
84.025C	Services for Children with Deaf-Blindness—Technical Assistance to State and Multi-State Projects.	8/25/92 (57 FR 38488)	2/8/93.
84.025D	Model Demonstration Projects	3/19/93 (58 FR 15138)	5/28/93.
84.026	Educational Media Research, Production, Distribution, and Training Program:		
84.026F	Closed-Captioned Movies, Mini-Series, and Special Programs Broadcast during Prime-Time.	9/21/92 (57 FR 43532)	3/3/93.
84.026J	Close-Captioned Syndicated Television Programming	9/21/92 (57 FR 43532)	5/5/93.

LIST OF APPLICATION NOTICES—Continued

CFDA No.	Name of program	Application notice	Application deadline date
84.026M	Symposium on Educational Media Technology Relating to Persons with Sensory Disabilities.	9/21/92 (57 FR 43532)	1/19/93.
84.026P	Closed-Captioned National News and Public Information Programs.	9/21/92 (57 FR 43532)	2/10/93.
84.026R	Special Research, Development, and Evaluation Projects.	9/21/92 (57 FR 43444)	4/27/93.
84.026T	Cultural Experiences for Deaf and Hard of Hearing Children and Youth.	9/21/92 (57 FR 43532)	2/1/93.
84.026V	Closed-Captioned Children's Program	9/21/92 (57 FR 43532)	4/21/93.
84.028A	Regional Resource Centers	12/10/92 (57 FR 58474)	2/5/93.
84.029A	Training Personnel to Serve Low-Incidence Disabilities.	12/29/92 (57 FR 62110)	2/26/93.
84.029B	Preparation of Personnel for Careers in Special Education.	7/24/92 (57 FR 33068)	10/19/92.
84.029C	Technical Assistance to Professional Development Partnerships.	12/29/92 (57 FR 62110)	2/26/93.
84.029D	Preparation of Leadership Personnel	7/24/92 (57 FR 33068)	10/19/92.
84.029E	Minority Institutions	12/29/92 (57 FR 62110)	2/26/93.
84.029F	Preparation of Related Services Personnel	7/24/92 (57 FR 33068)	9/18/92.
84.029K	Special Projects	7/24/92 (57 FR 33068)	11/30/92.
*84.029L	Interpreter Training	12/29/92 (57 FR 62110)	2/26/93.
84.029M	Parent Training and Information Centers	7/24/92 (57 FR 33068)	9/15/92.
*84.029N	Preparation of Personnel for Careers in Special Education (Serious Emotional Disturbance).	12/29/92 (57 FR 62110)	2/26/93.
84.029Q	Training Early Intervention and Preschool Personnel	7/24/92 (57 FR 33068)	9/18/92.
84.029V	Technical Assistance to State Educational Agencies	12/29/92 (57 FR 62110)	2/26/93.
84.030A	National Information Center	8/18/92 (57 FR 37360)	1/15/93.
84.030C	Postsecondary Clearinghouse	8/18/92 (57 FR 37360)	1/15/93.
84.030E	Special Education Employment Clearinghouse	8/18/92 (57 FR 37360)	1/15/93.
84.078C	Career Placement Opportunities for Students with Disabilities in Postsecondary Programs.	8/25/92 (57 FR 38489)	5/3/93.
84.086D	Developing Innovations for Educating Children with Severe Disabilities Full-Time in General Education Classrooms.	8/25/92 (57 FR 38488)	12/4/92.
84.086J	Statewide Systems Change	8/25/92 (57 FR 38488); 4/7/93 (est.)	12/11/92 5/28/93 (est.).
84.086R	Model Inservice Training Projects	8/25/92 (57 FR 38488)	12/11/92.
84.086U	Outreach—Serving Students with Severe Disabilities in Integrated Environments.	8/25/92 (57 FR 38488)	1/29/93.
*84.158A	State Systems for Transition Services for Youth With Disabilities.	12/30/92 (57 FR 62314)	4/9/93.
84.158D	Model Demonstration Projects to Identify, Recruit, Train and Place Youth with Disabilities Who Have Dropped Out of School.	8/25/92 (57 FR 38489)	4/9/93.
84.158K	Model Demonstration Projects to Identify and Teach Skills Necessary for Self Determination.	8/25/92 (57 FR 38489)	1/22/93.
84.158P	Research Projects on the Transition of Special Populations to Integrated Postsecondary Environments.	8/25/92 (57 FR 38489)	12/11/92.
84.159A	State Agency/Federal Evaluation Studies Projects	9/15/92 (57 FR 42562)	1/15/93.
84.159F	State Agency/Federal Evaluation Studies Projects	9/15/92 (57 FR 42562)	1/15/93.
84.180E	Demonstrating and Evaluating the Benefits of Educational Innovations Using Technology.	9/17/92 (57 FR 42989)	11/30/92
84.180G	Technology, Educational Media, and Materials Research Projects that Promote Literacy.	9/17/92 (57 FR 42988)	11/30/92.
84.180J	Application of Assistive Technology for Students Who Are Deaf or Hard of Hearing.	12/7/92 (57 FR 57867)	3/12/93.
84.237D	Development and Support for Enhancing Professional Knowledge, Skills, and Strategies.	9/17/92 (57 FR 42987)	3/19/93.
	National Institute on Disability and Rehabilitation Research		
84.133A-2	Research and Demonstration Projects	12/3/92 (57 FR 57284)	3/31/93.
84.133A-3	Research and Demonstration Projects	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	5/28/93.
84.133B	Rehabilitation Research and Training Centers	12/4/92 (57 FR 57617)	2/5/93.
84.133B	Rehabilitation Research and Training Centers	1/21/93 (58 FR 5535)	3/24/93.
84.133B	Rehabilitation Research and Training Centers	3/10/93 (58 FR 13313)	5/10/93.
*84.133B	Rehabilitation Research and Training Center in Pediatric Trauma Rehabilitation.	3/1/93 (58 FR 11941)	4/27/93.
84.133D	Knowledge Dissemination and Utilization Program	8/18/92 (57 FR 37338)	2/23/93.
84.133E	Rehabilitation Engineering Centers	12/4/92 (57 FR 57592)	2/5/93.

