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# Presidential Documents

**Title 3—**

## The President

**Executive Order 13263 of April 29, 2002**

## President's New Freedom Commission on Mental Health

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to improve America's mental health service delivery system for individuals with serious mental illness and children with serious emotional disturbances, it is hereby ordered as follows:

**Section 1.** *Establishment.* There is hereby established the President's New Freedom Commission on Mental Health (Commission).

**Sec. 2.** *Membership.* (a) The Commission's membership shall be composed of:

(i) Not more than fifteen members appointed by the President, including providers, payers, administrators, and consumers of mental health services and family members of consumers; and

(ii) Not more than seven ex officio members, four of whom shall be designated by the Secretary of Health and Human Services, and the remaining three of whom shall be designated—one each—by the Secretaries of the Departments of Labor, Education, and Veterans Affairs.

(b) The President shall designate a Chair from among the fifteen members of the Commission appointed by the President.

**Sec. 3.** *Mission.* The mission of the Commission shall be to conduct a comprehensive study of the United States mental health service delivery system, including public and private sector providers, and to advise the President on methods of improving the system. The Commission's goal shall be to recommend improvements to enable adults with serious mental illness and children with serious emotional disturbances to live, work, learn, and participate fully in their communities. In carrying out its mission, the Commission shall, at a minimum:

(a) Review the current quality and effectiveness of public and private providers and Federal, State, and local government involvement in the delivery of services to individuals with serious mental illnesses and children with serious emotional disturbances, and identify unmet needs and barriers to services.

(b) Identify innovative mental health treatments, services, and technologies that are demonstrably effective and can be widely replicated in different settings.

(c) Formulate policy options that could be implemented by public and private providers, and Federal, State, and local governments to integrate the use of effective treatments and services, improve coordination among service providers, and improve community integration for adults with serious mental illnesses and children with serious emotional disturbances.

**Sec. 4.** *Principles.* In conducting its mission, the Commission shall adhere to the following principles:

(a) The Commission shall focus on the desired outcomes of mental health care, which are to attain each individual's maximum level of employment, self-care, interpersonal relationships, and community participation;

(b) The Commission shall focus on community-level models of care that efficiently coordinate the multiple health and human service providers and public and private payers involved in mental health treatment and delivery of services;

(c) The Commission shall focus on those policies that maximize the utility of existing resources by increasing cost effectiveness and reducing unnecessary and burdensome regulatory barriers;

(d) The Commission shall consider how mental health research findings can be used most effectively to influence the delivery of services; and

(e) The Commission shall follow the principles of Federalism, and ensure that its recommendations promote innovation, flexibility, and accountability at all levels of government and respect the constitutional role of the States and Indian tribes.

**Sec. 5.** *Administration.* (a) The Department of Health and Human Services, to the extent permitted by law, shall provide funding and administrative support for the Commission.

(b) To the extent funds are available and as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701–5707), members of the Commission appointed from among private citizens of the United States may be allowed travel expenses while engaged in the work of the Commission, including per diem in lieu of subsistence. All members of the Commission who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(c) The Commission shall have a staff headed by an Executive Director, who shall be selected by the President. To the extent permitted by law, office space, analytical support, and additional staff support for the Commission shall be provided by executive branch departments and agencies.

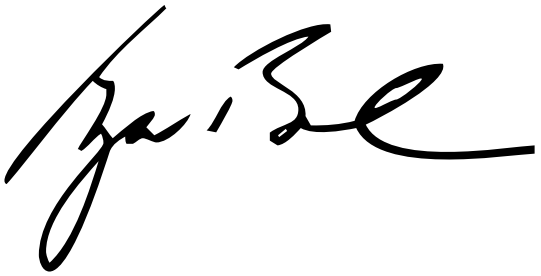
(d) Insofar as the Federal Advisory Committee Act, as amended, may apply to the Commission, any functions of the President under that Act, except for those in section 6 of that Act, shall be performed by the Department of Health and Human Services, in accordance with the guidelines that have been issued by the Administrator of General Services.

**Sec. 6.** *Reports.* The Commission shall submit reports to the President as follows:

(a) *Interim Report.* Within 6 months from the date of this order, an interim report shall describe the extent of unmet needs and barriers to care within the mental health system and provide examples of community-based care models with success in coordination of services and providing desired outcomes.

(b) *Final Report.* The final report will set forth the Commission's recommendations, in accordance with its mission as stated in section 3 of this order. The submission date shall be determined by the Chair in consultation with the President.

**Sec. 7.** *Termination.* The Commission shall terminate 1 year from the date of this order, unless extended by the President prior to that date.



THE WHITE HOUSE,
*April 29, 2002.*

[FR Doc. 02–11166
Filed 5–2–02; 8:45 am]
Billing code 3195–01–P

# Rules and Regulations

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## OFFICE OF PERSONNEL MANAGEMENT

## 5 CFR Part 591

**RIN 3206–AJ40 and 3206–AJ41**

## Cost-of-Living Allowances (Nonforeign Areas); Methodology Changes

**AGENCY:** Office of Personnel Management.

**ACTION:** Final rule.

**SUMMARY:** The Office of Personnel Management (OPM) is making wide-ranging changes in the methodology used to determine nonforeign area cost-of-living allowances (COLAs). OPM is implementing these changes pursuant to the settlement of litigation regarding the COLA program. These regulations also incorporate the changes OPM implemented in interim rules published last year. In addition, the regulations include other changes that improve their clarity and ease of use but do not change their meaning.

**EFFECTIVE DATE:** June 3, 2002.

**FOR FURTHER INFORMATION CONTACT:** Donald L. Paquin, (202) 606–2838; fax: (202) 606–4264; or email: *COLA@opm.gov.*

**SUPPLEMENTARY INFORMATION:** Section 5941 of title 5, United States Code, authorizes the payment of cost-of-living allowances (COLAs) to employees of the Federal Government stationed in certain nonforeign areas outside the contiguous 48 States whose rates of basic pay are fixed by statute. Executive Order 10000, as amended, delegates to the Office of Personnel Management (OPM) the authority to administer nonforeign area COLAs and prescribes certain operational features of the program. The Government pays nonforeign area COLAs to General Schedule, U.S. Postal Service, and certain other Federal employees in Alaska, Hawaii, Guam and the Commonwealth of the Northern Mariana Islands (CNMI), Puerto Rico, and the U.S. Virgin Islands.

OPM published proposed regulations in the November 9, 2001, **Federal Register** (at 66 FR 56741) that would modify significantly the current COLA methodology consistent with the agreement made by the parties in the settlement of *Caraballo, et al.* v. *United States,* No. 1997–0027 (D.V.I), August 17, 2000. In the same issue of the **Federal Register**, OPM published an interim rule (66 FR 56751) to implement recent amendments to Executive Order 10000 regarding the COLA program. Both the proposed regulations published on November 9, 2001, and these final regulations incorporate the changes required by the amendments to Executive Order 10000. Therefore, this final rule makes that interim rule final. OPM received no comments on the interim rule and six written comments in response to the proposed regulations. We discuss the comments we received below.

This final rule also incorporates part of an interim rule published on December 11, 2001 (66 FR 63909), which added administrative appeals judges paid under 5 U.S.C. 5372b to the list of pay plans covered under these regulations. This change is incorporated at 5 CFR 591.204(a)(8).

In addition, this rule corrects an error we discovered in the proposed rule. In § 591.215(b) of the proposed rule, we stated that OPM would average the price indexes for each of the three survey areas in the Washington, DC area. That is incorrect. OPM does not compute price indexes for the DC area because the DC area is the base or reference area and the price indexes are 100. Instead of averaging price indexes, OPM averages prices, and we have corrected that regulation, which is now codified at § 591.216(a).

Finally, these regulations incorporate several changes that improve their clarity and ease of use but do not change their meaning. The following table shows the sections where OPM made a change and the nature of the change:

| Section | Nature of change |
|---|---|
| § 591.210(b)(1) | Added clarifying language. |
| § 591.211(b) and (c) | Added and revised language for clarity. |
| § 591.212(c) | Revised language for clarity. |
| § 591.215, 216, and 217 | 1. Moved what was § 591.215(b) to § 591.216, made a correction, and added and revised language for clarity.<br>2. Redesignated § 591.215(c) as (b) and revised language for clarity.<br>3. Moved what was § 591.217 to § 591.215 (c) and added and revised language for clarity.<br>4. Redesignated what was § 591.216 as § 591.217. |
| § 591.221 | Added and revised language for clarity. |
| § 591.222(a) | Added clarifying language. |
| § 591.228(c) | Added clarifying language. |
| § 591.232 | Added clarifying language. |
| §§ 591.235 and 236 | Added clarifying language in section headings. |
| § 591.237(a) | Added and revised language for clarity. |

### Discussion of Comments

An office within one agency suggested that OPM address commissary and exchange privileges for civilian employees in nonforeign areas. The agency noted that OPM's regulations currently state that eligibility for commissary and exchange privileges ''is determined by the appropriate military department,'' but that the proposed regulations did not address the issue.

OPM believes it is no longer appropriate to reference commissary and exchange shopping privileges in the

regulations. Last year, the President amended Executive Order 10000 to remove the requirement that OPM take into consideration commissary and exchange shopping privileges in setting the COLA rates. Therefore, commissary and exchange shopping privileges and COLA rates are no longer related. Since OPM has no jurisdiction over access to commissaries and exchanges, employees should contact their employing agency, which can contact the appropriate military department if necessary.

A commenter from Alaska was concerned that OPM might not take into consideration seasonal temperature variations in computing home energy requirements and requested that OPM not use average temperatures reported at the Anchorage International Airport as the sole method for determining utility cost for Anchorage. As described in the supplementary information accompanying the proposed rule, OPM will use a utility function model to compute the energy usage of a standard home and the relative cost of maintaining an ambient temperature in that home in the COLA areas relative to the Washington, DC, area. OPM will publish details about how it computes energy requirements for a particular area in the survey results for the area. At present, OPM anticipates using hourly or daily average temperatures as reported by the National Weather Service for the area. OPM believes these temperatures are representative for the area. OPM does not believe it would be practical to use an approach that required average annual temperature readings for several locations within a COLA area.

The same commenter noted the cost of long distance travel from Alaska to areas in the continental United States and that, in many cases, driving is not a feasible alternative to flying. The commenter requested that OPM consider time, distance, and excessive travel expenses in setting COLA rates. The new COLA methodology will take travel expenses into account in two ways. First, as in the past, OPM will compare the cost of air travel from the various COLA areas to common destinations in the continental U.S. with the cost of air travel from the DC area to those same destinations. In previous surveys, OPM has found such travel to be relatively more expensive from the COLA areas than from the Washington, DC, area. Second, as provided in § 591.227, OPM will add to the overall price index for the COLA area an adjustment factor that reflects differences in need, access to and availability of goods and services, and quality of life in the COLA area relative to the DC area. This adjustment factor is designed to address such considerations as the difficulty of traveling long distances by road in Alaska.

The same commenter and three other commenters noted that COLA area employees do not receive locality pay under the Federal Employees Pay Comparability Act of 1990 (FEPCA). The commenters noted that as locality payments have increased, the relative difference between Federal pay in the COLA areas and in the Washington, DC, area has decreased even though COLA rates have remained the same or increased. The commenters also noted that locality pay is included in base pay for retirement purposes, while COLAs are not included. One of these commenters noted that locality payments are subject to Federal income taxes, while COLAs are not, and the commenter said it might be appropriate to tax COLAs if they were included in retirement calculations. Another commenter also noted that because COLAs are not considered taxable income, they are not used in the computation of Social Security benefits. Two of the commenters said that not considering COLAs in retirement calculations creates a disincentive to retire in a COLA area. All of the commenters believe OPM should investigate and address these issues.

OPM is aware that employees in the COLA areas do not receive locality payments under FEPCA. Sections 5304(c)(4)(B) and 5304(f)(1)(A) of title 5, United States Code, limit locality payments to Federal employees stationed in the continental United States. OPM also is aware that COLAs are not included in Federal retirement calculations. Under 5 U.S.C. 8331(3) and 8401(4), allowances are excluded from base pay for Federal retirement purposes. Furthermore, OPM is aware that because COLAs are excluded from income under 26 U.S.C. 912(2), COLAs are not subject to Federal income or Social Security taxes and, therefore, are not used in the computation of Social Security benefits. It would take changes in the law to extend locality payments to Federal employees in the COLA areas, to include COLAs in base pay for Federal retirement purposes, or to make COLAs subject to Federal income or Social Security taxes. Therefore, these issues are outside the scope of these regulations.

**Executive Order 12866, Regulatory Review**

The Office of Management and Budget has reviewed this rule in accordance with Executive Order 12866.

**Regulatory Flexibility Act**

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal agencies and employees.

**List of Subjects in 5 CFR Part 591**

Government employees, Travel and transportation expenses, Wages.

Office of Personnel Management.

**Kay Coles James,**

*Director.*

Accordingly, the Office of Personnel Management revises subpart B of 5 CFR part 591 to read as follows:

## PART 591—ALLOWANCES AND DIFFERENTIALS

### Subpart B—Cost-of-Living Allowance and Post Differential—Nonforeign Areas

Sec.

**Authority:** 5 U.S.C. 5941; E.O. 10000, 3 CFR, 1943–1948 Comp., p. 792; and E.O. 12510, 3 CFR, 1985 Comp., p. 338.

## Subpart B—Cost-of-Living Allowance and Post Differential—Nonforeign Areas

### § 591.201 Definitions.

In this subpart—

*Agency* means an Executive agency as defined in section 105 of title 5, United States Code, but does not include Government-controlled corporations.

*Bureau of Labor Statistics (BLS)* means the Bureau of Labor Statistics of the Department of Labor.

*Commonwealth of the Northern Mariana Islands (CNMI)* means the Commonwealth of the Northern Mariana Islands, which is part of the Guam/CNMI COLA area.

*Consumer Expenditure Survey (CES)* means the BLS survey of consumers and their expenditures.

*Consumer Price Index (CPI)* means the BLS survey of the change of consumer prices over time.

*Cost-of-living allowance (COLA)* means an allowance that the Office of Personnel Management (OPM) establishes under 5 U.S.C. 5941 at a location in a nonforeign area where living costs are substantially higher than in the Washington, DC, area.

*Cost-of-living allowance area* means a geographic area for which OPM has authorized a COLA. COLA areas are listed in § 591.207.

*Detailed Expenditure Category (DEC)* means the lowest level of expenditure shown in tabulated nationwide CES data.

*Major Expenditure Group (MEG)* means one of the nine major groups into which OPM categorizes expenditures. These categories are food, shelter and utilities, clothing, transportation, household furnishings and supplies, medical, education and communication, recreation, and miscellaneous.

*Nonforeign area* means one of the areas listed in § 591.205.

*Office of Personnel Management (OPM)* means the Office of Personnel Management.

*Official duty station* means the duty station for an employee's position of record as indicated on his or her most recent notification of personnel action. For an employee who is authorized to receive relocation allowances under 5 U.S.C. 5737 in connection with an extended assignment, the temporary duty station associated with that assignment is the employee's official duty station. *Exception:* A new duty station assignment that is followed within 3 working days by a reduction in force that results in the employee's separation before the employee is required to report for duty at the new location is not an official duty station.

*Post differential* means an allowance OPM establishes under 5 U.S.C. 5941 at a location in a nonforeign area where conditions of environment differ substantially from conditions of environment in the contiguous United States and warrant its payment as a recruitment incentive.

*Post differential area* means a geographic area for which OPM authorizes a post differential. Post differential areas are listed in § 591.231.

*Primary Expenditure Group (PEG)* means one of approximately 40 expenditure groups into which OPM categorizes expenditures. A PEG is the first level of categorization under the MEG.

*Rate of basic pay* means the rate of pay fixed by statute for the position held by an individual before any deductions and exclusive of additional pay of any kind, such as overtime pay, night differential, extra pay for work on holidays, or other allowances and differentials. For firefighters covered by 5 U.S.C. 5545b (as provided in § 550.1305(b) of this chapter), straight-time pay for regular overtime hours is basic pay.

*Washington, DC, area or DC area* means the District of Columbia; Montgomery County, MD; Prince Georges County, MD; Arlington County, VA; Fairfax County, VA; Prince William County, VA; and the independent cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park, Virginia.

### Cost-of-Living Allowances and Post Differentials

#### § 591.202 Why does the Government pay COLAs?

The Government pays COLAs as additional compensation to certain civilian Federal employees in specified nonforeign areas in consideration of higher living costs in the local area compared with living costs in the Washington, DC, area.

#### § 591.203 Why does the Government pay post differentials?

The Government pays post differentials to certain civilian Federal employees in specified nonforeign areas as a recruitment incentive based on conditions of environment in the local area compared with conditions in the continental United States. Post differentials are designed to attract persons from outside the area to work for the Federal Government in the post differential area.

#### § 591.204 Who can receive COLAs and post differentials?

(a) Agencies pay COLAs and post differentials authorized under this subpart to civilian Federal employees whose rates of basic pay are fixed by statute. The following pay plans are covered by this subpart:

(1) General Schedule,

(2) Veterans Health Administration (Department of Veterans Affairs),

(3) Foreign Service (including the Senior Foreign Service),

(4) Postal Service (where applicable under title 39, United States Code),

(5) Administrative law judges paid under 5 U.S.C. 5372,

(6) Senior Executive Service (including the Federal Bureau of Investigation and Drug Enforcement Administration Senior Executive Service),

(7) Senior-level and scientific or professional positions paid under 5 U.S.C. 5376, and

(8) Administrative appeals judges paid under 5 U.S.C. 5372b.

(b) At its sole discretion and consistent with the intent of 5 U.S.C. 5941, an agency may apply this subpart to other positions authorized by specific law.

(c) Agencies pay COLAs to employees covered by paragraphs (a) or (b) of this section and whose official duty station is in a COLA area as defined in § 591.207.

(d) Agencies pay post differentials to employees covered by paragraphs (a) or (b) of this section whose official duty station or detail to temporary duty is in a post differential area as defined in § 591.231 and who are eligible to receive a post differential under § 591.233.

### § 591.205 Which areas are nonforeign areas?

(a) The nonforeign areas are States, commonwealths, territories, and possessions of the United States outside the 48 contiguous United States and any additional areas the Secretary of State designates as being within the scope of Part II of Executive Order 10000, as amended.

(b) The following areas are nonforeign areas:

(1) State of Alaska;

(2) State of Hawaii;

(3) American Samoa (including the island of Tutuila, the Manua Islands, and all other islands of the Samoa group east of longitude 171 degrees west of Greenwich, together with Swains Island);

(4) Commonwealth of Puerto Rico;

(5) Commonwealth of the Northern Mariana Islands;

(6) Howland, Baker, and Jarvis Islands;

(7) Johnston Atoll;

(8) Kingman Reef;

(9) Midway Atoll;

(10) Navassaa Island;

(11) Palmyra Atoll;

(12) Territory of Guam;

(13) United States Virgin Islands;

(14) Wake Atoll;

(15) Any small guano islands, rocks, or keys that, in pursuance of action taken under the Act of Congress, August 18, 1856, are considered as pertaining to the United States; and

(16) Any other islands outside of the contiguous 48 states to which the U.S. Government reserves claim.

## Cost-of-Living Allowances

### § 591.206 How does OPM establish COLA areas?

(a) OPM designates, within nonforeign areas, areas where agencies pay employees a COLA by virtue of living costs that are substantially higher than those in the Washington, DC, area. In establishing the boundaries of COLA areas, OPM considers—

(1) The existence of a well-defined economic community,

(2) The availability of consumer goods and services,

(3) The concentration of Federal employees covered by this subpart, and

(4) Unique circumstances related to a specific location.

(b) If a department or agency wants OPM to consider establishing or revising the definition of a COLA area, the head of the department or agency or his or her designee must submit a request in writing to OPM.

### § 591.207 Which areas are COLA areas?

OPM has established the following COLA areas:

(a) City of Anchorage, AK, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;

(b) City of Fairbanks, AK, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;

(c) City of Juneau, AK, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;

(d) Rest of the State of Alaska;

(e) City and County of Honolulu, HI;

(f) County of Hawaii, HI;

(g) County of Kauai, HI;

(h) County of Maui (including Kalawao County), HI;

(i) Commonwealth of Puerto Rico;

(j) Territory of Guam and Commonwealth of the Northern Mariana Islands; and

(k) U.S. Virgin Islands.

### § 591.208 How does OPM establish COLA rates?

OPM establishes COLA rates based on price differences between the COLA area and the Washington, DC, area, plus an adjustment factor. OPM expresses price differences as indexes.

(a) OPM computes price indexes for various categories of consumer expenditures.

(b) OPM combines the price indexes using Consumer expenditure weights to produce an overall price index for the COLA area.

(c) To combine overall price indexes for COLA areas with multiple survey areas, OPM uses employment weights to combine overall price indexes by survey area for COLA areas. The COLA areas that have multiple survey areas are listed in § 591.215(b).

(d) OPM adds an adjustment factor to the overall price index for the COLA area.

### § 591.209 What is a price index?

(a) The price index is the COLA area price divided by the DC area price and multiplied by 100.

(b) Example:

COLA Area Average Price for Item A = $1.233

DC Area Average Price for Item A = $1.164

Computation:

$1.233/$1.164 = 1.0592783

$1.0592783 \times 100 = 105.92783$.

(c) In the case of the final index, OPM rounds the index to two decimal places.

### § 591.210 What are weights?

(a) A weight is the relative importance or share of a subpart of a group compared with the total for the group. A weight is frequently expressed as a percentage. For example, in a pie chart, each wedge has a percentage that represents its relative importance or the size of the wedge compared with the whole pie.

(b) OPM uses two kinds of weights: Consumer expenditure weights and employment weights.

(1) *Consumer expenditure weights.* The consumer expenditure weight for a category of expenditures (e.g., Food) is the relative importance or share (often expressed as a percentage) of that category in terms of total consumer expenditures. OPM derives consumer expenditure weights from the tabulated results of the Bureau of Labor Statistics (BLS) Consumer Expenditure Survey (CES).

(2) *Employment weights.* The employment weight is the relative employment population of the survey area compared with the employment population of the COLA area as a whole. OPM uses the number of General Schedule employees in the survey area to compute employment weights. OPM uses these employment weights as described in § 591.216(b).

### § 591.211 What are the categories of consumer expenditures?

OPM uses three different types of categories: Major expenditure groups, primary expenditure groups, and detailed expenditure categories.

(a) *Major expenditure groups.* OPM groups expenditures into nine major expenditure groups (MEGs). These categories are food, shelter and utilities, clothing, transportation, household furnishings and supplies, medical, education and communication, recreation, and miscellaneous.

(b) *Primary expenditure groups.* OPM subdivides each MEG into primary expenditure groups (PEGs). There are approximately 40 PEGs.

(c) *Detailed expenditure categories.* OPM further subdivides each PEG into

other categories down to the detailed expenditure categories (DECs), which are generally equivalent to the most detailed level of tabulated CES categories. OPM classifies each DEC into one of the PEGs to aggregate DECs with similar demand and cost characteristics into PEGs. Alternatively, OPM may remove the DEC entirely from the list of expenditures. Therefore, the classification of the DECs into PEGs and sub-PEGs does not necessarily follow that used in published CES tables.

**§ 591.212 How does OPM select survey items?**

(a) OPM selects a sufficient number of items to represent PEGs and reduce overall price index variability. In selecting these items, OPM applies the following guidelines. The item should be—

(1) Relatively important (i.e., represent a DEC with a relatively large weight) within the PEG;

(2) Relatively easy to find in both COLA and DC areas;

(3) Relatively common, *i.e.,* what people typically buy;

(4) Relatively stable over time, *e.g.,* not a fad item; and

(5) Subject to similar supply and demand functions.

(b) To the extent practical, the items OPM surveys in the COLA area must be identical to the items that OPM surveys in the DC area or be of closely similar quality and quantity, with quantity adjustments as necessary. An example of a quantity adjustment is converting prices for 10 and 12 oz. packages to a price per pound.

(c) Within any DEC, OPM may specify items that differ in quality and quantity from other items specified for the same DEC. However, when OPM compares prices for such items between the COLA area and the DC area, OPM compares prices of like products.

**§ 591.213 What prices does OPM collect?**

(a) OPM surveys the price charged to the consumer at the time of the survey. The price includes any sales, excise, or general business tax passed on to the consumer at the time of sale and any discounts, mark-downs, or ''sales'' in progress at the time the price was collected.

(b) Exceptions:

(1) OPM does not collect coupon prices, going-out-of-business prices, or area-wide distress sale prices.

(2) OPM prices automobiles at dealers and obtains the sticker (i.e. non-negotiated) price for the model and specified options. The prices are the manufacturer's suggested retail price (including options), destination charges, additional shipping charges, appropriate dealer-added items or options, dealer mark-up, and taxes.

(3) OPM estimates prices for selected items, such as health insurance and K–12 education, based on employee usage of the item. For example, OPM estimates health insurance prices based on the employee's share of the premium costs and weights reflecting Federal enrollment, as reported in OPM's Central Personnel Data File, in the various plans available to Federal employees in each area.

**§ 591.214 How does OPM collect prices?**

(a) OPM collects most prices by visiting or calling retail outlets in each survey area and observing or verbally obtaining the item prices.

(b) OPM prices some items by catalog, Internet, or a similar source. Other items, not normally sold within an area, may be priced in a different area. In either case, the price of such items includes any applicable taxes, shipping, and handling charges. When an item is normally sold within an area but is not available at the time of survey, OPM may, on a case-by-case basis, use the price of the item in a neighboring survey or COLA area.

**§ 591.215 Where does OPM collect prices in the COLA and DC areas?**

(a) *Survey areas.* Each COLA area has one survey area, except Hawaii County, HI, and the U.S. Virgin Islands COLA areas. Hawaii County has two survey areas: the City of Hilo and the Kailua-Kona area. The U.S. Virgin Islands also has two survey areas: the Island of St. Croix and the Islands of St. Thomas and St. John. The Washington, DC, area has three survey areas: the District of Columbia, the Maryland suburbs of the District of Columbia, and the Virginia suburbs of the District of Columbia. OPM collects non-housing data throughout the survey area. OPM may collect housing data throughout the survey area or in specific housing data collection areas. The following table shows the survey areas:

SURVEY AND DATA COLLECTION AREAS

| COLA areas & reference areas | Survey area |
|---|---|
| Anchorage | City of Anchorage. |
| Fairbanks | City of Fairbanks. |
| Juneau | Juneau, Mendenhall. |
| Rest of Alaska | See paragraph (c) of this section. |
| Honolulu | City and County of Honolulu. |
| Hawaii County | City of Hilo, Kailua-Kona area. |
| Kauai | Kauai Island. |
| Maui | Maui Island. |
| Guam & CNMI | Guam. |
| Puerto Rico | San Juan area. |
| U.S. Virgin Islands | St. Croix, St. Thomas, St. John (housing data only). |
| Washington, DC-DC | District of Columbia. |
| Washington, DC-MD | Montgomery County and Prince Georges County. |
| Washington, DC-VA | Arlington County, Fairfax County, Prince William County, City of Alexandria, City of Fairfax, City of Falls Church, City of Manassas, and City of Manassas Park. |

(b) *Rest of the State of Alaska COLA area.* OPM may collect survey data onsite, use alternative indicators of relative living costs (e.g., price and cost information published by the University of Alaska), or both. If the use of alternative indicators would result in a COLA rate reduction, OPM will conduct onsite surveys in one or more locations in the Rest of the State of Alaska COLA area, before making a reduction, to ensure that the reduction is warranted.

(c) *Determining Survey Coverage.* To aid OPM in determining survey coverage, OPM may from time to time conduct surveys of Federal employees in the COLA areas and/or the Washington, DC, area to determine

where employees shop and what they spend on certain goods or services and to collect other information related to the price surveys and the calculation of price indexes.

**§ 591.216 How does OPM combine survey data for the DC area and for COLA areas with multiple survey areas?**

(a) *Washington, DC, area.* For each survey item except shelter, OPM averages separately the prices collected in each of the DC survey areas identified in § 591.215(a) and then averages these average prices together using equal weights to compute an overall average by item for the DC area.

(b) *COLA areas with multiple survey areas.* OPM computes weighted average indexes at the PEG, MEG, and overall level by using the corresponding indexes and Federal employment weights from each survey area within the COLA area.

**§ 591.217 In which outlets does OPM collect prices?**

OPM collects prices in popular outlets in each survey area. OPM selects these outlets based on their proximity to the housing data collection areas, accessibility by road, physical size, advertising, and other characteristics that reflect sales volume. To the extent practical, OPM prices like items in the same types of outlets in the COLA areas and the Washington, DC, area. As warranted, OPM also may conduct point-of-purchase surveys and select outlets based on the results of those surveys.

**§ 591.218 How does OPM compute price indexes?**

Except for shelter and energy utilities, OPM averages by item the prices collected in each survey area. For the Washington, DC, area, OPM computes a simple average for each item based on the average prices from each DC survey area. On an item-by-item basis, OPM divides the COLA survey area average price by the DC average price and produces a price index.

**§ 591.219 How does OPM compute shelter price indexes?**

(a) In addition to rental and rental equivalence prices and/or estimates, OPM obtains for each unit surveyed information about the important characteristics of the unit, such as size, number of bathrooms, and other amenities that reflect the quality of the unit.

(b) OPM then uses these characteristics and rental prices and/or estimates in hedonic regressions (a type of multiple regression) to compute for each COLA area the price index for rental and/or rental equivalent units of comparable quality and size between the COLA survey area and the Washington, DC, area.

**§ 591.220 How does OPM calculate energy utility cost indexes?**

(a) OPM calculates energy utility cost indexes based on the relative cost of maintaining a standard size dwelling in each area at a given ambient temperature and the cost of other energy uses. Although the dwelling size may vary from one COLA survey area to another, OPM compares the utility cost for the same size dwelling in the COLA survey area and the Washington, DC, area.

(b) OPM applies the following six-step process to compute a cost index(es) for heating and cooling a standard home to a given ambient temperature and to combine the cost index(es) by energy type (*e.g.,* electricity and natural gas) with cost indexes for other energy uses.

(1) *Step 1.* OPM obtains technical information about the requirements by major energy type for heating and cooling a standard size dwelling, built according to current local building practices and codes in each area, given local climatic conditions (*e.g.,* seasonal temperature and humidity). OPM also obtains similar information for use of energy types in other household operations (*e.g.,* hot water, cooking, cleaning, recreation).

(2) *Step 2.* OPM obtains from the shelter survey, a survey of Federal employees, or other appropriate sources, information on dwelling size and the types and prevalence of heating and cooling equipment and energy types (*e.g.,* electricity, gas, and oil) in each area.

(3) *Step 3.* OPM computes estimates of total home energy requirements by energy type attributable to heating and cooling plus all other household energy uses for the COLA survey area and the Washington, DC, area.

(4) *Step 4.* OPM surveys utility prices for each major energy type appropriate to the area.

(5) *Step 5.* OPM combines the above data to produce for each COLA survey area the cost of maintaining the standard size dwelling at a given ambient temperature and the cost of other household energy uses.

(6) *Step 6.* OPM compares the COLA survey area cost with the DC area cost to produce a price index.

**§ 591.221 How does OPM compute the consumer expenditure weights it uses to combine price indexes?**

OPM uses the following ten-step process to compute consumer expenditure weights:

(a) *Step 1.* OPM obtains the latest BLS tabulated CES data nationwide and for the Washington, DC, area.

(b) *Step 2.* In both the nationwide and DC area tabulated data, OPM replaces the homeowners' expenditures for shelter with estimated rental values of owned homes that are available elsewhere in tabulated CES data. Note: These replacements are consistent with the rental equivalence approach described in § 591.219.

(c) *Step 3.* OPM selects the central income groups in the nationwide CES tabulation.

(d) *Step 4.* OPM calculates the expenditure shares (*i.e.,* percentages) for each central income group by dividing each of its DEC expenditures by total expenditures for the income group. OPM also calculates expenditure shares for total nationwide expenditures by dividing each nationwide DEC expenditure by total nationwide expenditures.