LIST OF APPLICATION NOTICES—Continued

CFDA No.	Name of program	Application notice	Application deadline date
84.133F	Rehabilitation Research Fellowships Program	8/18/92 (57 FR 37338)	10/5/92.
84.133G	Field-Initiated Research	8/18/92 (57 FR 37338)	10/5/92.
84.133P	Research Training and Career Development Program	8/18/92 (57 FR 37338)	10/5/92.
84.224A	State Grants for Technology-Related Assistance for Individuals with Disabilities.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	4/16/93.
	Rehabilitation Services Administration		
84.128A	Special Projects and Demonstrations for Providing Supported Employment Services to Individuals with Severe Handicaps—Community-Based Projects.	6/12/92 (57 FR 25025); 9/24/92 (57 FR 44179)	10/9/92.
84.128G	Vocational Rehabilitation Service Projects for Migratory Agricultural and Seasonal Farmworkers with Handicaps.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	11/30/92.
84.128J	Projects for Initiating Special Recreation Programs for Individuals with Handicaps.	6/15/93 (est.*)	8/16/93 (est.).
84.129A–1	Rehabilitation Long-Term Training—Rehabilitation Medicine.	9/21/92 (57 FR 43498)	11/30/92.
84.129A–5	Rehabilitation Long-Term Training—Prosthetics and Orthotics.	9/21/92 (57 FR 43498)	11/30/92.
84.129B	Rehabilitation Long-Term Training—Rehabilitation Counseling.	9/21/92 (57 FR 43498)	2/3/93.
84.129C–1	Rehabilitation Long-Term Training—Rehabilitation Facility Administration.	9/21/92 (57 FR 43498)	11/30/92.
84.129C–3	Rehabilitation Long-Term Training—Rehabilitation Administration.	9/21/92 (57 FR 43498)	11/30/92.
84.129D	Rehabilitation Long-Term Training—Occupational Therapy.	9/21/92 (57 FR 43498)	11/30/92.
84.129E	Rehabilitation Long-Term Training—Rehabilitation Engineering.	9/21/92 (57 FR 43498)	11/30/92.
84.129F	Rehabilitation Long-Term Training—Vocational Evaluation and Work Adjustment.	9/21/92 (57 FR 43498)	11/30/92.
84.129G	Rehabilitation Long-Term Training—Rehabilitation Workshop and Facility Personnel.	9/21/92 (57 FR 43498)	11/30/92.
84.129H	Rehabilitation Long-Term Training—Rehabilitation of the Mentally Ill.	9/21/92 (57 FR 43498)	11/30/92.
84.129K	Rehabilitation Long-Term Training—Specialized Personnel for Supported Employment.	9/21/92 (57 FR 43498)	11/30/92.
84.129L	Rehabilitation Long-Term Training—Undergraduate Education in Rehabilitation Services.	9/21/92 (57 FR 43498)	11/30/92.
84.129M	Rehabilitation Long-Term Training—Independent Living.	9/21/92 (57 FR 43498)	11/30/92.
84.129P	Rehabilitation Long-Term Training—Rehabilitation of the Blind.	9/21/92 (57 FR 43498)	11/30/92.
84.129Q	Rehabilitation Long-Term Training—Rehabilitation of the Deaf.	9/21/92 (57 FR 43498)	11/30/92.
84.129R	Rehabilitation Long-Term Training—Rehabilitation Job Development and Placement.	9/21/92 (57 FR 43498)	11/30/92.
84.129T	Rehabilitation Training—Experimental and Innovative Training.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064)	11/23/92.
*84.129T–1	Rehabilitation Long-Term Training—Distance Learning Through Telecommunications.	4/30/93 (est.)	6/30/93 (est.).
84.129U	Rehabilitation Training—Rehabilitation Continuing Education Programs.	8/6/92 (57 FR 34766)	10/1/92.
*84.129U–1	Rehabilitation Long-Term Training—Parent Information and Training.	4/30/93 (est.)	6/30/93 (est.).
84.132A	Centers for Independent Living	6/15/93 (est.*)	8/16/93 (est.).
*84.132B	Centers for Independent Living—Training and Technical Assistance.	6/15/93 (est.*)	8/16/93 (est.).
84.177A	Independent Living Services for Older Blind Individuals.	Withdrawn	Withdrawn.
84.234K	Projects With Industry	9/21/92 (57 FR 43498)	11/30/92.
84.235C	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Non-Priority.	9/21/92 (57 FR 43498)	11/30/92.
*84.235D	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Demonstration Projects to Increase Client Choice.	6/4/93 (est.*)	8/5/93 (est.).

LIST OF APPLICATION NOTICES—Continued

CFDA No.	Name of program	Application notice	Application deadline date
*84.235E	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Transportation Services.	1/25/93 (58 FR 5963)	4/5/93.
84.235F	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Low Functioning Adults Who Are Deaf or Hard of Hearing.	11/4/92 (57 FR 52685)	1/11/93.
84.235M	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Model Systems of Collaboration to Assist in the Training and Employment of Individuals Who Are Disabled Due to the Abuse of Drugs Other than Alcohol.	11/4/92 (57 FR 52685)	1/11/93.
84.235N	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Functional Assessment of Individuals with Cognitive Disabilities.	11/4/92 (57 FR 52685)	1/11/93.
84.235P	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Linkages between State Vocational Rehabilitation Agencies and Consumer-Run Programs for Individuals with Severe Mental Illness.	11/4/92 (57 FR 52685)	1/11/93.
84.235Q	Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Individuals with Severe Handicaps—Transition Rehabilitation Services for Handicapped Youth with Special Needs.	9/21/92 (57 FR 43498); 12/3/92 (57 FR 57160)	12/21/92.
*84.240A	Program of Protection and Advocacy of Individual Rights.	6/15/93 (est.)	7/30/93 (est.).
84.246D	Rehabilitation Short-Term Training—Functional Assessment of Individuals with Cognitive Disabilities.	11/16/92 (57 FR 54146)	1/15/93.
84.246E	Rehabilitation Short-Term Training—Training Rehabilitation Practitioners and Educators on Provisions of the Individuals with Disabilities Education Act (IDEA).	11/16/92 (57 FR 54146)	1/15/93.
*84.246F	Rehabilitation Short-Term Training—Braille Training	4/30/93 (est.)	6/30/93 (est.).
84.250C	Vocational Rehabilitation Service Projects for American Indians with Handicaps.	9/21/92 (57 FR 43498)	11/30/92.
84.265A	Rehabilitation Training—State Vocational Rehabilitation Unit Inservice Training.	9/21/92 (57 FR 43498); 11/16/92 (57 FR 54064); 3/18/93 (58 FR 14564).	5/24/93.
	Office of Vocational and Adult Education		
84.051	National Center or Centers for Research in Vocational Education.	7/10/92 (57 FR 30836)	9/4/92.
84.077	Bilingual Vocational Training Program	9/21/92 (57 FR 43552)	12/11/92.
84.099	Bilingual Vocational Instructor Training Program	9/21/92 (57 FR 43534)	12/11/92.
84.101A	Indian Vocational Education Program	6/16/92 (57 FR 26904)	7/30/92.
84.101C	Native Hawaiian Vocational Education Program	9/21/92 (57 FR 43498)	4/16/93.
84.192	Adult Education for the Homeless Program	3/24/92 (57 FR 10159)	6/5/92.
84.198	National Workplace Literacy Program	6/5/92 (57 FR 24130)	7/10/92.
84.244	Business and Education Standards Program	9/30/92 (57 FR 45146)	11/20/92.
84.255	Functional Literacy for State and Local Prisoners Program.	6/5/92 (57 FR 24112)	7/21/92.