(e) *Step 5.* OPM computes a democratic distribution of expenditure shares by averaging the central income groups' shares at each DEC and higher level of aggregation.

(f) *Step 6.* OPM computes a set of ratios by dividing each expenditure share of the nationwide democratic distribution by the corresponding expenditure share of the total national distribution.

(g) *Step 7.* OPM computes estimated expenditures for Washington DC for each DC DEC and higher level of aggregation that BLS reported by multiplying the reported expenditure by the corresponding ratio derived in Step 6.

(h) *Step 8.* For each DC DEC and higher level of aggregation that BLS did not report, OPM computes expenditures for DC by distributing the DC expenditure calculated in step 7 using the distribution of expenditure shares derived in step 5.

(i) *Step 9.* As described in § 591.211(c), OPM classifies each DEC and aggregate into PEGs.

(j) *Step 10.* OPM computes expenditure weights by dividing each DEC or aggregate by the total expenditure derived from the DC expenditure computed in step 8. Therefore, the sum of the MEGs, PEGs, and DECs, will separately total 100, *i.e.,* so that all consumer expenditures in the original tabulation are accounted for.

**§ 591.222 How does OPM use the expenditure weights to combine price indexes?**

OPM uses a three-step process to combine price indexes.

(a) *Step 1.* For each DEC represented by one or more items for which OPM

could make valid price comparisons (*e.g.,* OPM was able to collect representative prices in both the COLA and DC areas), OPM computes the unweighted geometric average (the *nth* root of the product of *n* numbers) of the price index(es) of all item(s) representing the DEC.

(b) *Step 2.* OPM multiplies the price index for each DEC by its expenditure weight, sums the cross products, and divides by the sum of the weights used in the calculation. This produces a price index for the level of aggregation (*e.g.,* PEG or sub-PEG) in which the DEC is categorized.

(c) *Step 3.* OPM repeats the process described in step 2 at each level of aggregation within the PEG to produce a price index for the PEG, at the PEG level to produce an index for the MEG, and at the MEG level to produce the overall price index for the survey area.

### § 591.223 When does OPM conduct COLA surveys?

(a) OPM conducts a survey in each COLA area once every 3 years on a rotational basis and surveys the Washington, DC, area concurrently with each COLA area survey. The order of the COLA area surveys is as follows:

(1) *Year 1.* All COLA areas in the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

(2) *Year 2.* All COLA areas in the State of Alaska, except as provided in paragraph (b)(2) of this section.

(3) *Year 3.* All COLA areas in the State of Hawaii and the Territory of Guam and CNMI.

(b) *Exceptions:*

(1) Nothing in this subpart precludes OPM from conducting interim surveys or implementing some other change in response to conditions caused by a natural disaster or similar emergency, provided OPM publishes a notice or rule in the **Federal Register** explaining the change and the reason(s) for it.

(2) As provided in § 591.215(c), OPM does not conduct surveys in the Rest of the State of Alaska COLA area unless COLA rate reductions appear warranted.

### § 591.224 How does OPM adjust price indexes between surveys?

(a) OPM adjusts price indexes between the triennial surveys in each COLA area that is not surveyed in that year. To do this, OPM uses the annual or biennial change in the Consumer Price Index (CPI) for the COLA area relative to the annual or biennial change in the CPI for the Washington, DC, area. OPM uses the annual change for those areas surveyed the preceding year. OPM uses the biennial change for those areas surveyed 2 years before.

(b) This section applies beginning with the effective date of the results of the second survey conducted in Puerto Rico and the U.S. Virgin Islands under these regulations.

### § 591.225 Which CPIs does OPM use?

OPM uses the following CPIs:

(a) For the Washington, DC, area—the BLS Consumer Price Index, All Urban Consumers (CPI–U);

(b) For all COLA areas in the State of Alaska—the BLS CPI–U for Anchorage, AK;

(c) For all COLA areas in the State of Hawaii and for Guam and the CNMI—the BLS CPI–U for Honolulu, HI; and

(d) For Puerto Rico and the U.S. Virgin Islands—the Puerto Rico CPI as produced by the Puerto Rico Department of Work and Human Resources.

### § 591.226 How does OPM apply the CPIs?

(a) OPM uses a three-step process to adjust price indexes by relative annual or biennial changes in the CPIs. For steps 1 and 2, OPM computes the annual change by dividing the CPI from 1 year after the survey by the CPI from the time of the survey. OPM computes the biennial change by dividing the CPI from 2 years after the survey by the CPI from the time of the survey.

(1) *Step 1.* OPM computes the annual or biennial CPI change for the COLA area.

(2) *Step 2.* OPM computes the annual or biennial CPI change for the DC area.

(3) *Step 3.* OPM multiplies the COLA area price index from the last survey by the COLA area CPI change computed in step 1 divided by the DC area CPI change computed in step 2. The adjusted price index is rounded to the second decimal place.

(b) *Example:*

| | 2008 | 2009 |
|---|---|---|
| COLA Area CPI | 172.2 | 174.7 |
| DC Area CPI | 159.7 | 161.9 |
| COLA Area Survey Index | 117.33 | [1] |
| COLA Area CPI Adjusted Index | [2] | 117.42 |

[1] No survey.
[2] N/A

Computation:

117.33 × (174.7/172.2)/(161.9/159.7) = 117.4159, which would round to 117.42.

### § 591.227 What adjustment factors does OPM add to the price indexes?

OPM adds to the price index an adjustment factor that reflects differences in need, access to and availability of goods and services, and quality of life in the COLA area relative to the DC area. The following table shows the adjustment factor for each area:

| COLA area | Amount |
|---|---|
| Anchorage, AK | 7.0 |
| Fairbanks, AK | 9.0 |
| Juneau, AK | 9.0 |
| Rest of the State of Alaska | 9.0 |
| City and County of Honolulu, HI | 5.0 |
| Hawaii County, HI | 7.0 |
| Kauai County, HI | 7.0 |
| Maui County, HI | 7.0 |
| Guam and CNMI | 9.0 |
| Commonwealth of Puerto Rico | 7.0 |
| U.S. Virgin Islands | 9.0 |

[1] Amount added to the price index.

### § 591.228 How does OPM convert the price index plus adjustment factor to a COLA rate?

(a) OPM converts the price index plus the adjustment factor to a COLA rate as shown in the following table:

| Price index plus adjustment factor | COLA rate subject to paragraph (b) of this section |
|---|---|
| Equal to or greater than 124.50 | 25 percent. |
| Equal to or greater than 102.00 but less than 124.50 | Price index plus the adjustment factor, minus 100, expressed to the nearest whole percent. |
| Less than 102.00 | 0 percent. |

(b) This section is applicable on an area-by-area basis beginning with the effective date of the results of the first survey conducted in each area.

(c) OPM may reduce the COLA rate in any area by no more than 1 percentage point in any 12-month period. Any reduction in the COLA rate for any COLA area cannot be effective until the effective date of the first survey conducted in Hawaii and Guam and CNMI under these regulations.

### § 591.229 How does OPM inform agencies and employees of COLA rate changes?

OPM publishes COLA area survey summary reports, MEG and PEG indexes, and COLA rates in the **Federal Register**. OPM makes survey data and

other information available to the public to the extent authorized by the Freedom of Information Act and the Privacy Act.

**Post Differentials**

**§ 591.230 When does OPM establish post differential areas?**

(a) OPM establishes post differential areas in response to agency requests when—

(1) Conditions of environment within the post differential area differ substantially from conditions of environment in the continental United States, and

(2) The major Federal employers within the area believe payment of a post differential is warranted as a recruitment incentive to attract candidates from outside the post differential area to work for the Government in the post differential area.

(b) If a department or agency wants OPM to consider establishing or revising the definition of a post differential area, the head of the department or agency or his or her designee must submit a request in writing to OPM.

**§ 591.231 Which areas are post differential areas?**

OPM has established the following post differential areas:

(a) American Samoa as defined in § 591.205,

(b) Territory of Guam,

(c) Commonwealth of the Northern Mariana Islands,

(d) Johnston Atoll (including Sand Island),

(e) Midway Atoll, and

(f) Wake Atoll.

**§ 591.232 How does OPM establish and review post differentials?**

(a) OPM establishes a post differential by rulemaking if Government agencies require it for recruitment purposes and if one or more of the following conditions exist:

(1) Extraordinarily difficult living conditions,

(2) Excessive physical hardship, and/or

(3) Notably unhealthful conditions.

(b) OPM periodically reviews with Federal agencies whether conditions of environment have changed in the post differential areas and whether payment of the post differential continues to be warranted as a recruitment incentive.

**§ 591.233 Who can receive a post differential?**

An employee must meet all of the following conditions to be eligible to receive a post differential:

(a) The employee must be a citizen or national of the United States,

(b) The employee's official duty station or detail to temporary duty must be in the post differential area, and

(c) Immediately prior to being assigned to duty in the post differential area, the employee must have maintained his or her actual place(s) of residence outside the post differential area for an appropriate period of time (generally at least 1 year or more), except as provided in § 591.234.

**§ 591.234 Under what circumstances may people recruited locally receive a post differential?**

(a) Current residents of the area qualify for a post differential if they were originally recruited from outside the differential area and have been in substantially continuous employment by the United States or by U.S. firms, interests, or organizations.

(b) Examples of persons recruited locally but eligible to receive a post differential include, but are not limited to—

(1) Those who were originally recruited from outside the area and have been in substantially continuous employment by other Federal agencies, contractors of Federal agencies, or international organizations in which the U.S. Government participates and whose conditions of employment provide for their return transportation to places outside the post differential area,

(2) Those who are temporarily present in the post differential area for travel or formal study at the time they are hired and have maintained actual places of residence outside the area for an appropriate period of time, and

(3) Those who are discharged from U.S. military service in the differential area to accept employment with a Federal agency and have maintained actual places of residence outside the differential area for an appropriate period of time.

**Program Administration**

**§ 591.235 When do COLA and post differential payments begin?**

(a) Agencies begin paying an employee a COLA or post differential on the effective date of the change in the employee's official duty station to a duty station within the COLA or post differential area or, in the case of local recruitment, on the effective date of the appointment.

(b) For an employee detailed to temporary duty in a post differential area and who is otherwise eligible for a post differential, agencies must begin paying a post differential after 42 consecutive calendar days of temporary duty in the post differential area.

**§ 591.236 When do COLA and post differential payments end?**

Subject to § 591.237(a), agencies stop paying an employee a COLA or post differential on—

(a) Separation,

(b) The effective date of assignment or transfer to a new official duty station outside the COLA or post differential area, or

(c) In the case of an employee on detail to temporary duty in a post differential area, the ending date of the detail.

**§ 591.237 Under what circumstances may employees on leave or travel receive a COLA and/or post differential?**

(a) An employee on leave or travel may receive a COLA or post differential only if the agency anticipates that the employee will return to duty in the area. *Exceptions:* If the employee does not return to duty in the area, the agency may still pay a COLA and/or a post differential for the period of leave or travel, subject to paragraph (b) of this section, if the agency determines that—

(1) It is in the public interest not to return the employee to the duty station, or

(2) The employee will not return because of compelling personal reasons or circumstances over which the employee has no control.

(b) *Post differentials.* Agencies may pay a post differential to an employee only during the employee's first 42 consecutive calendar days of absence from the post differential area.

**§ 591.238 How do agencies pay COLAs and post differentials?**

(a) Agencies pay COLAs and post differentials as a percentage of an employee's hourly rate of basic pay, including a retained rate of pay under 5 U.S.C. 3594(c) or 5363, for those hours during which the employee receives basic pay. This includes all periods of paid leave, detail, or travel status outside the COLA or post differential area.

(b) Agencies pay employees eligible for both a COLA and a post differential the full amount of the COLA, plus so much of the post differential as will not cause the combined total of the COLA and post differential to exceed 25 percent of the hourly rate of basic pay.

**§ 591.239 How do agencies treat COLAs and post differentials for the purpose of overtime pay and other entitlements?**

(a) Agencies include COLAs in the employee's straight time rate of pay and include COLAs and post differentials in an employee's regular rate of pay for computing overtime pay entitlements for nonexempt employees under the

Fair Labor Standards Act of 1938, as amended.

(b) Agencies may not include a COLA or post differential as part of an employee's rate of basic pay for the purpose of computing entitlements to overtime pay, retirement, life insurance, or any other additional pay, COLA, or post differential under title 5, United States Code.

(c) Payment of a COLA or post differential is not an equivalent increase in pay within the meaning of 5 U.S.C. 5335.

**§ 591.240 How are agency and employee representatives involved in the administration of the COLA and post differential programs?**

(a) OPM may establish a COLA Advisory Committee in each COLA survey area. The committees are composed of agency and employee representatives from the COLA survey area and one or more representatives from OPM.

(b) To the extent practical, the COLA Advisory Committees coordinate and work with the Survey Implementation Committee established pursuant to *Caraballo, et al.* v. *United States,* No. 1997–0027 (D.V.I).

**§ 591.241 What are the key activities of the COLA Advisory Committees?**

(a) The COLA Advisory Committees may—

(1) Advise and assist OPM in planning living-cost surveys;

(2) Provide or arrange for observers for data collection during living-cost surveys;

(3) Advise and assist OPM in the review of survey data;

(4) Advise OPM on its administration of the COLA program, including survey methodology; and

(5) Assist OPM in disseminating information to affected employees about the living-cost surveys and the COLA program.

(b) The committees also may advise OPM on special situations or conditions, such as hurricanes and earthquakes, as they relate to OPM's authority under § 591.223(b) to conduct interim surveys or implement some other change in response to conditions caused by a natural disaster or similar emergency.

**§ 591.242 What is the tenure of a COLA Advisory Committee?**

OPM may establish a COLA Advisory Committee in each area prior to each living-cost survey conducted in that area. OPM will appoint committee members for 3-year renewable terms. To the extent practical, the committee will continue to exist between surveys, but OPM may periodically review with the committee whether there is a continuing need for the committee.

**§ 591.243 How many members are on each COLA Advisory Committee?**

A COLA Advisory Committee has up to 12 members composed of OPM representatives and other agency and employee representatives, unless OPM determines that the committee should be larger. In determining the number of committee members, OPM considers the amount of work the committee is likely to be requested to do (based on the size and complexity of the local living-cost survey) and the availability of employee and agency representatives to participate as committee members.

**§ 591.244 How does OPM select COLA Advisory Committee members?**

(a) In establishing a COLA Advisory Committee, OPM invites local agencies and employee organizations to nominate committee members. OPM also invites COLA Defense Corporations and the local Federal Executive Board or Federal Executive Association each to nominate committee members. Subject to § 591.243, OPM selects committee members from these nominations in a manner designed to achieve a balanced representation that is reflective of agencies and employee organizations in the area. In consultation with the committee, OPM may select additional nominees to serve as alternates to the primary committee members. OPM designates not more than two OPM representatives to serve on each committee.

(b) Each Executive agency, as defined in 5 U.S.C. 105, must cooperate and release appointed employees for committee proceedings and activities unless the agency can demonstrate that exceptional circumstances directly related to accomplishing the mission of the employee's work unit require his or her presence on the job. Executive agency employees serving as committee members are considered to be on official assignment to an interagency function, rather than on leave, and are eligible to receive reimbursement for authorized travel expenses from their respective agencies.

## Appendix A of Subpart B—Places and Rates at Which Allowances Are Paid

This appendix lists the places approved for a cost-of-living allowance and shows the authorized allowance rate for each. The allowance percentage rate shown is paid as a percentage of an employee's rate of basic pay. The rates are subject to change based on the results of future surveys.

| Geographic coverage | Allowance rate (percent) |
|---|---|
| State of Alaska: | |
| City of Anchorage and 80-kilometer (50-mile) radius by road | 25.00 |
| City of Fairbanks and 80-kilometer (50-mile) radius by road | 25.00 |
| City of Juneau and 80-kilometer (50-mile) radius by road | 25.00 |
| Rest of the State | 25.00 |
| State of Hawaii: | |
| City and County of Honolulu | 25.00 |
| County of Hawaii | 16.50 |
| County of Kauai | 23.25 |
| County of Maui and County of Kalawao | 23.75 |
| Territory of Guam and Commonwealth of the Northern Mariana Islands | 25.00 |
| Commonwealth of Puerto Rico | 11.50 |
| U.S. Virgin Islands | 22.50 |

## Appendix B of Subpart B—Places and Rates At Which Differentials Are Paid

This appendix lists the places where a post differential has been approved and shows the differential rate to be paid to eligible employees. The differential percentage rate shown is paid as a percentage of an employee's rate of basic pay.

| Geographic coverage | Percentage differential rate |
|---|---|
| American Samoa (including the island of Tutuila, the Manua Islands, and all other islands of the Samoa group east of longitude 171° west of Greenwich, together with Swains Island) | 25.0 |
| Johnston Atoll | 25.0 |
| Midway Atoll | 25.0 |
| Territory of Guam and Commonwealth of the Northern Mariana Islands | 20.0 |
| Wake Atoll | 25.0 |

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## OFFICE OF GOVERNMENT ETHICS

## 5 CFR Part 2634

**RIN 3209–AA00**

## Technical Amendments to Qualified Trust Model Certificates Privacy and Paperwork Notices

**AGENCY:** Office of Government Ethics (OGE).

**ACTION:** Final rule; technical amendments.

**SUMMARY:** The Office of Government Ethics is revising the Privacy Act and Paperwork Reduction Act notices for the model qualified trust certificates of independence and compliance, as codified in an appendix to its executive branchwide financial disclosure regulations, to make a couple minor updating changes.

**EFFECTIVE DATE:** June 3, 2002.

**FOR FURTHER INFORMATION CONTACT:** William E. Gressman, Senior Associate General Counsel, Office of Government Ethics; Telephone: 202–208–8000, extension 1110; TDD: 202–208–8025; FAX: 202–208–8037.

**SUPPLEMENTARY INFORMATION:** In this rulemaking, OGE is making technical Privacy Act and paperwork-related revisions to appendix C of its executive branchwide financial disclosure regulation codified at 5 CFR part 2634. Appendix C sets forth the Privacy Act and Paperwork Reduction Act (public burden) notices for the certificates of independence and compliance (as themselves codified at appendixes A and B to part 2634) for qualified blind and qualified diversified trusts under the Ethics in Government Act of 1978, 5 U.S.C. appendix. First, OGE is adding the words ''judge- issued'' before the word ''subpoena'' in the routine use paraphrased in paragraph (3) of the Privacy Act Statement in appendix C order to more accurately reflect case law requirements for any such disclosures. The Office of Government Ethics is also working on a revised notice for its executive branchwide OGE/GOVT–1 system of records that will include a similar revision. Second, OGE is revising the Public Burden Information and Paperwork Reduction Act Statement in appendix C to indicate the current title of the OGE official to contact for any paperwork comments, the Deputy Director for Administration and Information Management. These changes were included in the recent three-year paperwork renewal OGE received from the Office of Management and Budget for the model certificates and ten other uncodified model trust documents.

### Matters of Regulatory Procedure

*Administrative Procedure Act*

Pursuant to 5 U.S.C. 553(b) and (d), as Director of the Office of Government Ethics, I find good cause exists for waiving the general notice of proposed rulemaking and the opportunity for public comment as to these revisions. The notice and comment are being waived because these technical amendments concern matters of agency organization, practice and procedure. Moreover, it is in the public interest that these updating technical revisions take effect promptly.

*Executive Order 12866*

In promulgating these technical amendments to appendix C to the branchwide financial disclosure regulations, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have not been reviewed by the Office of Management and Budget under the Executive order, since they are not deemed ''significant'' thereunder.

*Executive Order 12988*

As Director of the Office of Government Ethics, I have reviewed this final amendatory regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

*Regulatory Flexibility Act*

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities because it primarily affects high-level Federal executive branch officials who seek OGE approval for the creation of Ethics Act-qualified blind and diversified trusts and their trust fiduciaries.

*Paperwork Reduction Act*

The certificates of independence and compliance are information collections within the scope of the Paperwork Reduction Act (44 U.S.C. chapter 35). As noted above, the Office of Management and Budget recently granted its paperwork approval for a period of three years for the certificates as codified in appendixes A, B and C to 5 CFR part 2634, with only the latter procedural appendix C being amended in this rulemaking document.

*Unfunded Mandates Reform Act*

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

*Congressional Review Act*

The Office of Government Ethics has determined that this amendatory rulemaking is a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and has submitted a report thereon to the United States Senate, House of Representatives and General Accounting Office in accordance with that law.

### List of Subjects in 5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Financial disclosure, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Trusts and trustees.

Approved: April 29, 2002.

**Amy L. Comstock,**

*Director, Office of Government Ethics.*

For the reasons set forth in the preamble, the Office of Government Ethics is amending 5 CFR part 2634 as follows:

## PART 2634—[AMENDED]

1. The authority citation for part 2634 continues to read as follows:

**Authority:** 5 U.S.C. App. (Ethics in Government Act of 1978); 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

### Appendix C to Part 2634—[Amended]

2. Appendix C to part 2634 is amended by adding the words ''judge-issued'' before the word ''subpoena'' in the paragraph numbered (3) of the Privacy Act Statement, and by removing the words ''Associate Director for Administration'' from the second sentence of the first paragraph of the Public Burden Information and Paperwork Reduction Act Statement and adding in their place the words ''Deputy Director for Administration and Information Management''.

[FR Doc. 02–11025 Filed 5–2–02; 8:45 am]

BILLING CODE 6345–01–P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2001–SW–37–AD; Amendment 39–12737; AD 2002–09–04]**

**RIN 2120–AA64**

## Airworthiness Directives; Bell Helicopter Textron, Inc. Model 205A, 205A–1, 205B, 212, 412, 412EP, and 412CF Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) for Bell Helicopter Textron, Inc. (BHTI) Model 205A, 205A–1, 205B, 212, 412, 412EP, and 412CF helicopters, that requires inspecting each affected tail rotor blade forward tip weight retention block (tip block) and the aft tip closure (tip closure) for adhesive bond voids, and removing any tail rotor blade with an excessive void from service. This AD also requires modifying certain tail rotor blades by installing shear pins and tip closure rivets. This amendment is prompted by five occurrences of missing tip blocks or tip closures resulting in minor to substantial damage. The actions specified by this AD are intended to prevent loss of a tip block or tip closure, loss of a tail rotor blade, and subsequent loss of control of the helicopter.

**DATES:** Effective June 7, 2002.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 7, 2002.

**ADDRESSES:** The service information referenced in this AD may be obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280–3391, fax (817) 280–6466. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Michael Kohner, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas 76193–0170, telephone (817) 222–5447, fax (817) 222–5783.

**SUPPLEMENTARY INFORMATION:** A proposal to amend 14 CFR part 39 to include an AD for BHTI Model 205A, 205A–1, 205B, 212, 412, 412EP, and 412CF helicopters was published in the **Federal Register** on November 28, 2001 (66 FR 59374). That action proposed to require inspecting the tip block and the tip closure for adhesive bonding voids, and removing any tail rotor blade with an excessive void from service. It also proposed to require modifying certain tail rotor blades by installing shear pins and tip closure rivets in the tip area of affected tail rotor blades.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 281 helicopters of U.S. registry will be affected by this AD, that it will take approximately 3 work hours per helicopter to inspect certain tail rotor blades and to install the shear pins and tip closure rivets, and that the average labor rate is $60 per work hour. Required parts will cost approximately $25 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $57,605.

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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

### List of Subjects in 14 CFR Part 39

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

### Adoption of the Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**2002–09–04 Bell Helicopter Textron, Inc.:** Amendment 39–12737. Docket No. 2001–SW–37–AD.

*Applicability:* Model 205A, 205A–1, 205B, 212, 412, 412EP, and 412CF helicopters with a tail rotor blade, part number 212–010–750–009, -011, -105, -107, -109, or -111, having a serial number (S/N) prefix ATR or A3, or a S/N with a prefix A and a number less than or equal to 11529, installed, certificated in any category.

**Note 1:** This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Within 100 hours time-in-service, unless accomplished previously.

To prevent loss of the forward tip weight retention block (tip block) or aft tip closure (tip closure), loss of the tail rotor blade, and subsequent loss of control of the helicopter, accomplish the following:

(a) Inspect the tip block and tip closure for voids. Remove from service any tail rotor blade with a void in excess of that allowed by the Component Repair and Overhaul Manual limitations.

(b) Inspect the tip block attachment countersink screws in four locations to determine if the head of each countersunk screw is flush with the surface of the abrasion strip. The locations of these four screws are depicted on Figure 1 of Bell Helicopter Textron, Inc. Alert Service Bulletins 205–00–80, 205B–00–34, 212–00–111, 412–00–106, and 412CF–00–13, all Revision A, all dated December 20, 2000 (ASB). If any of these screws are set below the surface of the abrasion strip or are covered with filler material, install shear pins in accordance with the Accomplishment Instructions, Shear Pin Installation paragraphs, of the applicable ASB.

(c) Install the aft tip closure rivets on all affected tail rotor blades in accordance with the Accomplishment Instructions, Aft Tip Closure Rivet Installation paragraphs, of the applicable ASB.

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

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

(e) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) The inspection, removal, and modification shall be done in accordance with Bell Helicopter Textron, Inc. Alert Service Bulletins 205–00–80, 205B–00–34, 212–00–111, 412–00–106, and 412CF–00–13, all Revision A, all dated December 20, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280–3391, fax (817) 280–6466. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on June 7, 2002.

Issued in Fort Worth, Texas, on April 22, 2002.

**David A. Downey,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 02–10650 Filed 5–2–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Coast Guard

## 33 CFR Part 165

**[CGD01–01–077]**

**RIN 2115–AA97**

## Safety Zone; Long Island Sound, Thames River, Great South Bay, Shinnecock Bay, Connecticut River and the Atlantic Ocean Seventeen Annual Fireworks Displays

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing seventeen permanent safety zones for fireworks displays located on or in Long Island Sound, the Atlantic Ocean, the Thames River, Great South Bay, Shinnecock Bay and the Connecticut River. This action is necessary to provide for the safety of life on navigable waters during the events. This action establishes permanent exclusion areas that are only active prior to the start of the fireworks display until shortly after the fireworks display is completed, and it is intended to restrict vessel traffic in a portion of the affected waterways.

**DATES:** This rule is effective June 3, 2002.

**ADDRESSES:** Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part docket (CGD01–01–077) and are available for inspection or copying at U.S. Coast Guard Group/Marine Safety Office (MSO) Long Island Sound, 120 Woodward Ave, New Haven, Connecticut 06512, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Petty Officer R. L. Peebles, Marine Events Coordinator, Coast Guard Group/MSO Long Island Sound at (203) 468–4408.

**SUPPLEMENTARY INFORMATION:**

### Regulatory Information

On August 7, 2001, we published a notice of proposed rulemaking (NPRM) entitled ''Safety Zone; Long Island Sound, Thames River, Great South Bay, Shinnecock Bay, Connecticut River and the Atlantic Ocean Annual Fireworks Displays'' in the **Federal Register** (66 FR 41170). We received no letters commenting on the proposed rule. No public hearing was requested, and none was held.

### Background and Purpose

The Coast Guard is establishing seventeen permanent safety zones that will be activated for fireworks displays that normally occur on an annual basis and are normally held in one of the following seventeen locations: On the Connecticut River off of Old Saybrook, CT; on the Connecticut River off Hartford, CT; in Greenwich Harbor on Long Island Sound, CT; on the Thames River off of New London, CT; on the Thames River off of Norwich, CT; in Long Island Sound off Madison, CT; in Long Island Sound off Rowayton, CT; in New Haven Harbor on Long Island Sound, CT; in Long Island Sound off Groton Long Point in Groton, CT; in Cold Springs Harbor on Long Island Sound, NY; in Shinnecock Bay off Southampton, NY; in Great South Bay off Davis Park, NY; in Great South Bay off Patchogue, NY; in Great South Bay off Cherry Cove, NY; and in the Atlantic Ocean off Sagaponack, NY. By establishing permanent safety zones, the Coast Guard will eliminate the need to establish temporary rules annually.

### Connecticut River

There are three safety zones for the Connecticut River. The safety zone for the annual Arnold L. Chase fireworks display encompasses all waters of the Connecticut River within a 600-foot radius of the fireworks barge in approximate position 41°15′56″ N, 072°21′49″ W, located off Fenwick Pier, Old Saybrook, CT. The safety zone for the annual Saybrook Summer Pops fireworks display encompasses all waters of Connecticut River within a 600-foot radius of the fireworks barge located in approximate position 41°17′35″ N, 072°21′20″ W, located north of the dock on Saybrook Point, Old Saybrook, CT. The safety zone for

the annual Riverfest Fireworks display encompasses all waters of the Connecticut River within a 600-foot radius of the fireworks barge located in approximate position 41°45′34″ N, 072°39′37″ W, located in Hartford, CT.

**Thames River**

There are two safety zones for the Thames River. The zone for the annual Mashantucket Pequot fireworks display encompasses all waters of the Thames River within a 1200-foot radius of the fireworks barges located in approximate positions: barge one, 41°21′01″ N, 072°05′25″ W, barge two, 41°20′58″ N, 072°05′23″ W, barge three, 41°20′53″ N, 072°05′21″ W, located off New London, CT. The safety zone for the annual Harbor Day Fireworks display encompasses all waters of the Thames River within a 600-foot radius of the fireworks barge in approximate position 41°31′14″ N, 072°04′44″ W, located off the marina at the American Warf, Norwich, CT.

**Long Island Sound**

There are seven safety zones for Long Island Sound. The safety zone for the annual Indian Harbor Yacht Club fireworks display encompasses all waters of Captains Harbor within an 800-foot radius of the fireworks barge located in approximate position 41°00′35″ N, 073°37′05″ W, located off of Greenwich, CT. The safety zone for the annual Madison Cultural Arts fireworks display encompasses all waters of Long Island Sound off the city of Madison within an 800-foot radius of the fireworks barge in approximate position 41°16′10″ N, 072°36′30″ W. The safety zone for the annual City of Rowayton fireworks display encompasses all waters of Sheffield Channel on Long Island Sound off Ballast Reef, CT, within a 1000-foot radius of the fireworks barge in approximate position 41°03′11″ N, 073°26′41″ W. The safety zone for the annual City of West Haven fireworks display encompasses all waters of New Haven Harbor in Long Island Sound off Bradley Point within a 1200-foot radius of the fireworks barge located in approximate position 41°15′07″ N, 072°57′26″ W. The safety zone for the annual New Haven Festival fireworks display encompasses all waters of New Haven Harbor in Long Island Sound within a 1200-foot radius of the fireworks barge located in approximate position 40°17′31″ N, 072°54′48″ W.

The safety zone for the annual Groton Long Point Yacht Club fireworks display encompasses all waters of Long Island Sound off of Groton Long Point in Groton, CT, within a 600-foot radius of the fireworks barge located in approximate position 41°18′05″ N, 072°02′08″ W. The safety zone for the annual Yampol Family fireworks display encompasses all waters of Long Island Sound off Cove Neck, NY, within a 1200-foot radius of the fireworks barge located in approximate position 40°53′00″ N, 073°29′13″ W.

**Shinnecock Bay (Off Southampton, NY)**

The safety zone for the annual Southampton Fresh Air Home fireworks display encompasses all waters of Shinnecock Bay off Southampton, NY within a 600-foot radius of the fireworks barge located in approximate position 40°51′48″ N, 072°28′30″ W.

**Great South Bay (Off Long Island, NY)**

The safety zone for the annual T.E.L. Enterprises fireworks display encompasses all waters of Great South Bay off Davis Park, NY within a 600-foot radius of the fireworks barge located in approximate position 40°41′17″ N, 073°00′20″ W. The safety zone for the annual Patchogue Chamber of Commerce fireworks display encompasses all waters of Great South Bay off Patchogue, NY within an 800-foot radius of the fireworks barge located in approximate position 40°44′38″ N, 073°00′33″ W.

The safety zone for the annual Fire Island Tourist Bureau fireworks display encompasses all waters of Great South Bay off Cherry Grove, NY within a 600-foot radius of the fireworks barge located in approximate position 40°35′45″ N, 073°05′23″ W.