[1] For institutions needing to establish eligibility (Part I only).
[2] For all project descriptions (Part II).
[3] Applicants for 84.116B were required to submit preapplications under 84.116A by 10/14/92.

Invitation to Comment:

The Secretary welcomes comments on the usefulness of this update of the annual combined application notice and suggestions for improving this update or the combined application notice.

Please direct any comments and suggestions to Steven N. Schatken, Assistant General Counsel for Regulations, U.S. Department of Education, 400 Maryland Avenue, SW. (room 5131, FOB–6), Washington, DC 20202–2241.

Dated: April 16, 1993.

Richard W. Riley,

Secretary of Education.

Appendix

Intergovernmental Review of Federal Programs

This appendix applies to each program that is subject to the requirements of Executive Order 12372 (Intergovernmental Review of Federal Programs) and the regulations in 34 CFR part 79.

The objective of the Executive order is to foster an intergovernmental partnership and to strengthen federalism by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance.

Applicants must contact the appropriate State Single Point of Contact to find out about, and to comply with, the State's process under Executive Order 12372. Applicants proposing to perform activities in more than one State should immediately contact the Single Point of Contact for each of those States and follow the procedure established in each of those States under the Executive order. A listing containing the Single Point of Contact for each State is included in this appendix.

In States that have not established a process or chosen a program for review, State, areawide, regional, and local entities may submit comments directly to the Department.

Any State Process Recommendation and other comments submitted by a State Single Point of Contact and any comments from State, areawide, regional, and local entities must be mailed or hand-delivered by the date indicated in this notice to the following address: The Secretary, EO 12372—CFDA# [commenter must insert number—including suffix letter, if any], U.S. Department of Education, room 4161, 400 Maryland Avenue, SW., Washington, DC 20202–0125.

Proof of mailing will be determined on the same basis as applications (see 34 CFR 75.102). Recommendations or comments may be hand-delivered until 4:30 p.m. (Washington, DC time) on the date indicated in this notice.

PLEASE NOTE THAT THE ABOVE ADDRESS IS NOT THE SAME ADDRESS AS THE ONE TO WHICH THE APPLICANT SUBMITS ITS COMPLETED APPLICATION. *DO NOT SEND APPLICATIONS TO THE ABOVE ADDRESS.*

State Single Points of Contact

Arizona

Ms. Janice Dunn, Arizona State Clearinghouse, 3800 N. Central Avenue, Fourteenth Floor, Phoenix, Arizona 85012, Telephone (602) 280–1315.

Arkansas

Mr. Joseph Gillespie, Manager, State Clearinghouse, Office of Intergovernmental Service, Department of Finance and Administration, P.O Box 3278, Little Rock, Arkansas 72203, Telephone (501) 682–1074.

California

Glenn Stober, Grants Coordinator, Office of Planning and Research, 1400 Tenth Street, Sacramento, California 95814, Telephone (916) 323–7480.

Colorado

State Single Point of Contact, State Clearinghouse, Division of Local Government, 1313 Sherman Street, room 520, Denver, Colorado 80203, Telephone (303) 866–2156.

Connecticut

Mr. William T. Quigg, Intergovernmental Review Coordinator, State Single Point of Contact, Office of Policy and Management, Intergovernmental Policy Division, 80 Washington Street, Hartford, Connecticut 06106–4459, Telephone (203) 566–3410.

Delaware

Francine Booth, State Single Point of Contact, Executive Department, Thomas Collins Building, Dover, Delaware 19903, Telephone (302) 739–3326.

District of Columbia

Rodney Holman, State Single Point of Contact, Executive Office of the Mayor, Office of Intergovernmental Relations, Room 416, District Building, 1350 Pennsylvania Avenue, NW., Washington, DC. 20004, Telephone (202) 727–6551.

Florida

Janice L. Alcott, Director, Florida State Clearinghouse, Executive Office of the Governor, Office of Planning and Budgeting, The Capitol, Tallahassee, Florida 32399–0001, Telephone (904) 488–8114.

Georgia

Charles H. Badger, Administrator, Georgia State Clearinghouse, 270 Washington Street, SW., Atlanta, Georgia 30334, Telephone (404) 656–3855.

Hawaii

Mary Lou Kobayashi, Planning Program Manager, Office of State Planning, Office of the Governor, P.O. Box 3540, Honolulu, Hawaii 96811, Telephone (808) 587–2802

Illinois

Jami Owens, State Single Point of Contact Office of the Governor, State of Illinois, 107 Stratton Building, Springfield, Illinois 62706 Telephone (217) 782–1671.

Indiana

Frank Sullivan, Budget Director, State Budget Agency, 212 State House, Indianapolis, Indiana 46204, Telephone (317) 232–5610.

Iowa

Steven R. McCann, Division for Community Progress, Iowa Department of Economic Development, 200 East Grand Avenue, Des Moines, Iowa 50309, Telephone (515) 281–3725.