**Atlantic Ocean (Off Sagaponack, NY)**

The safety zone for the annual Treibeck's fireworks display encompasses all waters of the Atlantic Ocean off Sagaponack, NY within a 1200-foot radius of the fireworks barge located in approximate position 40°54′04″ N, 072°16′50″ W.

These safety zones will be enforced from 8 p.m. until 11 p.m. (e.s.t.) each day a barge with a ''FIREWORKS—STAY AWAY'' sign is posted in zone. However, vessels may enter, remain in, or transit through these safety zones during this time frame if authorized by the Captain of the Port Long Island Sound, or designated Coast Guard patrol personnel on scene, as provided for in 33 CFR 165.23. Enforcement of the safety zones will not prevent vessels from using affected bodies of water by simply transiting around the safety zones. Vessels are not precluded from mooring at or getting underway from commercial or recreational piers in the vicinity of any of the 17 safety zones. These safety zones provide for the safety of life on navigable waters during the events. Public notifications will be made prior to the events by all means to effect the widest publicity among the affected segments of the public, including publication in the local notice to mariners, marine information broadcasts, and facsimile.

**Discussion of Comments and Changes**

The Coast Guard received no letters commenting on the proposed rulemaking. No changes were made to this rulemaking.

**Regulatory Evaluation**

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. The impact of this rule is expected to be minimal for the following reasons: Vessels may still transit through these safety zones except during the 45 minute period that a Coast Guard Patrol vessel is present; the safety zones are enforced during night hours when maritime traffic within the effected areas is the lightest; our historical experience with fireworks displays in these locations suggests that the maritime public is not burdened by the brief imposition of restrictions on vessel movement, as no objections have been lodged against previous safety zones established during fireworks displays in the same areas; vessels can moor and transit around the safety zones at all times. Advance notifications will also be made to the local maritime community by the Local Notice to Mariners. Marine information and facsimile broadcasts may also be made.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and

governmental jurisdictions with populations of less than 50,000.

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

These safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: Vessel traffic can transit around all 17 safety zones during their enforcement period; vessels will not be precluded from getting underway, or mooring at, any piers or marinas currently located in the vicinity of the safety zones; the zones are only effective for a brief period; before the effective period of any zone, we will issue maritime advisories widely available to users of Long Island Sound, the Connecticut and Thames Rivers, Great South Bay, Shinnecock Bay, and the Atlantic Ocean off Connecticut and New York by local notice to mariners. Marine information and facsimile broadcasts may also be made.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. However, we received no requests for assistance from small entities.

**Collection of Information**

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

**Federalism**

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that this rule does not have implications for federalism under that Order.

**Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This rule will not impose an unfunded mandate.

**Taking of Private Property**

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

**Indian Tribal Governments**

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. A rule with tribal implications has a substantial direct effect on one or more Indian tribe, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

**Energy Effects**

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. This rule fits paragraph 34(g) as it establishes a safety zone. A ''Categorical Exclusion Determination'' is available in the docket where indicated under **ADDRESSES.**

**List of Subjects in 33 CFR Part 165**

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. Add § 165.151 to read as follows:

### § 165.151 Safety Zones; Long Island Sound annual fireworks displays.

(a) *Safety Zones.* The following areas are designated safety zones. All coordinates references 1983 North American Datum (NAD83).

(1) *Indian Harbor Yacht Club Fireworks Safety Zone.* All waters of Long Island Sound off Greenwich CT, within a 800-foot radius of the fireworks barge located in approximate position 41°00 ′35″ N, 073°37′05″ W.

(2) *City of Rowayton Fireworks Safety Zone.* All waters of Long Island Sound in Sheffield Channel off of Ballast Reef within a 1000-foot radius of the fireworks barge located in approximate position 41°03′11″ N, 073°26′41″ W.

(3) *The Yampol Family Fireworks Safety Zone.* All waters of Long Island Sound off Cold Springs Harbor, Cove Neck New York within a 1200-foot radius of the fireworks barge located in approximate position 40°53′00″ N, 073°29′13″ W.

(4) *Groton Long Point Yacht Club Fireworks Safety Zone.* All waters of Long Island Sound off of Groton Long Point, Groton, CT, within a 600-foot radius of the fireworks barge in approximate position 41°18′05″ N, 072°02′08″ W.

(5) *City of West Haven Fireworks Safety Zone.* All waters of New Haven Harbor on Long Island Sound off Bradley Point within a 1200-foot radius of the fireworks barge in approximate position 41°15′07″ N, 072°57′26″ W.

(6) *New Haven Festival Fireworks Safety Zone.* All waters of New Haven Harbor on Long Island Sound within a 1200-foot radius of the fireworks barge in approximate position 40°17′31″ N, 072°54′48″ W.

(7) *Madison Cultural Arts Fireworks Safety Zone.* All the waters of Long Island Sound located off the City of Madison within an 800-foot radius of the fireworks barge in approximate position 41°16′10″ N, 072°36′30″ W.

(8) *Arnold L. Chase Fireworks Safety Zone.* All waters of Connecticut River within a 600 foot radius of the fireworks

barge located in approximate position 41°15′56″ N, 072°21′49″ W, about 100-yards off Fenwick Pier.

(9) *Saybrook Summer Pops Fireworks Safety Zone.* All waters of Connecticut River within a 600-foot radius of the fireworks barge located in approximate position 41°17′35″ N, 072°21′20″ W.

(10) *Mashantucket Pequot Fireworks Safety Zone.* All waters of Thames River within a 1200-foot radius of the fireworks barges located in approximate positions: barge one, 41°21′01″ N, 072°05′25″ W, barge two, 41°20′58″ N, 072°05′23″ W, barge three, 41°20′53″ N, 072°05′21″ W, located off New London, CT.

(11) *Harbor Day Fireworks Safety Zone.* All waters of Thames River within a 600-foot radius of the fireworks barge located in approximate position 41°31′14″ N 072°04′44″ W, located off American Warf Marina, Norwich, CT.

(12) *Riverfest Fireworks Safety Zone.* All the waters of the Connecticut River within a 600-foot radius of the fireworks barge located in approximate position 41°45′34″ N, 072°39′37″ W.

(13) *Southampton Fresh Air Home Fireworks Safety Zone.* All the waters of Shinnecock Bay within a 600-foot radius of the fireworks barge located in approximate position 40°51′48″ N, 072°28′30″ W, off of Southampton, NY.

(14) *T.E.L. Enterprises Fireworks Safety Zone.* All the waters of Great South Bay within a 600-foot radius of the fireworks barge located in approximate position 40°41′17″ N, 073°00′20″ W, off of Davis Park, NY.

(15) *Patchogue Chamber of Commerce Fireworks Safety Zone.* All the waters of Great South Bay within an 800-foot radius of the fireworks barge located in approximate position 40°44′38″ N, 073°00′33″ W, off of Patchogue, NY.

(16) *Fire Island Tourist Bureau Fireworks Safety Zone.* All the waters of Great South Bay within a 600-foot radius of the fireworks barge located in approximate position 40°35′45″ N, 073°05′23″ W, off of Cherry Cove, NY.

(17) *Treibeck's Party Fireworks Safety Zone.* All the waters of the Atlantic Ocean within a 1200-foot radius of the fireworks barge located in approximate position 40°54′04″ N, 072°16′50″ W, off of Sagaponack, NY.

(b) *Notification.* Coast Guard Group/Marine Safety Office Long Island Sound and Coast Guard Group Moriches will cause notice of the activation of these safety zones to be made by all appropriate means to effect the widest publicity among the affected segments of the public, including publication in the local notice to mariners, marine information broadcasts, and facsimile. Fireworks barges used in these locations will also have a sign on their port and starboard side labeled ''FIREWORKS—STAY AWAY'' with the same dimensions listed previously.

(c) *Enforcement period.* Specific zones in this section will be enforced from 8 p.m. to 11 p.m. (e.s.t.) each day a barge with a ''FIREWORKS—STAY AWAY'' sign is posted in that zone.

(d) *Regulations.* Vessels may not enter, remain in, or transit through the safety zones in this section during the enforcement period unless authorized by the Captain of the Port Long Island Sound or designated Coast Guard patrol personnel on scene.

Dated: April 15, 2002.

**J.J. Coccia,**

*Captain, U. S. Coast Guard, Captain of the Port, Long Island Sound.*

[FR Doc. 02–11061 Filed 5–2–02; 8:45 am]

BILLING CODE 4910–15–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 9

**[FRL–7173–6]**

## OMB Approvals Under the Paperwork Reduction Act; Technical Amendment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Restructuring by the OGWDW of its existing drinking water program Information Collection Requests (ICR) has resulted in the consolidation of rules and activities of standalone ICRs into three main drinking water program ICRs.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA), this technical amendment amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for the Public Water System Supervision Program (PWSS) Information Collection Request (ICR), Microbial Rules ICR and Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides (DBP/Chem/Rads) Rules ICR.

**EFFECTIVE DATE:** This is effective May 3, 2002.

**FOR FURTHER INFORMATION CONTACT:** Lisa Christ at 202–564–8354.

**SUPPLEMENTARY INFORMATION:** EPA is amending the table of currently approved information collection request (ICR) control numbers issued by OMB for various regulations. The amendment updates the table to list those information collection requirements which have moved due to the restructure and consolidation of the Office of Ground Water Drinking Water ICRs. An announcement that the following ICRs: PWSS ICR, OMB Control No. 2040–0090; Microbial ICR, OMB Control No. 2040–0205; and the DBP/Chem/Rads ICR, OMB Control No 2040–0204, have been forwarded to the Office of Management and Budget (OMB) for review and approval, appeared in the **Federal Register** on October 5, 2001 (66 FR 194). The affected regulations are codified at 40 CFR parts (141.21–142.312). EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations, and in each CFR volume containing EPA regulations. The table lists CFR citations with reporting, recordkeeping, or other information collection requirements, and the current OMB control numbers. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320.

These ICRs were previously subject to public notice and comment prior to OMB approval. Due to the technical nature of the table, EPA finds that further notice and comment is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), to amend this table without prior notice and comment.

### I. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This action also does not require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or Executive Order 13084 (63 FR 27655 (May 10, 1998), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C.

601 *et seq.*). This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This action is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

*Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore. EPA has submitted reports containing these rules and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 9**

Environmental protection, Reporting and recordkeeping requirements.

Dated: April 10, 2002.

**Oscar Morales,**

*Director, Collection Strategies Division, Office of Information Collection.*

For the reasons set out in the preamble, 40 CFR part 9 is amended as follows:

## PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended to revise existing entries for '' National Primary Drinking Water Regulations'' and ''National Primary Drinking Water Regulations Implementation'' to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act**

* * * * *

NATIONAL PRIMARY DRINKING WATER REGULATIONS

| | |
|---|---|
| 141.2 | 2040–0090 |
| 141.4 | 2040–0090 |
| 141.11–141.15 | 2040–0090 |
| 141.21 | 2040–0205 |
| 141.22 | 2040–0090 |
| 141.23A(a)–(b) | 2040–0204 |
| 141.23(d)–141.24 | 2040–0204 |
| 141.25 | 2040–0090 |
| 141.26 | 2040–0204 |
| 141.27–141.30 | 2040–0090 |
| 141.31(a)–(c) and (e) | 2040–0204 |
| 141.32(a)–(g) | 2040–0090 |
| 141.33(a)–(d) | 2040–0204 |
| 141.33(e) | 2040–0090 |
| 141.35 | 2040–0204 |
| 141.40 | 2040–0204 |
| 141.41 | 2040–0090 |
| 141.42–141.43 | 2040–0204 |
| 141.50–141.52 | 2040–0090 |
| 141.60–141.63 | 2040–0090 |
| 141.70–141.74 | 2040–0090 |
| 141.75 | 2040–0205 |
| 141.76 | 2040–0205 |
| 141.80–141.91 | 2040–0210 |
| 141.100 | 2040–0090 |
| 141.110 | 2040–0090 |
| 141.111 | 2040–0204 |
| 141.130–141.132 | 2040–0204 |
| 141.134–141.135 | 2040–0204 |
| 141.140–141.144 | 2040–0090 |
| 141.153–141.154 | 2040–0201 |
| 141.155(a)–(g)(1) and (h) | 2040–0090 |
| 141.170 | 2040–0205 |
| 141.172 | 2040–0205 |
| 141.173 | 2040–0205 |
| 141.174(a)–(b) | 2040–0205 |
| 141.175(a)–(b) | 2040–0205 |
| 141.175(c) | 2040–0090 |
| 141.201–141.210 | 2040–0090 |
| 141.530–141.536 | 2040–0229 |
| 141.540–141.544 | 2040–0229 |
| 141.550–141.553 | 2040–0229 |
| 141.560–141.564 | 2040–0229 |
| 141.570–141.571 | 2040–0229 |

NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

| | |
|---|---|
| 142.2–142.3 | 2040–0090 |
| 142.10 | 2040–0090 |
| 142.11 | 2040–0090 |
| 142.12 | 2040–0090 |
| 142.14(a) | 2040–0205 |
| 142.14(b)–(d)(1) | 2040–0090 |
| 142.14(d)(2)–(7) | 2040–0204 |
| 142.14(d)(12)(i)–(iv) | 2040–0204 |
| 142.14(d)(13)–(16) | 2040–0204 |
| 142.15(a)–(b) | 2040–0090 |
| 142.15(c)(1)–(5) | 2040–0205 |
| 142.16(b) | 2040–0205 |
| 142.16(c) | 2040–0090 |
| 142.16(e) | 2040–0204 |
| 142.16(f) | 2040–0090 |
| 142.16(g) | 2040–0205 |
| 142.16(h) | 2040–0204 |
| 142.16(i) | 2040–0205 |
| 142.16(j) | 2040–0229 |
| 142.16(k)(1) | 2040–0204 |
| 142.16(l)(1) and (2) | 2040–0204 |
| 142.17–142.24 | 2040–0090 |
| 142.51 | 2040–0090 |
| 142.56–142.57 | 2040–0090 |
| 142.60–142.61 | 2040–0090 |
| 142.62 | 2040–0090 |
| 142.63–142.64 | 2040–0090 |
| 142.70–142.78 | 2040–0090 |
| 142.81 | 2040–0090 |
| 142.306–142.308 | 2040–0090 |
| 142.311–142.312 | 2040–0090 |

* * * * *

[FR Doc. 02–11007 Filed 5–2–02; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 62

**[PA–131–4090a; FRL–7205–6]**

## Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Pennsylvania; Control of Emissions From Existing Hospital/Medical/Infectious Waste Incinerators

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve the Commonwealth of Pennsylvania 111(d)/129 plan (the ''plan'') for the control of air pollutant emissions from hospital/medical /infectious waste incinerators (HMIWIs). The plan was developed and submitted to EPA by the Pennsylvania Department of Environmental Protection (PADEP), Bureau of Air Quality, on October 26, 1998, and as amended on December 3, 1999, May 4, August 9, and October 22, 2001. The plan covers all affected facilities in the geographic area of the Commonwealth of Pennsylvania, except for Allegheny County where designated facilities are regulated under the Allegheny County Health Department HMIWI 111(d)/129 plan, approved by EPA on April 7, 2000, and amended on May 26, 2000. Also, EPA is approving the PADEP requested delegation of the increments of progress and compliance schedules promulgated under the

August 15, 2000, Federal HMIWI 111(d)/129 plan (65 FR 49868).

**DATES:** This final rule is effective June 17, 2002 unless by June 3, 2002 adverse or critical comments are received. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Written comments should be mailed to David L. Arnold, Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, Rachel Carson State Office Building, 400 Market Street, Harrisburg, Pennsylvania 17105–8465.

**FOR FURTHER INFORMATION CONTACT:** James B. Topsale at (215) 814–2190, or by e-mail at *topsale.jim@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

This document is divided into Sections I through V and answers the questions posed below.