Kentucky

Ronald W. Cook, Office of the Governor, Department of Local Government, 1024 Capitol Center Drive, Frankfort, Kentucky 40601,Telephone (502) 564–2382.

Maine

Joyce Benson, State Planning Office, State House Station #38, Augusta, Maine 04333, Telephone (207) 289–3261.

Maryland

Mary Abrams, Chief, Maryland State Clearinghouse, Department of State Planning, 301 West Preston Street, Baltimore, Maryland 21201, Telephone (301) 225–4490.

Massachusetts

Karen Arone, State Clearinghouse, Executive Office of Communities and Development, 100 Cambridge Street, room 1803, Boston, Massachusetts 02202, Telephone (617) 727–7001.

Michigan

Milton Waters, Director of Operations, Michigan Department of Commerce, *Michigan Neighborhood Alliance.*

Please direct correspondence to: Manager, Federal Project Review, Michigan Department of Commerce, Michigan Neighborhood Builders Alliance, P.O. Box 30242, Lansing, Michigan 48909, Telephone (517) 373–6223.

Mississippi

Cathy Mallette, Clearinghouse Officer, Office of Federal Grant Management and Reporting, Department of Finance and Administration, 301 West Pearl Street, Jackson, Mississippi 39203, Telephone (601) 949–2174.

Missouri

Lois Pohl, Federal Assistance Clearinghouse, Office of Administration, P.O. Box 809, Room 430, Truman Building, Jefferson City, Missouri 65102, Telephone (314) 751–4834.

Nevada

Department of Administration, State Clearinghouse, Capitol Complex, Carson City, Nevada 89710, Attn: Dana G. Strum, Clearinghouse Coordinator, Telephone (702) 687–4065.

New Hampshire

Jeffrey H. Taylor, Director, New Hampshire Office of State Planning, Attn: Intergovernmental Review Process/James E. Bieber, 2½ Beacon Street, Concord, New Hampshire 03301, Telephone (603) 271–2155.

New Jersey

Richard J. Porth, Director, *Division of Community Resources.*

Please direct all correspondence and questions about intergovernmental review to: Andrew J. Jaskolka, State Review Process, Division of Community Resources, CN 814, room 609, Trenton, New Jersey 08625–0814, Telephone (609) 292–9025.

New Mexico

George Elliott, Deputy Director, State Budget Division, room 190, Bataan Memorial Building, Santa Fe, New Mexico 87503, Telephone (505) 827–3640.

New York

New York State Clearinghouse, Division of the Budget, State Capitol, Albany, New York 12224, Telephone (518) 474–1605.

North Carolina

Mrs. Chrys Baggett, Director, Intergovernmental Relations, N.C. Department of Administration, 116 W. Jones Street, Raleigh, North Carolina 27611, Telephone (919) 733–0499.

North Dakota

North Dakota Single Point of Contact, Office of Intergovernmental Assistance, Office of Management and Budget, 600 East Boulevard Avenue, Bismarck, North Dakota 58505–0170, Telephone (701) 224–2094.

Ohio

Larry Weaver, State Single Point of Contact, State/Federal Funds Coordinator, State Clearinghouse, Office of Budget and Management, 30 East Broad Street, 34th Floor, Columbus, Ohio 43266–0411, Telephone (614) 466–0698.

Rhode Island

Daniel W. Varin, Associate Director, Statewide Planning Program, Department of Administration, Division of Planning, 265 Melrose Street, Providence, Rhode Island 02907, Telephone (401) 277–2656.

Please direct correspondence and questions to: Review Coordinator, Office of Strategic Planning.

South Carolina

State Single Point of Contact, Grant Services, Office of the Governor, 1205 Pendleton Street, room 477, Columbia, South Carolina 29201, Telephone (803) 734–0494.

South Dakota

Susan Comer, State Clearinghouse Coordinator, Office of the Governor, 500 East Capitol, Pierre, South Dakota 57501, Telephone (605) 773–3212.

Tennessee

Charles Brown, State Single Point of Contact, State Planning Office, 500 Charlotte Avenue, 309 John Sevier Building, Nashville, Tennessee 37219, Telephone (615) 741–1676.

Texas

Tom Adams, Governor's Office of Budget and Planning, P.O. Box 12428, Austin, Texas 78711, Telephone (512) 463–1778.

Utah

Utah State Clearinghouse, Office of Planning and Budget, ATTN: Carolyn Wright, Room 116 State Capitol, Salt Lake City, Utah 84114, Telephone (801) 538–1535.

Vermont

Bernard D. Johnson, Assistant Director, Office of Policy Research & Coordination, Pavilion Office Building, 109 State Street, Montpelier, Vermont 05602, Telephone (802) 828–3326.

West Virginia

Fred Cutlip, Director, Community Development Division, Governor's Office of Community and Industrial Development, Building No. 6, room 553, Charleston, West Virginia 25305, Telephone (304) 348–4010.

Wisconsin

William C. Carey, Federal/State Relations, Wisconsin Department of Administration, 101 South Webster Street, P.O. Box 7864, Madison, Wisconsin 53707.

Please direct correspondence and questions to: William C. Carey, Section Chief, Federal/State Relations Office, Wisconsin Department of Administration, Telephone (608) 266–0267.

Wyoming

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Territories

Guam

Michael J. Reidy, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone (671) 472–2285.

Northern Mariana Islands

State Single Point of Contact, Planning and Budget Office, Office of the Governor, Saipan, CM, Northern Mariana Islands 96950.

Puerto Rico

Patria Custodio/Israel Soto Marrero, Chairman/Director, Puerto Rico Planning Board, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940–9985, Telephone (809) 727–4444.

Virgin Islands

Jose L. George, Director, Office of Management and Budget, No. 32 & 33 Kongens Gade, Charlotte Amalie, V.I. 00802, Telephone (809) 774–0750.

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federal register

Friday
April 23, 1993

Part VI

Department of Agriculture

Commodity Credit Corporation

1993 Options Pilot Program; Notice

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

RIN No. 0560–AD15

1993 Options Pilot Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice.

SUMMARY: On October 28, 1992, the Secretary of Agriculture announced the establishment of a pilot program for options contracts (the options program) for the 1993 crop year in conjunction with the Chicago Board of Trade (CBOT).

Under the program, the Commodity Credit Corporation (CCC) will enter into contracts with eligible producers who (1) agree to purchase at least one CBOT put option for their chosen commodity; and (2) agree to forego other program benefits on any enrolled bushels. Producers will be reimbursed by CCC for the cost of the premium for purchasing the put option and will receive an incentive payment of 15 cents or 5 cents per enrolled bushel for participating in the program, depending on whether producers enroll at the target price equivalent level or the price support equivalent level, respectively.

DATES: The enrollment period for this program begins March 1, 1993, and concludes April 30, 1993.

ADDRESSES: Requests to receive further information should be submitted to: Director, Cotton, Grain and Rice Division, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture, P.O. Box 2415, Washington, DC 20013–2415.

FOR FURTHER INFORMATION CONTACT: Bruce D. Hiatt, Program Specialist, Cotton, Grain and Rice Price Support Division, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture, P.O. Box 2415, Washington, DC 20013–2415 on 202–690–2798.

SUPPLEMENTARY INFORMATION: Section 1151 et. seq. of the 1990 Food, Agriculture, Conservation, and Trade Act of 1990, Public Law 101–624 (November 28, 1990), authorizes the Secretary to conduct an options pilot program for the 1993 corn, wheat, and soybean crops. The purpose of this program is to conduct research necessary to ascertain: (1) Whether futures option trading would provide reasonable protection to producers from fluctuations in the value of the commodities they produce; (2) whether producers will accept and fully utilize this method of price protection if information is provided to the producers concerning its proper use; and (3) what effect widespread adoption of such futures options trading program would have on commodity prices.

Notice of Program Availability

This program is available to corn producers in nine counties in three states: Champaign, Logan, and Shelby counties in Illinois; Carroll, Clinton, and Tippecanoe counties in Indiana; and Boone, Grundy, and Hardin counties in Iowa. In the three Illinois counties, wheat and soybean producers may also participate. Producers must participate in the annual acreage reduction program for corn and wheat to be eligible for the options program on those commodities. Soybean producers must accurately report their soybean plantings in order to be eligible to participate.

Program Summary

In general, the options program will work as follows:

A. *Participation Choices.* Producers may participate in the options program at levels that are alternatives to either (1) deficiency payments, or (2) loan program protection. Producers who choose the "deficiency payments" alternative will enroll production in the options program as "target price bushels" and agree to forego deficiency payments, price support benefits and loan deficiency payments on any enrolled bushels. Producers who choose the "loan program protection" alternative will enroll production in the options program as "price support bushels" and agree to forego price support benefits and loan deficiency payments on any enrolled bushels. Production can be enrolled at either the targeted price or price support level, but not both. However, a producer may enroll some production at each level.

B. *Premiums and Incentives.* Producers participating in the options program will receive: (1) A subsidy to cover the cost of the premium for the purchase of the put option(s), and (2) an incentive payment of 15 cents per bushel on target price bushels, or 5 cents per bushel on price support bushels.

C. *Target Price Participation.* Corn participants must buy at least one CBOT December 1993 corn put option contract (5,000 bushels) at a strike price equivalent to the $2.75 per bushel target price on or before June 15, 1993. Wheat participants must buy at least one CBOT September 1993 wheat put option contract (5000 bushels) at a strike price equivalent to the $4.00 per bushel target price on or before May 15, 1993.

D. *Price Support Participation.* Corn participants must buy at least one CBOT March 1994 corn put option contract at a strike price equivalent to the county price support price for corn. Wheat participants must buy at least one CBOT December 1993 wheat put option contract at a strike price equivalent to the county price support price for wheat. Soybean participants must buy at least one CBOT March 1994 soybean put option contract at a strike price equivalent to the county soybean price support price, minus the 2 percent loan origination fee. Put options at the price support level may be purchased until the options expire beginning at harvest of the crop (at the time the crop was otherwise eligible to be placed under loan).

E. *Other Production.* Eligible production not enrolled in either the target price or price support levels of the options program will be eligible to be pledged as collateral for CCC price support loans and for deficiency payments.

F. *Other Requirements and Restrictions.* All put options purchased as required by the options program must be done through a separate account with a registered commodity broker. A sub-account is not "separate" for purposes of the options program.

G. *Documentation.* Documentation of all transactions involving the commodities covered by the program must be provided to CCC. This includes, but is not limited to, copies of brokers' trade confirmations, account statements, and copies of cash contracts or bills of sale.

H. *Corn and Wheat Options Program Participants.* Options program participants for corn and wheat shall comply with the acreage limitations and other requirements of the acreage reduction programs. Additionally, participants agree that (1) in the case of target price participation, the total of the premium subsidies received under the options program and the deficiency payments received under the annual acreage reduction programs will not exceed $50,000 per person; and (2) in the case of price support participation, the total of premium subsidies received under the option program and loan deficiency payments, marketing loan gains and "Findley" deficiency payments received under such programs will not exceed $75,000 per person. A "person" will be determined in the same manner as a "person" is determined for payment limitation purposes for such annual programs. See 7 CFR part 1497.

I. *Incentive Payments.* Incentive payments made under either

participation level are not subject to any payment limit, except to the extent that the total number of bushels any one producer may enroll in the options program is limited as set forth in item J below. In the event that CCC makes disaster assistance available with respect to the 1993 crops of wheat, corn, or soybeans to producers participating in the options program at the target price level, such producers must refund any premium subsidies and incentive payments received on any enrolled commodities in order to receive disaster assistance from CCC.

J. *Crop Limitations.* A participant may enroll up to 50,000 bushels of corn and up to 15,000 bushels each of wheat and soybeans in the options program. However, overall participation in the options program for corn is limited to no more than 20 million bushels. Each county's share of this limit will be allocated based on the total corn crop acreage bases in the county times the average of the percentage of such bases enrolled in the 1990–1992 CCC price support and production adjustment programs. If more bushels are enrolled than are allocated to a county, a drawing will be held to determine participants within a county. Authority: Sections 1151–1156 of the Food, Agriculture, Conservation, and Trade Act of 1990, as amended.

Signed this 16th day of April 1993 in Washington, DC.