## I. General Provisions

Q. What action is EPA approving?

A. EPA is approving the Commonwealth of Pennsylvania 111(d)/129 plan (the ''plan'') for the control of air pollutant emissions from hospital/medical/infectious waste incinerators (HMIWIs). The plan was developed and submitted to EPA by the Pennsylvania Department of Environmental Protection (PADEP), Bureau of Air Quality, on October 26, 1998, and as amended on December 3, 1999, May 4, August 9, and October 22, 2001. Also, EPA is approving the requested delegation of the August 15, 2000 Federal HMIWI 111(d)/129 plan (65 FR 49868) increments of progress and compliance schedules. The plan covers all affected facilities in the geographic area of the Commonwealth of Pennsylvania, except for Allegheny County where affected facilities are regulated under the Allegheny County Health Department HMIWI 111(d)/129 plan, approved (65 FR 18249 and 34104) by EPA on April 7, 2000, and amended (65 FR 340104) on May 26, 2000.

Q. What is a State/local 111(d)/129 plan?

A. Section 111(d) of the Clean Air Act (CAA) requires that ''designated'' pollutants, controlled under standards of performance for new stationary sources by section 111(b) of the Clean Air Act (CAA), must also be controlled at existing sources in the same source category to a level stipulated in an emission guidelines (EG) document. Section 129 of the CAA specifically addresses solid waste combustion and emissions controls based on what is commonly referred to as ''maximum achievable control technology'' (MACT). Section 129 requires EPA to promulgate a MACT based emission guideline (EG) document for HMIWIs, and then requires states to develop 111(d)/129 plans that implement the EG requirements. The HMIWI EG under 40 CFR part 60, subpart Ce, establish emission and operating requirements under the authority of the CAA, sections 111(d) and 129. These requirements must be incorporated into a State/local 111(d)/129 plan that is ''at least as protective'' as the EG, and is Federally enforceable upon approval by EPA.

The procedures for adoption and submittal of State plans are codified in 40 CFR part 60, subpart B. Additional information on the submittal of State plans is provided in the EPA document, ''Hospital/Medical/Infectious Waste Incinerator Emission Guidelines: Summary of the Requirements for section 111(d)/129 State Plans, EPA–456/R–97–007, November 1997''.

Q. What is a Federal 111(d)/129 plan?

A. As required by section 129(b)(3) of the CAA, on August 15, 2000, EPA promulgated a Federal plan for HMIWIs for which construction commenced on or before June 20, 1996. The Federal plan is a set of MACT requirements that implement the 1998 HMIWI emission guidelines. The Federal plan is applicable to those existing HMIWIs not specifically covered by an approved State plan under sections 111(d) and 129 of the CAA. It fills an EPA EG enforceablilty gap until state plans are approved and assures that the HMIWI units stay on track to complete pollution control equipment retrofits and other requirements on or before the statutory compliance date of September 15, 2002. This compliance date is based on the September 15, 1997 EG promulgation date and the requirements of section 129(f)(2) of the CAA. The Federal plan no longer applies once a state plan is fully approved. Unlike a Federal plan for sources regulated under sections 110 or 172 of the CAA, the section 111(d)/129 Federal plan imposes no statutory or other sanctions because of deficient or unapproved state plans. However, EPA approval of a state plan does not void or negate the need for affected sources to achieve expeditious compliance as required under section 129(f)(2) of the CAA, and the Federal plan compliance schedules. Approval of the subject Pennsylvania plan will be the first step in the removal of Pennsylvania from the list of states that are now subject to Federal plan requirements.

Q. What pollutant(s) will this action control?

A. The September 15, 1997 promulgated EG, subpart Ce, are applicable to all existing HMIWIs (i.e., the designated facilities) that emit organics (dioxins/furans), carbon monoxide, metals (cadmium, lead, mercury), acid gases (hydrogen chloride, sulfur dioxide, and nitrogen oxides) and particulate matter. This action establishes emission limitations for each of these pollutants, including an opacity limitation.

Q. What are the expected environmental and public health benefits from controlling HMIWI emissions?

A. HMIWI emissions can have adverse effects on both public health and the

environment. Dioxin, lead, and mercury can bioaccumulate in the environment. Exposure to dioxins/furans has been linked to reproductive and developmental effects, changes in hormone levels, and chloracne. Respiratory and other effects are associated with exposure to particulate matter, sulfur dioxide, cadmium, hydrogen chloride, and mercury. Health effects associated with exposure to cadmium, and lead include probable carcinogenic effects. Acid gases contribute to the acid rain that lowers the pH of surface waters and watersheds, harms crops and forests, and damages buildings. Implementation of the emissions control measures required under the Pennsylvania (PA) plan will help mitigate most of the noted adverse environmental and public health impacts associated with the operation of HMIWI units.

**II. Federal Requirements the Pennsylvania HMIWI 111(d)/129 Plan Must Meet for Approval**

Q. What general requirements must the PADEP plan meet in order to receive approval of its 111(d)/129 plan?

A. The plan must meet the requirements of 40 CFR part 60, subparts B, and Ce; and the Federal plan, 40 CFR part 62, subpart HHH. Subpart B specifies detailed procedures for the adoption and submittal of State plans for designated facilities. The EG, subpart Ce, and the related new source performance standard (NSPS), subpart Ec, both promulgated on September 15, 1997, contain the requirements for the control of specific designated pollutants in accordance with sections 111(d) and 129 of the CAA. Subpart Ce cross-references applicable provisions of subpart Ec, related to compliance and performance testing, monitoring, reporting, and recordkeeping. State plans, approved after the promulgation date of the Federal plan, must include expeditious compliance schedules that are no less stringent than those in the Federal plan. In summary, the Pennsylvania plan must meet the requirements of (1) 40 CFR part 60, subpart B, §§ 60.23 through 60.26; (2) 40 CFR part 60, subpart Ce, §§ 60.30e through 60.39e, and related subpart Ec provisions, as noted above; and (3) part 62, subpart HHH, enforceable compliance dates and increments of progress. In addition, any State requesting delegation of authority under the Federal plan must demonstrate that it has adequate resources and the legal authority to administer and enforce the program. The PADEP has made the required demonstration with respect to the task of implementing the cited Federal plan compliance schedules.

Q. What does the Pennsylvania plan contain?

A. Consistent with the requirements of subparts B, Ce, Ec and HHH, the plan contains the following elements:

1. A demonstration of Pennsylvania's legal authority to implement the plan;
2. Identification of the enforceable mechanism(s)—Federally enforceable state operating permits, Federally enforceable state plan approvals, and Title V operating permits;
3. Source and emission inventories, as required;
4. Emission limitation requirements that are no less stringent than those in subpart Ce;
5. Source compliance schedules, including increments of progress, no less stringent than those stipulated in subpart HHH;
6. Source testing, monitoring, recordkeeping, and reporting requirements;
7. HMIWI operator training and qualification requirements;
8. Requirements for development of a Waste Management Plan;
9. Records of the public hearing on the PA plan;
10. Provision for PADEP submittal to EPA of annual reports on progress in plan enforcement; and
11. A Title V permit application due date (if permit not issued).

The emission standards and other applicable requirements, including Federally enforceable compliance schedules and increments of progress will be enforced through either the Federally enforceable plan approvals ( *i.e.*, construction permits), operating permits, or Title V permits issued under 25 Pa. Code Chapter 127, subchapters B, F, and G, respectively.

Q. Does the Pennsylvania 111(d)/129 plan meet all EPA requirements for approval?

A. Yes. The PADEP has submitted a plan that conforms to all EPA requirements—40 CFR part 60, subparts B, Ce, Ec, including the expeditious compliance schedule requirements of 40 CFR part 62, subpart HHH. Details regarding the approvability of the plan elements are included in the technical support document (TSD) associated with this action. A copy of the TSD is available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this document.

**III. Requirements Affected HMIWI Owners/Operators Must Meet**

Q. How do I determine if my HMIWI is a designated facility subject to the Pennsylvania 111(d)/129 plan?

A. If construction commenced on your HMIWI on or before June 20, 1996, then it is subject to the plan. The plan contains no lower applicability threshold based on incinerator capacity. However, there are designated facility exemptions, as referenced in 40 CFR part 60, subpart Ce, section 60.32e. These exemptions include incinerators that burn only pathological, low level radioactive, and/or chemotherapeutic waste; co-fired combustors; incinerators permitted under section 3005 of the Solid Waste Disposal Act; municipal waste combustors (MWC) subject to a Clean Air Act combustor rule; pyrolysis units; and cement kilns.

Q. What general requirements must I meet under the approved EPA 111(d)/129 plan?

A. The PADEP plan contains enforceable mechanisms that include operating permits, plan approvals (*i.e.*, construction permits), and Title V permits. These permits establish the following requirements:

- Emission limitations for particulate matter (PM), opacity, carbon monoxide (CO), dioxins/furans (CDD/CDF), hydrogen chloride (HCl), sulfur dioxide ($SO_2$), nitrogen oxides ($NO_X$), lead (Pb), cadmium (Cd), and mercury (Hg)
- Compliance and performance testing
- Operating parameter limitations and monitoring
- Operator training and qualification
- Development of a waste management plan
- Recordkeeping and reporting
- Title V permit application submittal date (if an application has not been submitted)

A full and comprehensive statement of the above requirements is incorporated in each of the submitted HMIWI air quality permits.

Q. What emissions limits must I meet, and in what time frame?

A. The pollutant emission limitations and compliance schedules are stipulated in your PADEP facility air quality permit that was submitted to EPA as part of the 111(d)/129 plan. Your 111(d)/129 plan emission limitations are determined by the size category of your HMIWI unit—small, medium, or large. HMIWI size categories are defined in subpart Ec, § 60.51, and are determined by either the ''maximum design waste burning capacity,'' or by the ''maximum charge rate.''

Since PADEP's initial submittal of its plan, EPA has promulgated a Federal plan (40 CFR part 62, subpart HHH) that contains expeditious compliance schedules and increments of progress. As a result, the Federal plan, promulgated on August 15, 2000, may

contain more stringent compliance schedules than what is now required under your PADEP air quality permit. This is because some permit compliance schedules are linked to EPA's approval of the Pennsylvania 111(d)/129 plan. As a result, some exiting permit schedules may now be no longer expeditious and consistent with CAA section 129(f)(2) requirements. Accordingly, in order to meet the requirements of section 129(f)(2), the PADEP has requested EPA authority to implement the Federal plan's (65 FR 49868) increments of progress and compliance schedules. As noted above, EPA is granting the requested authority.

If you chose to continue operating your HMIWI rather than shut it down, then you must install an emissions control system or make process changes in order to meet the maximum available control technology (MACT) emission limitations for the pollutants identified in the previous answer above. As a HMIWI owner/operator, you must either (1) achieve compliance on or before August 15, 2001, or (2) meet certain specific increments of progress and achieve compliance by September 15, 2002, the statutory compliance date, based on the requirements of the CAA Section 129(f)(2). The delegated PA plan increments of progress for the noted extended compliance date are given in the table below.

EXTENDED COMPLIANCE SCHEDULE AND INCREMENTS OF PROGRESS UNDER THE PENNSYLVANIA 111(d)/129 PLAN

| Increments(s) | Compliance date(s) |
|---|---|
| Submit a final control plan | On or before September 15, 2000 |
| Award contracts for onsite construction, installation of on or before control equipment, or incorporation of process changes. | On or before April 15, 2001. |
| Begin onsite construction, installation of control equipment, or incorporation of process changes. | On or before December 15, 2001. |
| Complete onsite construction, installation of control equipment, or incorporation of process changes. | On or before July 15, 2002 |
| Achieve final compliance | On or before September 15, 2002. |

The first increment of progress, the final control plan, must have been submitted to EPA (or the PADEP) on or before September 15, 2000. If you have submitted a final control plan to EPA with a compliance date extension request, it is now the responsibility of the PADEP to respond to your request and take appropriate action. Nevertheless, if your extended compliance schedule was submitted after September 15, 2000, there is no expressed authority, under the provisions of either the Federal or Pennsylvania plan, to allow approval of such request by either EPA or PADEP.

If your plan has been to shut down your HMIWI facility after August 15, 2001, but no later than September 15, 2002, then you are subject to certain petition, compliance schedule documentation, and reporting requirements, as stipulated in the Federal plan (subpart HHH), §§ 62.14471 and 62.14472. All petitions for allowing HMIWI operations after August 15, 2001 must have been submitted to the EPA (or PADEP) no later than November 13, 2000. See the Federal plan § 62.14471, relating to compliance schedules. If your petition was submitted after that date, neither the EPA or the PADEP have the authority under the provisions of the Federal plan to approve a shutdown plan and schedule submitted after that date.

Whether your final compliance date is (1) on or before August 15, 2001, or (2) after August 15, 2001, but on or before September 15, 2002, the initial performance test must be completed within 180 days after the date when you are required to achieve final compliance with all applicable emission limitations. Also, you must submit to PADEP the initial compliance report, including the results of the initial performance test, and the waste management plan no later than 60 days following the initial performance test.

Further details regarding compliance schedule requirements can be found in the Federal plan, subpart HHH, §§ 62.14470, 62.14471, and 62.14472.

Q. Are there any operational requirements for my HMIWI and emissions control system?

A. Yes, there are operational requirements. In summary, the operational requirements relate to: (1) The HMIWI and air pollution control devices (APCD) operating within certain established parameter limits, determined during the initial performance test; (2) the use of a trained and qualified HMIWI operator; and (3) the completion of an annual update of operation and maintenance information, and its review by your HMIWI operator (s).

Failure to operate the HMIWI and/or APCD within certain established operating parameter limits constitutes an emissions violation for the controlled air pollutant. However, as a HMIWI owner/operator, you are provided an opportunity to establish revised operating limits, and demonstrate that your facility is meeting the required emission limitation, providing a repeat performance test is conducted in a timely manner, as specified in your air quality permit and subpart Ce, § 60.37e(b)(5).

Consistent with the Federal plan requirements of §§ 62.14425(b), on or before February 15, 2001, you were required to conduct an initial review of the training documents (e.g., operation and maintenance manual) with each operator on site under the provisions of 40 CFR 60.34e and 60.53c(h), which also requires an annual update and review of the documentation. Also, under both the Pennsylvania and Federal plan compliance dates, beginning no later than August 15, 2001, a fully trained and qualified operator is required on site whenever your HMIWI unit is in operation. See the Federal plan §§ 62.14425, 62.14470(b)(1), and 6214471(b)(3). In order to be classified as a qualified operator, one must complete an appropriate HMIWI operator training course that meets the criteria referenced in 40 CFR part 60, subparts Ce and Ec, §§ 60.34e and 60.53c, respectively.

The Pennsylvania 111(d)/129 plan HMIWI air quality permits incorporate by reference all applicable operational requirements of the EG, subpart Ce, and the related NSPS, subpart Ec.

Q. What are the testing, monitoring, recordkeeping, and reporting requirements for my HMIWI?

A. Testing, monitoring, recordkeeping, and reporting requirements are summarized below. You are required to conduct an initial source (stack) test to determine compliance with the emission limitations for PM, opacity, CO, CDD/CDF, HCl, Pb, Cd, and Hg. As noted

above, the initial source test must be completed no later than 180 days after your final compliance date. Consistent with the EG, no initial compliance test is required for sulfur dioxide and nitrogen oxides. Nevertheless, both the PADEP and the EPA have discretionary authorities under existing state and Federal regulations to require, if deemed necessary, source tests for these pollutants. After the initial source test, compliance testing is then required annually (no more than 12 months following the previous test) to determine compliance with the emission limitations for PM, opacity, CO, and HCl.

As noted above, operating parameter limits are monitored and established during the initial performance test. Monitored HMIWI operating parameters include, for example, charge rate, secondary chamber and bypass stack temperatures. APCD operating parameters include, for example, CDD/CDF and Hg sorbent (e.g., activated carbon) flow rate, HCl sorbent (e.g., lime) flow rate, PM control device inlet temperature, pressure drop across the control system, and liquid flow rate, including pH.

Recordkeeping and reporting are required to document the results of the initial and annual performance tests, continuous monitoring of site-specific operating parameters, compliance with the operator training and qualification requirements, and development of a waste management plan (WMP). Records must be maintained for at least five years.

The Pennsylvania plan HMIWI operating permits incorporate by reference all the applicable testing, monitoring, recordkeeping, and reporting requirements of the EG and the related NSPS.