Thomas A. Vongarlem,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 93–9670 Filed 4–21–93; 8:45 am]

BILLING CODE 3410–05–P

federal register

Friday
April 23, 1993

Part VII

The President

Executive Order 12843—Procurement Requirements and Policies for Federal Agencies for Ozone-Depleting Substances

Executive Order 12844—Federal Use of Alternative Fueled Vehicles

Executive Order 12845—Requiring Agencies To Purchase Energy Efficient Computer Equipment

Federal Register
Vol. 58, No. 77
Friday, April 23, 1993

Presidential Documents

Title 3—

The President

Executive Order 12843 of April 21, 1993

Procurement Requirements and Policies for Federal Agencies for Ozone-Depleting Substances

WHEREAS, the essential function of the stratospheric ozone layer is shielding the Earth from dangerous ultraviolet radiation; and

WHEREAS, the production and consumption of substances that cause the depletion of stratospheric ozone are being rapidly phased out on a worldwide basis with the support and encouragement of the United States; and

WHEREAS, the Montreal Protocol on Substances that Deplete the Ozone Layer, to which the United States is a signatory, calls for a phaseout of the production and consumption of these substances; and

WHEREAS, the Federal Government, as one of the principal users of these substances, is able through affirmative procurement practices to reduce significantly the use of these substances and to provide leadership in their phaseout; and

WHEREAS, the use of alternative substances and new technologies to replace these ozone-depleting substances may contribute positively to the economic competitiveness on the world market of U.S. manufacturers of these innovative safe alternatives;

NOW, THEREFORE, I, WILLIAM JEFFERSON CLINTON, by the authority vested in me as President by the Constitution and the laws of the United States of America, including the 1990 amendments to the Clean Air Act ("Clean Air Act Amendments"), Public Law 101–549, and in order to reduce the Federal Government's procurement and use of substances that cause stratospheric ozone depletion, do hereby order as follows:

Section 1. *Federal Agencies.* Federal agencies shall, to the extent practicable:

(a) conform their procurement regulations and practices to the policies and requirements of Title VI of the Clean Air Act Amendments, which deal with stratospheric ozone protection;

(b) maximize the use of safe alternatives to ozone-depleting substances;

(c) evaluate the present and future uses of ozone-depleting substances, including making assessments of existing and future needs for such materials and evaluate their use of and plans for recycling;

(d) revise their procurement practices and implement cost-effective programs both to modify specifications and contracts that require the use of ozone-depleting substances and to substitute non-ozone-depleting substances to the extent economically practicable; and

(e) exercise leadership, develop exemplary practices, and disseminate information on successful efforts in phasing out ozone-depleting substances.

Sec. 2. *Definitions.* (a) "Federal agency" means any executive department, military department, or independent agency within the meaning of 5 U.S.C. 101, 102, or 104(1), respectively.

(b) "Procurement" and "acquisition" are used interchangeably to refer to the processes through which Federal agencies purchase products and services.

(c) "Procurement regulations, policies and procedures" encompasses the complete acquisition process, including the generation of product descriptions by individuals responsible for determining which substances must be acquired by the agency to meet its mission.

(d) "Ozone-depleting substances" means the substances controlled internationally under the Montreal Protocol and nationally under Title VI of the Clean Air Act Amendments. This includes both Class I and Class II substances as follows:

(i) "Class I substance" means any substance designated as Class I in the **Federal Register** notice of July 30, 1992 (57 Fed. Reg. 33753), including chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform and any other substance so designated by the Environmental Protection Agency ("EPA") by regulation at a later date; and

(ii) "Class II substance" means any substance designated as Class II in the **Federal Register** notice of July 30, 1992 (57 Fed. Reg. 33753), including hydrochlorofluorocarbons and any other substances so designated by EPA by regulation at a later date.

(e) "Recycling" is used to encompass recovery and reclamation, as well as the reuse of controlled substances.

Sec. 3. *Policy.* It is the policy of the Federal Government that Federal agencies: (i) implement cost-effective programs to minimize the procurement of materials and substances that contribute to the depletion of stratospheric ozone; and (ii) give preference to the procurement of alternative chemicals, products, and manufacturing processes that reduce overall risks to human health and the environment by lessening the depletion of ozone in the upper atmosphere. In implementing this policy, prior to final promulgation of EPA regulations on Federal procurement, Federal agencies shall begin conforming their procurement policies to the general requirements of Title VI of the Clean Air Act Amendments by:

(a) minimizing, where economically practicable, the procurement of products containing or manufactured with Class I substances in anticipation of the phaseout schedule to be promulgated by EPA for Class I substances, and maximizing the use of safe alternatives. In developing their procurement policies, agencies should be aware of the phaseout schedule for Class II substances;

(b) amending existing contracts, to the extent permitted by law and where practicable, to be consistent with the phaseout schedules for Class I substances. In awarding contracts, agencies should be aware of the phaseout schedule for Class II substances in awarding contracts;

(c) implementing policies and practices that recognize the increasingly limited availability of Class I substances as production levels capped by the Montreal Protocol decline until final phaseout. Such practices shall include, but are not limited to:

(i) reducing emissions and recycling ozone-depleting substances;

(ii) ceasing the purchase of nonessential products containing or manufactured with ozone-depleting substances; and

(iii) requiring that new contracts provide that any acquired products containing or manufactured with Class I or Class II substances be labeled in accordance with section 611 of the Clean Air Act Amendments.

Sec. 4. *Responsibilities.* Not later than 6 months after the effective date of this Executive order, each Federal agency, where feasible, shall have in place practices that, where economically practicable, minimize the procurement of Class I substances. Agencies also shall be aware of the phaseout schedule for Class II substances. Agency practices may include, but are not limited to:

(a) altering existing equipment and/or procedures to make use of safe alternatives;

(b) specifying the use of safe alternatives and of goods and services, where available, that do not require the use of Class I substances in new procurements and that limit the use of Class II substances consistent with section 612 of the Clean Air Act Amendments; and

(c) amending existing contracts, to the extent permitted by law and where practicable, to require the use of safe alternatives.

Sec. 5. *Reporting Requirements.* Not later than 6 months after the effective date of this Executive order, each Federal agency shall submit to the Office of Management and Budget a report regarding the implementation of this order. The report shall include a certification by each agency that its regulations and procurement practices are being amended to comply with this order.