Q. What must be included in my Waste Management Plan (WMP), and when must it be completed?

A. In summary, your WMP must identify both the feasibility of, and the approach for, separating certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from the incinerated waste. Also, in developing your WMP, you must consider the American Hospital Association publication entitled ''An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities.'' This publication (AHA Catalog No. 057007) is available for purchase from the American Hospital Association Service, Inc., Post Office Box 92683, Chicago, Illinois 60675–2683. For more details regarding these requirements see 40 CFR part 60, subpart Ec, § 60.55c. Submittal of the WMP to PADEP (or EPA) is required no later than 60 days following the initial performance tests required under subpart HHH, § 62.14432.

Q. Is there a requirement for obtaining a Title V permit?

A. Yes, if your HMIWI is an affected facility, you must have submitted a complete Title V application to the PADEP no later than September 15, 2000.

## IV. Final EPA Action

EPA is approving the Pennsylvania 111(d)/129 plan for controlling HMIWI emissions from designated facilities. This approval is based upon the rationale discussed above and in further detail in the TSD associated with this action. Also, EPA is approving PADEP's request for delegation of authority to implement and enforce the Federal plan increments of progress and compliance schedules for HMIWI, as codified at 40 CFR part 62, subpart HHH.

As provided by 40 CFR 60.28(c), any revisions to the Pennsylvania plan or associated permits will not be considered part of the applicable plan until submitted by the PADEP in accordance with 40 CFR 60.28(a) or (b), as applicable, and until approved by EPA in accordance with 40 CFR part 60, subpart B.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action simply reflects already existing Federal requirement for existing HMIWIs that are subject to the provisions of the Federal HMIWI 111(d)/129 plan. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the 111(d) plan should relevant adverse or critical comments be filed. This rule will be effective June 17, 2002 without further notice unless the Agency receives relevant adverse comments by June 3, 2002. If EPA receives such comments, then EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

## V. Administrative Requirements

### *A. General Requirements*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing 111(d)/129 plan submissions, EPA's role is to approve state choices, provided that they meet

the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a 111(d)/129 plan submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a 111(d)/129 plan submission, to use VCS in place of a 111(d)/129 plan submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

*B. Submission to Congress and the Comptroller General*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

*C. Petitions for Judicial Review*

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 2, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving the Pennsylvania 111(d)/129 plan for HMIWI may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 62**

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

Dated: April 25, 2002.

**Thomas C. Voltaggio,**

*Acting Regional Administrator, Region III.*

40 CFR Part 62, Subpart NN, is amended as follows:

## PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

**Authority:** 42 U.S.C. 7401–7671q.

## Subpart NN—Pennsylvania

2. Amend Subpart NN-Pennsylvania, by adding the subheading and §§ 62.9650, 62.9651 and 62.9652 after § 62.9644 to read as follows:

**Emissions From Existing Hospital/ Medical/Infectious Waste Incinerators (HMIWIs)—Section 111(d)/129 Plans**

**§ 62. 9650 Identification of plan.**

Section 111(d)/129 plan for designated HMIWIs and the associated state issued air quality construction and operating permits, as submitted on October 26, 1998, amended December 3, 1999, May 4, August 9, and October 22, 2001.

**§ 62.9651 Identification of sources.**

The plan applies to all existing HMIWIs located in Pennsylvania, excluding Allegheny County, for which construction was commenced on or before June 20, 1996.

**§ 62.9652 Effective date.**

The effective date of the plan is June 17, 2002.

[FR Doc. 02–10873 Filed 5–2–02; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

## 50 CFR Part 622

**[Docket No. 011015252–2081–02; I.D. 053001E]**

**RIN 0648–AO23**

## Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Golden Crab Fishery off the Southern Atlantic States; Amendment 3

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

**ACTION:** Final rule.

**SUMMARY:** NMFS issues this final rule to implement Amendment 3 to the Fishery Management Plan for the Golden Crab Fishery of the South Atlantic Region (FMP). This rule extends through December 31, 2002, the allowed use of cable for a mainline attached to golden crab traps; clarifies the size of the required escape panel or door on a golden crab trap; removes the historical catch requirement for renewing a commercial vessel permit for golden crab; allows the issuance of a commercial vessel permit for golden crab for the southern zone for a vessel that held a valid permit for the southern zone in October 2000 but did not meet the 5,000–lb (2,268–kg) requirement for renewal in the following year; allows a vessel with a documented length overall greater than 65 ft (19.8 m) that is permitted to fish in the southern zone to fish also in the northern zone; allows two new commercial vessel permits to be issued for the northern zone; provides that a commercial vessel permit will not be renewed if the Regional Administrator (RA) does not receive an application for renewal by June 30 each year; liberalizes the allowed increase in the size of a permitted vessel; creates a small-vessel sub-zone in the southern zone in which only permitted vessels 65 feet (19.8 m) or less in length may fish for golden crab but may not do so in the remainder of the southern zone; and adds measures related to the proposed sub-zone to the list of management measures that may be modified via the FMP's framework procedure for regulatory adjustments. The intended effect is to protect the golden crab resource while allowing development of the fishery that is dependent on that resource.

**DATES:** This final rule is effective June 3, 2002, except for the amendments to § 622.17(b)(1) and (2) that are effective May 3, 2002.

**ADDRESSES:** Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this rule should be submitted to Robert Sadler, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503 (Attention: NOAA Desk Officer).

**FOR FURTHER INFORMATION CONTACT:** Dr. Peter J. Eldridge, Southeast Regional Office, NMFS; phone: 727–570–5305; fax: 727–570–5583; e-mail: *Peter.Eldridge@noaa.gov*.

**SUPPLEMENTARY INFORMATION:** The golden crab fishery off the southern Atlantic states is managed under the FMP. The FMP was prepared by the South Atlantic Fishery Management

Council (Council) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

On June 12, 2001, NMFS announced the availability of Amendment 3 and requested comments on it (66 FR 31608); no comments were received. NMFS partially approved Amendment 3 on September 12, 2001; the estimate of maximum sustainable yield was disapproved. NMFS published a proposed rule to implement the approved portions of Amendment 3 on November 27, 2001 (66 FR 59221) and requested comments on the proposed rule. The background and rationale for the measures in Amendment 3 and the proposed rule are contained in the preamble to the proposed rule and are not repeated here.

**Comments and Responses**

A total of nine comments were received on the proposed rule. The comments and NMFS' responses are provided below.

*Comment 1*: A vessel owner opposed the removal of the 5,000–lb (2,268–kg) harvest requirement for renewing the biannual permit. In addition, he opposed granting permits to permit holders in the southern zone who had not met the 5,000–lb (2,268–kg) catch requirement by October 2000, but who had met the catch requirement in October 1998. He stated that these measures would benefit fishermen who had chosen not to participate in the fishery. He also opposed the provision that would allow up to a 20 percent increase in vessel size from the vessel size on the original permit. He concluded by stating that a maximum sustainable yield (MSY) or guideline harvest level should be established for this fishery before fishing power is increased in the southern zone.

*Response*: During the 1998–2000 period, a large vessel set numerous traps over traps that had been set by smaller vessels. The traps became entangled and because the smaller vessels lacked gear that could retrieve the entangled traps, they lost their traps. Consequently, the smaller vessels did not participate further in the fishery because they were afraid that they would lose additional gear and, thus, were not able to land at least 5,000 lb (2,268 kg) of golden crab by October 2000. Vessel owners notified the Council that they would participate in the fishery if a sub-zone was established where only smaller vessels could fish. The approval of Amendment 3, which removes the 5,000–lb (2,268–kg) catch requirement, also establishes a sub-zone where smaller vessels can fish. This should ensure a more constant supply of golden crab which in turn should increase revenues for this fishery. In addition, the Council concluded that because of the low number of current participants, the minimum required harvest level is no longer necessary. The Council decided to ease the restriction on vessel size because such a measure would enhance vessel safety and could result in improved vessel operations which could reduce costs of fishing. The Council believes that increasing vessel capacity will not jeopardize the continued viability of the fishery.

Amendment 3 proposed an MSY range of 4 to 12 million lb (1.8 to 5.4 million kg). NMFS disapproved the estimate because the best scientific information available indicated that the range was too high. For reasons set forth in the response to Comment 2 below, NMFS believes that the proposed MSY estimate, if implemented, could have led to overfishing of the golden crab resource. NMFS and the Council will continue to monitor landings and other biological information on this fishery. As soon as sufficient information becomes available, an improved MSY estimate will be implemented.

*Comment 2*: Two fishermen supported the proposed MSY estimate and were disappointed that NMFS had disapproved that measure.

*Response*: The fishery is conducted only in the southern and middle zones. The best scientific information available for these zones indicates that this area can support an annual harvest of somewhat less than 700,000 pounds (317,515 kg). The northern zone, which is equivalent in size to the combined southern and middle zones, lacks catch data to derive an MSY proxy. Nonetheless, information in the original FMP indicates that the MSY proxy for the northern zone could be between 0.54 and 1.65 million pounds (0.25 and 0.75 million kg). Adding the two sets of estimates together indicates an MSY proxy of between 1.25 and 2.35 million pounds (0.57 and 1.07 million kg). This information constitutes the best scientific information available and indicates that the true MSY for the combined areas most likely is between l.5 and 2.5 million pounds (0.68 and 1.13 million kg).

Since one large vessel has the capability of landing up to 3 million pounds annually, one or two larger vessels together with existing participants could have overfished the golden crab resource if the proposed MSY proxy of 4 to 12 million pounds (1.8 to 5.4 million kg) had been approved. Consequently, NMFS disapproved the proposed MSY proxy to minimize the possibility of overfishing this resource.

*Comment 3*: Six comments received on the proposed rule supported implementation of Amendment 3. In addition, these comments requested that NMFS waive the Administrative Procedure Act's (APA's) 30-day delayed effectiveness for the provision that would allow vessels in the southern zone to fish in the northern zone without losing their permit to return and fish in the southern zone. The comments stated that waiving the 30-day delayed effectiveness would allow larger vessels to transfer operations immediately to the northern zone which would reduce vessel conflict in the southern zone. Also, the comments noted that reduced conflict in the southern zone would result in safer fishing conditions.

*Response*: NMFS agrees with these comments and is waiving the APA's 30-day delayed effectiveness for that provision that would allow vessels to transfer their operations to the northern zone but permit them to return to the southern zone without penalty.

**Changes From the Proposed Rule**

In § 622.17(d), the first sentence is revised slightly to maintain consistency with § 622.4(h).

In the last sentence of § 622.38(h), the cross reference to paragraph (i) is corrected to read paragraph (h). The erroneous cross reference was introduced in a prior rulemaking.

In §§ 622.1, 622.4, 622.6, and 622.40, the phrase, ''35°15.3′ N. lat.'', is replaced with the phrase, ''35°15.19′ N. lat.'', to correct the latitude of the Cape Hatteras Light, consistent with a recent relocation of that structure.

**Classification**

NMFS has determined that Amendment 3, except for the disapproved MSY, is necessary for the conservation and management of the golden crab fishery and that it is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws.

This final rule has been determined to be not significant for purposes of E.O. 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel of Advocacy of the Small Business Administration when this rule was proposed that it would not have a significant economic impact on a substantial number of small entities. As a result, no regulatory flexibility analysis was required and none was prepared. No comments were received

regarding the economic impact of this rule.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number.

This rule contains but does not change two collection-of-information requirements subject to the PRA; namely, the application for a permit for the South Atlantic golden crab fishery and the submission of fishing vessel logbooks in that fishery. These collections of information have been approved by OMB under control numbers 0648–0205 and 0648–0016, respectively. The public reporting burdens for these collections of information are estimated at 20 minutes for each permit application and 10 minutes for each fishing vessel logbook submission. The estimates of public reporting burdens for these collections of information include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspects of the collections of information, including suggestions for reducing the burdens, to NMFS and OMB (see **ADDRESSES**).

Under 5 U.S.C. 553(d)(3), the Assistant Administrator for Fisheries, NOAA finds for good cause that a 30–day delay in the effective date of § 622.17(b)(1) of this rule is unnecessary. Furthermore, under 5 U.S.C. 553(d)(1) a 30–day delay in the effective date of § 622.17(b)(2) is also unnecessary because § 622.17(b)(2) relieves a restriction by allowing a vessel greater than 65 ft (19.8m) in documented length overall that is permitted to fish in the southern zone to fish also in the northern zone. Current regulations restrict such vessels to fishing in the southern zone only. In addition, § 622.17(b)(2) is expected to reduce user conflict in the more-congested southern zone by allowing some shift of fishing effort to the northern zone. The revision of § 622.17(b)(1) provided in this rule is necessary to eliminate regulatory text that would otherwise conflict with the provision of § 622.17(b)(2) that relieves the regulatory restriction on authorized fishing zones. Section 622.17(b)(1) of this rule does not contain any new regulatory requirements; it eliminates text that would otherwise result in internal inconsistency in the regulations and restates the description of the three fishing zones for the convenience of the reader. Additionally, if the 30-day delay in effectiveness for § 622.17(b)(1) is not waived, the waiver for § 622.17(b)(2) will be ineffective. These reasons constitute good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness for § 622.17(b)(1).

**List of Subjects in 50 CFR Part 622**

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: April 26, 2002.

**Willioam T. Hogarth,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

## PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

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

2. In § 622.7, paragraph (z) is revised to read as follows:

### § 622.7 Prohibitions.

* * * * *

(z) Fish for or possess golden crab in or from a fishing zone or sub-zone of the South Atlantic EEZ other than the zone or sub-zone for which the vessel is permitted or authorized, as specified in § 622.17(b).

* * * * *

3. Section 622.17 is revised to read as follows:

### § 622.17 South Atlantic golden crab controlled access.

(a) *General.* In accordance with the procedures specified in the Fishery Management Plan for the Golden Crab Fishery of the South Atlantic Region, initial commercial vessel permits have been issued for the fishery. All permits in the fishery are issued on a fishing-year (calendar-year) basis. No additional permits may be issued except as follows:

(1) *For the southern zone.* (i) Upon application, the RA will reissue a permit for the southern zone for a vessel that held a valid permit for that zone in October 2000 but did not meet the 5,000-lb (2,268-kg) requirement for renewal in the following year.

(ii) An application for a permit under paragraph (a)(1) of this section must be received by the RA no later than July 2, 2002.

(2)*For the northern zone.* (i) The RA will issue up to two new vessel permits for the northern zone. Selection will be made from the list of historical participants in the South Atlantic golden crab fishery. Such list was used at the October 1995 meeting of the South Atlantic Fishery Management Council and was prioritized based on pounds of golden crab landed, without reference to a specific zone. Individuals on the list who originally received permits will be deleted from the list.

(ii) The RA will offer in writing an opportunity to apply for a permit for the northern zone to the individuals highest on the list until two accept and apply in a timely manner. An offer that is not accepted within 30 days after it is received will no longer be valid.

(iii) An application for a permit from an individual who accepts the RA's offer must be received by the RA no later than 30 days after the date of the individual's acceptance. Application forms are available from the RA.

(iv) A vessel permit for the northern zone issued under paragraph (a)(2) of this section, and any successor permit, may not be changed to another zone. A successor permit includes a permit issued to that vessel for a subsequent owner and a permit issued via transfer from that vessel to another vessel.

(b) *Fishing zones*—(1) *Designation of fishing zones.* The South Atlantic EEZ is divided into three fishing zones for golden crab as follows:

(i) Northern zone—the South Atlantic EEZ north of 28° N. lat.

(ii) Middle zone—the South Atlantic EEZ from 28° N. lat. to 25° N. lat.

(iii) Southern zone—the South Atlantic EEZ south of 25° N. lat.

(2) *Authorization to fish in zones.* Each vessel permit indicates one of the zones specified in paragraph (b)(1) of this section. A vessel with a permit to fish for golden crab in the northern zone or the middle zone may fish only in that zone. A vessel with a documented length overall greater than 65 ft (19.8 m) with a permit to fish for golden crab in the southern zone may fish in that zone, consistent with the provisions of paragraph (b)(3) of this section, and, through May 3, 2005, may also fish in the northern zone. A vessel may possess golden crab only in a zone in which it is authorized to fish, except that other zones may be transited if the vessel notifies NMFS, Office of Enforcement, Southeast Region, St. Petersburg, FL, by telephone (727–570–5344) in advance and does not fish in a zone in which it is not authorized to fish.