Sec. 6. *Exceptions.* Exceptions to compliance with this Executive order may be made in accordance with section 604 of the Clean Air Act Amendments and with the provisions of the Montreal Protocol.

Sec. 7. *Effective Date.* This Executive order is effective 30 days after the date of issuance. Although full implementation of this order must await revisions to the Federal Acquisition Regulations ("FAR"), it is expected that Federal agencies will take all appropriate actions in the interim to implement those aspects of the order that are not dependent upon regulatory revision.

Sec. 8. *Federal Acquisition Regulatory Councils.* Pursuant to section 6(a) of the Office of Federal Procurement Policy Act, as amended, 41 U.S.C. 405(a), the Defense Acquisition Regulatory Council and the Civilian Agency Acquisition Council shall ensure that the policies established herein are incorporated in the FAR within 180 days from the date this order is issued.

Sec. 9. *Judicial Review.* This order does not create any right or benefit, substantive or procedural, enforceable by a non-Federal party against the United States, its officers or employees, or any other person.

William J. Clinton

THE WHITE HOUSE,
April 21, 1993.

[FR Doc. 93-9744
Filed 4-22-93; 10:18 am]
Billing code 3195-01-M

Editorial note: For the President's remarks on Earth Day, see issue 16 of the *Weekly Compilation of Presidential Documents.*

Presidential Documents

Executive Order 12844 of April 21, 1993

Federal Use of Alternative Fueled Vehicles

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Energy Policy and Conservation Act, as amended (42 U.S.C. 6201 *et seq.*), the Motor Vehicle Information and Cost Savings Act, as amended (15 U.S.C. 1901 *et seq.*), the Energy Policy Act of 1992 (Public Law 102–486), and section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. *Federal Leadership and Goals.* The use of alternative fueled motor vehicles can, in some applications, substantially reduce pollutants in the atmosphere, create significant domestic economic activity and stimulate jobs creation, utilize domestic fuel sources as defined by the Energy Policy Act of 1992, and reduce vehicle maintenance costs.

Moreover, Federal action can provide a significant market impetus for the development and manufacture of alternative fueled vehicles, and for the expansion of the fueling infrastructure necessary to support large numbers of privately owned alternative fueled vehicles.

The Federal Government can exercise leadership in the use of alternative fueled vehicles. To that end, each agency shall adopt aggressive plans to substantially exceed the alternative fueled vehicle purchase requirements established by the Energy Policy Act of 1992.

Sec. 2. *Alternative Fueled Vehicle Requirements.* The Federal Government shall acquire, subject to the availability of funds and considering life cycle costs, alternative fueled vehicles in numbers that exceed by 50 percent the requirements for 1993 through 1995 set forth in the Energy Policy Act of 1992. The Federal fleet vehicle acquisition program shall be structured with the objectives of: (a) continued reduction in the incremental cost associated with specific vehicle and fuel combinations; (b) long-term movement toward increasing availability of alternative fueled vehicles produced as standard manufacturers' models; and (c) minimizing life cycle costs in the acquisition of alternative fueled vehicles. In addition, there is established, for a period not to exceed 1 year, the Federal Fleet Conversion Task Force, a Federal interagency implementation committee to be constituted by the Secretary of Energy, in consultation with a Task Force Chairman to be named by the President. The Task Force will advise on the implementation of this Executive order. The Task Force will issue a public report within 90 days, setting forth a recommended plan and schedule of implementation and, no later than 1 year from the date of this order, in cooperation with the Secretary of Energy, file a report on the status of the conversion effort.

Sec. 3. *Alternative Fueled Vehicle Acquisition Assistance.* Within available appropriations, and as required by the Energy Policy Act of 1992, the Secretary of Energy shall provide assistance to other agencies that acquire alternative fueled vehicles. This assistance includes payment of incremental costs of alternative fueled vehicles, including any incremental costs associated with acquisition and disposal. All vehicles, whether conversions or purchases as original equipment manufacturer models, shall comply with all applicable Federal and State emissions and safety standards, consistent with those requirements placed on original equipment manufacturers, including years and mileage.

Sec. 4. *Alternative Fueled Vehicle Purchase and Use Incentives.* The Administrator of the General Services Administration, to the extent allowed by law, may provide incentives to purchase alternative fueled vehicles, including priority processing of procurement requests, and, with the Secretary of Energy, provide any other technical or administrative assistance aimed at accelerating the purchase and use of Federal alternative fueled vehicles.

Sec. 5. *Cooperation with Industry and State and Local Authorities on Alternative Fueled Vehicle Refueling Capabilities.* The Secretary of Energy shall coordinate Federal planning and siting efforts with private industry fuel suppliers, and with State and local governments, to ensure that adequate private sector refueling capabilities exist or will exist wherever Federal fleet alternative fueled vehicles are sited. Each agency's fleet managers are expected to work with appropriate organizations at their respective locations on initiatives to promote alternative fueled vehicle use.

Sec. 6. *Reporting.* The head of each agency shall report annually to the Secretary of Energy on actions and progress under this order, consistent with guidance provided by the Secretary. The Secretary shall prepare a consolidated annual report to the President and to the Congress on the implementation of this order. As part of the report, the Secretary and the Director of the Office of Management and Budget shall complete a thorough, objective evaluation of alternative fueled vehicles. The evaluation shall consider operating and acquisition costs, fuel economy, maintenance, and other factors as appropriate.

Sec. 7. *Definitions.* For the purpose of this order, the terms "agency" and "alternative fueled vehicle" have the same meanings given such terms in sections 151 and 301 of the Energy Policy Act of 1992, respectively.

Sec. 8. *Exceptions.* The Secretary of Defense, the Secretary of the Treasury, and the Attorney General, consistent with the national security and protective and law enforcement activities of their respective agencies, shall determine the extent to which the requirements of this order apply to the national security and protective and law enforcement activities of their respective agencies.

Sec. 9. *Judicial Review.* This order is not intended to create any right or benefit, substantive or procedural, enforceable by a non-Federal party against the United States, its officers or employees, or any other person.

William J. Clinton

THE WHITE HOUSE,
April 21, 1993.

[FR Doc. 93–9751
Filed 4–22–93; 10:33 am]
Billing code 3195–01–M

Editorial note: For the President's remarks on Earth Day, see issue 16 of the *Weekly Compilation of Presidential Documents.*

Presidential Documents

Executive Order 12845 of April 21, 1993

Requiring Agencies To Purchase Energy Efficient Computer Equipment

WHEREAS, the Federal Government should set an example in the energy efficient operation of its facilities and the procurement of pollution preventing technologies;

WHEREAS, the Federal Government should minimize its operating costs, make better use of taxpayer-provided dollars, and reduce the Federal deficit; and

WHEREAS, the Federal Government is the largest purchaser of computer equipment in the world and therefore has the capacity to greatly accelerate the movement toward energy efficient computer equipment;

NOW, THEREFORE, by the authority vested in me as President by the Constitution and the laws of the United States of America, including section 381 of the Energy Policy and Conservation Act, as amended (42 U.S.C. 6361), section 205 of the Federal Property and Administrative Services Act, as amended (40 U.S.C. 486), section 152 of the Energy Policy Act of 1992 (Public Law 102–486), and section 301 of title 3, United States Code, and to ensure the energy efficient operation of the Federal Government's facilities and to encourage the procurement of pollution preventing technologies that will save taxpayer money, reduce the Federal deficit, and accelerate the movement to energy efficient designs in standard computer equipment, it is hereby ordered as follows:

Section 1. *Procurement of Computer Equipment that Meets EPA Energy Star Requirements for Energy Efficiency.* (a) The heads of Federal agencies shall ensure that, within 180 days from the date of this order, all acquisitions of microcomputers, including personal computers, monitors, and printers, meet "EPA Energy Star" requirements for energy efficiency. The heads of Federal agencies may grant, on a case-by-case basis, exemptions to this directive for acquisitions, based upon the commercial availability of qualifying equipment, significant cost differential of the equipment, the agency's performance requirements, and the agency's mission.

(b) Within 180 days from the date of this order, agencies shall specify that microcomputers, including personal computers, monitors, and printers, acquired by the agency shall be equipped with the energy efficient low-power standby feature as defined by the EPA Energy Star computers program. This feature shall be activated when the equipment is shipped and shall be capable of entering and recovering from the low-power state unless the equipment meets Energy Star efficiency levels at all times. To the extent permitted by law, agencies shall include this specification in all existing and future contracts, if both the Government and the contractor agree, and if any additional costs would be offset by the potential energy savings.

(c) Agencies shall ensure that Federal users are made aware of the significant economic and environmental benefits of the energy efficient low-power standby feature and its aggressive use by including this information in routine computer training classes.

(d) Each agency shall report annually to the General Services Administration on acquisitions exempted from the requirements of this Executive order, and the General Services Administration shall prepare a consolidated annual report for the President.

Sec. 2. *Definition.* For purposes of this order, the term "agency" has the same meaning given it in section 151 of the Energy Policy Act of 1992.

Sec. 3. *Judicial Review.* This order does not create any right or benefit, substantive or procedural, enforceable by a non-Federal party against the United States, its officers or employees, or any other person.

William J. Clinton

THE WHITE HOUSE,
April 21, 1993.

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Editorial note: For the President's remarks on Earth Day, see issue 16 of the *Weekly Compilation of Presidential Documents.*

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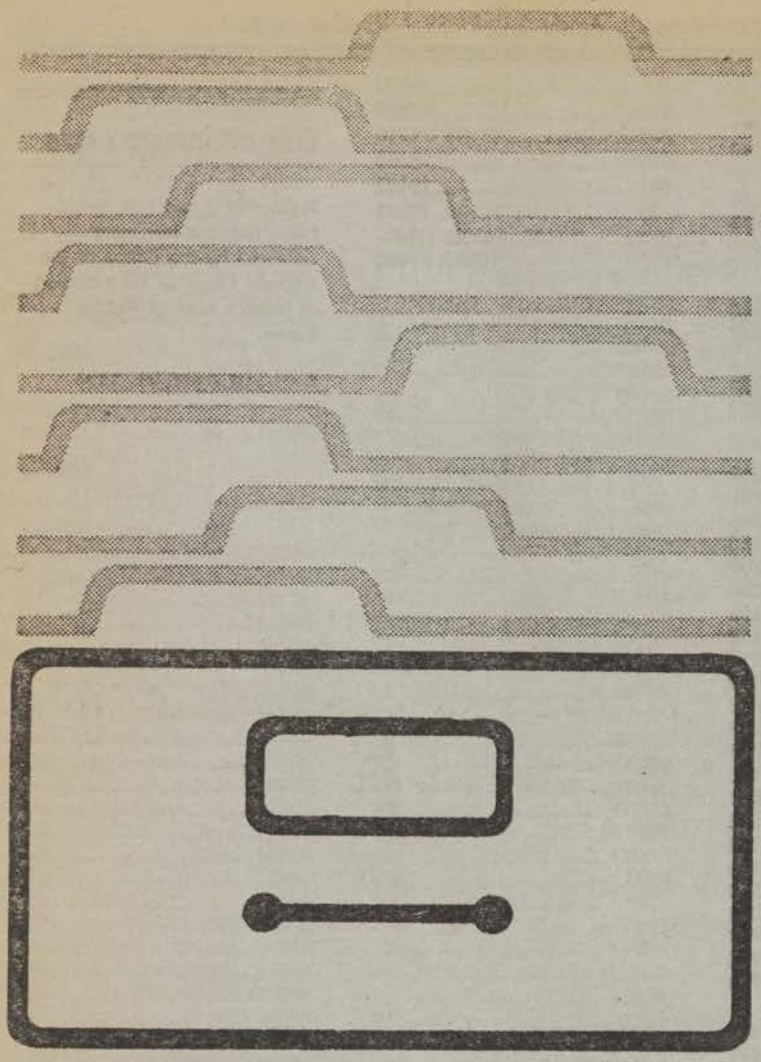

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in the Code of Federal Regulations (CFR)

GUIDE: Revised January 1, 1992

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The various abstracts in the GUIDE tell the user (1) what records must be kept, (2) who must keep them, and (3) how long they must be kept.

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