(3) *Small-vessel sub-zone.* Within the southern zone, a small-vessel sub-zone is established bounded on the north by

24°15′ N. lat., on the south by 24°07′ N. lat., on the east by 81°22′ W. long., and on the west by 81°56′ W. long. No vessel with a documented length overall greater than 65 ft (19.8 m) may fish for golden crab in this sub-zone, and a vessel with a documented length overall of 65 ft (19.8 m) or less that is permitted for the southern zone may fish for golden crab only in this sub-zone.

(4) *Procedure for changing zones.* (i) Upon request from an owner of a permitted vessel, the RA will change the zone specified on a permit from the middle or southern zone to the northern zone. No other changes in the zone specified on a permit are allowed, except as specified in paragraph (b)(4)(ii) of this section. An owner of a permitted vessel who desires a change to the northern zone must submit his/her request with the existing permit to the RA.

(ii) Through May 3, 2005, upon request, the RA will change a vessel permit back to the southern zone for an owner of a vessel, or the subsequent owner of a vessel, whose permit was changed from the southern zone to the northern zone provided that the documented length overall of the vessel to be used in the southern zone is not more than 20 percent greater than the vessel whose permit was originally changed from the southern zone to the northern zone.

(c) *Transferring permits between vessels*—(1) *Procedure for transferring.* An owner of a vessel who desires a golden crab permit may request that NMFS transfer an existing permit or permits to his or her vessel by returning an existing permit or permits to the RA with an application for a permit for the replacement vessel.

(2) *Vessel size limitations on transferring.* (i) To obtain a permit for the middle or southern zone via transfer, the documented length overall of the replacement vessel may not exceed the documented length overall, or aggregate documented lengths overall, of the replaced vessel(s) by more than 20 percent. The owner of a vessel permitted for the middle or southern zone who has requested that NMFS transfer that permit to a smaller vessel (i.e., downsized) may subsequently request NMFS transfer that permit to a vessel of a length calculated from the length of the permitted vessel immediately prior to downsizing.

(ii) There are no vessel size limitations to obtain a permit for the northern zone via transfer.

(d) *Permit renewal.* NMFS will not renew a commercial vessel permit for South Atlantic golden crab if the permit is revoked or if the RA does not receive a required application for renewal within 6 months after the permit's expiration. See § 622.4(h) for the applicable general procedures and requirements for permit renewals.

4. In § 622.38, the last sentence of paragraph (h) is revised to read as follows:

**§ 622.38 Landing fish intact.**

* * * * *

(h) * * * For the purpose of this paragraph, a vessel is in transit through the South Atlantic EEZ when it is on a direct and continuous course through the South Atlantic EEZ and no one aboard the vessel fishes in the EEZ.

5. In § 622.40, the first sentence of paragraph (b)(3)(ii)(B) and paragraph (d)(2)(ii) are revised to read as follows:

**§ 622.40 Limitations on traps and pots.**

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(B) A golden crab trap constructed of material other than webbing must have an escape panel or door measuring at least 11 7/8 by 11 7/8 inches (30.2 by 30.2 cm), located on at least one side, excluding top and bottom. * * *

* * * * *

(d) * * *

(2) * * *

(ii) Rope is the only material allowed to be used for a buoy line or mainline attached to a golden crab trap, except that wire cable is allowed for a mainline through December 31, 2002.

6. In § 622.48, paragraph (g) is revised to read as follows:

**§ 622.48 Adjustment of management measures.**

* * * * *

(g) *South Atlantic golden crab.* Biomass levels, age-structured analyses, MSY, ABC, TAC, quotas (including quotas equal to zero), trip limits, minimum sizes, gear regulations and restrictions, permit requirements, seasonal or area closures, sub-zones and their management measures, time frame for recovery of golden crab if overfished, fishing year (adjustment not to exceed 2 months), observer requirements, authority for the RA to close the fishery when a quota is reached or is projected to be reached, definitions of essential fish habitat, and essential fish habitat HAPCs or Coral HAPCs.

* * * * *

**§§ 622.1, 622.4, 622.6, 622.40 [Amended]**

7. In addition to the amendments set forth above, in 50 CFR part 622, remove the phrase, ''35°15.3′ N lat.'' and add, in its place, the phrase, ''35°15.19′ N. lat.'' in the following places:

(a) Section 622.1, in footnote 4 of Table 1;

(b) Section 622.4(a)(2)(vi);

(c) Section 622.6(b)(1)(i)(B); and

(d) Section 622.40(b)(3)(i).

[FR Doc. 02–11027 Filed 5–2–02; 8:45 am]

BILLING CODE 3510–22–S

# Proposed Rules

Federal Register
Vol. 67, No. 86
Friday, May 3, 2002

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

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Parts 25 and 121

**[Docket No. 28061, Notice No. 95–1]**

**RIN 2120–AF01**

## Revised Access to Type III Exits

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM); withdrawal.

**SUMMARY:** The FAA is withdrawing a previously published NPRM that proposed to adjust requirements for access to Type III emergency exits (typically smaller over-wing exits) in transport category airplanes with 60 or more passenger seats. These adjustments reflected the results of additional testing by the FAA's Civil Aeromedical Institute (CAMI) conducted after the standards had been adopted. We are withdrawing the document because CAMI research on the issues is still ongoing and the Aviation Rulemaking Advisory Committee (ARAC) is currently considering a recommendation for a harmonized proposal on the issues addressed by Notice No. 95–1. ARAC will make its recommendation after completion of a FAA research program to study access to Type III exits. The FAA has determined that it should wait and see if some future regulatory action including the broader scope of this harmonized proposal would better serve the public interest.

**FOR FURTHER INFORMATION CONTACT:** Jayson Claar, Transport Airplane Directorate, Airframe and Cabin Safety Branch, Federal Aviation Administration, 1601 Lind Avenue SW, Renton, WA 98055; telephone (425) 227–2194.

**SUPPLEMENTARY INFORMATION:**

### Background

On May 4, 1992, the FAA published a final rule (Amendment Nos. 25–76 and 121–228) which set standards for access to Type III emergency exits in transport category airplanes with 60 or more passenger seats (57 FR 19220). These standards were the result of testing conducted by the FAA's Civil Aeromedical Institute and were intended to improve the ability of occupants to evacuate an airplane under emergency conditions. CAMI conducted further testing as time and resources became available, and the FAA subsequently proposed adjustments to those standards in Notice No. 95–1, published on January 30, 1995 (60 FR 5794).

Part 25 of Title 14 of the Code of Federal Regulations defines a number of different types of passenger emergency exits for use in transport category airplanes. As defined in § 25.807(a)(3), a Type III exit must have an opening not less than 20 inches wide by 36 inches high. It need not be rectangular in shape, provided a rectangle of those dimensions can be inscribed within the opening. The corner radii must not exceed one-third the width of the exit. The step-up distance inside the cabin must not exceed 20 inches. Type III exits are typically located over the wing; when so located, the step-down to the wing must not exceed 27 inches. Type III exits are typically removable hatches, but they may be hinged or tracked doors. They are sometimes referred to as ''window exits.''

CAMI tested various exit configurations with three-seat rows to obtain a more comprehensive understanding of effects of passageway widths and offsets from the exit opening. For these tests, CAMI used the same test fixture as that used for the tests conducted prior to the adoption of Amendment 25–76. It consisted of the fuselage of a Douglas C–124 airplane with seats and other equipment installed to represent an airline airplane in all aspects relevant to the tests. The test methods and procedures used for these tests were similar to those used during the earlier series of tests. And, as in the earlier tests, the purpose was to measure, on a comparative basis, the effectiveness of the features of an airplane when used in a typical, reasonable manner. The purpose was not to measure the performance of any particular group of test subjects, nor to evaluate the total elapsed time needed to evacuate an airplane under any specific crash scenario. The CAMI tests were intended to evaluate comparatively the effects of passageway width and seat-row encroachment on total time for egress through Type III exits.

Testing determined that the total egress times with 13-, 15-, and 20-inch passageways were nearly identical. In contrast, the total egress times for the narrower 10- and 6-inch passageways, were much greater. These tests also measured the effect of centerline offset; i.e., the distance that the centerline of the passageway is offset from the centerline of the exit. The tests showed that 13-inch passageways with centerline offsets up to 6½ inches provide egress capability equal to that of 20-inch passageways with the 5-inch maximum offset allowed by the current rule. Tests conducted with a group of older subjects found that egress times were slower for older occupants, but the relative merits of the various passageway widths and offsets were similar.

Testing also proved consistent with a series of evacuation tests that had been conducted in the United Kingdom, generally referred to as the ''competitive tests.'' Although providing more space adjacent to an exit would intuitively seem to improve the evacuation flow rate, the competitive tests showed that providing more space does not always improve the flow rate and may, in some instances, actually prove to be counterproductive. This is primarily because evacuees sometimes form multiple files when additional space is available and compete for access to the exit, rather than pass through it in one orderly file. It must be emphasized that the competitive tests were conducted for a different purpose than either the CAMI tests or the tests conducted prior to the adoption of Amendment 25–76. The competitive behavior tests were conducted to analyze human behavior under emergency conditions, while the FAA tests were to compare the capability of various configurations when used in a typical, reasonable manner. Nevertheless, the CAMI tests were consistent with the competitive tests, in that a 13-inch passageway was shown to provide an egress capability as good as that provided by a 20-inch passageway.

In view of the results of the CAMI tests, the FAA determined that an

unobstructed passageway 13 inches wide, with its centerline offset no more than 6½ inches from the centerline of the exit, provides a level of safety equal to that provided by the 20-inch passageway specified in § 25.813(c)(1)(i). Had data from those tests been available prior to the adoption of Amendment 25–76, the FAA would have specified 13 inches minimum width and 6½ inches maximum offset at that time. Notice No. 95–1 proposed to amend § 25.813(c)(1)(i) to specify 13 inches minimum width and a maximum centerline offset of 6½ inches for rows with three seats.

Notice No. 95–1 would also have proposed the correction of an editorial error by amending § 121.310(f)(3)(iii) to incorporate § 25.813(a)(2) by reference. Further, the incorporation by reference of § 25.813(c) in § 121.310(f)(3)(iii) would have been clarified by replacing the reference to § 25.813(c) in its entirety with a reference to only §§ 25.813(c)(1) and (3).

The NPRM invited public comment to assist the FAA in the rulemaking process. The comment period closed on May 1, 1995.

**Discussion of Comments**

Two aircraft manufacturers, a consumer advocate, an organization representing European aircraft manufacturers, and three individuals responded to Notice No. 95–1. In addition, an organization representing U.S. airlines and another representing three airline flight attendant unions also responded. One foreign airworthiness authority also reviewed the notice, but submitted no comments.

One manufacturer concurred with the notice, concluding that it would lessen the overly tight pitch requirement for seats adjacent to Type III exits. The commenter also commended CAMI for its study and noted that it will alleviate a potential financial burden on the aircraft industry while still maintaining the high level of safety that currently exists. The other manufacturer concurred, but offered no further comment.

The consumer advocate opposed requiring the minimum passageway width to be only 13 inches, claiming it would be detrimental to passenger safety, would ignore the critical lessons of past fatal accidents, and would offer no demonstrable benefits. The commenter offered no evidence to support those opinions, and they are contradicted by evidence outlined in the preamble of Notice No. 95–1.

A number of commenters questioned the validity of the CAMI testing. Generally, they believe the study to be unrealistic because it did not represent an actual crash. They noted that there was no fire, smoke or toxic fumes, no panic, subjects did not represent a cross-section of the flying public, the competitive behavior that might be exhibited in an actual crash was not experienced, and the exit hatch was not required to be removed by one of the passengers. These comments would have been applicable if the purpose of the testing had been to measure how passengers would respond in an actual crash. However, the purpose of these tests was not to evaluate the performance of passengers. The purpose was to determine the minimum passageway width and maximum centerline offset that would allow egress equivalent to that allowed by a 20-inch passageway with a 5-inch offset. The CAMI tests targeted airplane configuration—not vision, motivation, variations in passenger behavior, airplane crashes, or any combination of those variables.

It must be noted that evacuation demonstrations are not conducted under actual conditions of fire, smoke, or toxic fumes for two basic reasons. The first and foremost consideration is the safety and well-being of the test subjects. Testing under those conditions could very likely result in unnecessary serious injuries to the test subjects. Second, the purpose of such demonstrations is not to show that test subjects can evacuate an airplane in a specified time under all possible emergency conditions. Due to the myriad of different possible crash scenarios that could occur and the varying need for urgency, it would be impossible to develop a series of tests that would encompass all of those possible conditions. Instead, the evacuation capability of an airplane is evaluated under standard, repeatable conditions. By testing under such controlled, consistent conditions, the evacuation capability of an airplane can be compared with that of the other airplanes that have been tested previously under the same conditions. Through this indirect means, the evacuation capability of the airplane is related to the accidents that have actually occurred with those earlier airplanes. The evacuation capability of an airplane under the variables cited by the commenters is, therefore, considered without exposing test subjects to intolerable risk of serious injury.

A second set of tests conducted with older subjects was invalid in certain respects because some of the test subjects stepped on the seat cushions rather than fully utilizing the passageway. One commenter believes that older passengers adopted this practice because the passageway was too narrow for older passengers who are not as agile. Actually, this practice was the result of an inadvertent incorrect instruction given by a flight attendant rather than an ingenious response to insufficient passageway space, as suggested by the commenter. The video records of the testing clearly show that the older test subjects did not step on the seat cushions simply because the passageway lacked sufficient width at floor level, nor that they had any difficulty with a 13-inch wide passageway for that matter. In fact, all of the video records of testing of both 13-inch and 20-inch passageways demonstrated that the subjects generally lined up in the passageway awaiting their turn to pass through the exit. In other words, the egress pace was determined not by the width of the passageway, but by the rate of movement through the exit.

Two commenters referred to the tragic US Air accident at Los Angeles, California, in 1991. In that regard, one quoted from a document entitled, ''Eighteenth Report by the Committee on Government Operations in 1992.'' According to the commenter, the document states, in part, ''if the passageway to the overwing exit had been just a few inches wider, more people might have escaped.'' While that statement would intuitively seem to be true, there were mitigating circumstances involved in the evacuation of that airplane. In any event, the reference to that accident is not relevant. Since the passageways leading to the Type III exits in the USAir airplane were approximately 6 to 6½ inches wide, the proposed minimum passageway width of 13 inches is approximately twice as great.

The organization representing U.S. airlines forwarded responses received from three of their member airlines. One airline supported the proposed changes without further comment. In addition to supporting the changes that were proposed, two other airlines raised issues concerning previously granted deviations from the requirements. Section 121.310(f)(3)(iv) permits the FAA to authorize deviations from § 25.813 that allow recline on the inboard seats only. This concession applies only to existing airplanes. Later airplane designs must comply with § 25.813 as a condition of type certification. Accordingly, no change to either § 25.813 or § 121.310 is warranted.

The organization representing European aircraft manufacturers described a series of tests conducted

later at the Cranfield Institute in the United Kingdom. (This is the same facility in which the previously mentioned ''competitive tests'' were conducted.) According to the commenter, the later tests were conducted using the same protocol as the CAMI tests, but with a passageway as narrow as 10 inches and 9 inches offset. Based on this test series, the commenter believes that a passageway only 10 inches wide provides the same level of safety as a wider passageway. The commenter implied that § 25.813(c)(1)(i) should, therefore, be amended to require only a passageway 10 inches wide with three-abreast seat rows, rather than 13 inches wide as proposed in Notice No. 95–1. Although the results of this series of tests would appear to be inconsistent in this regard with the results of both the FAA testing and testing conducted earlier at Cranfield, adopting a minimum width of less than 13 inches would be beyond the scope of the notice, even if these test results would justify such a change.

The same commenter referred to a pending proposed amendment to Joint Aviation Requirements for Large Aeroplanes-25 (JAR–25) concerning access to Type III exits. The commenter noted that part 25 will not contain all of the requirements concerning access to Type III exits being considered for inclusion in JAR–25 and believes that the NPRM should not proceed to the final rule stage until the standards of the two codes can be harmonized.

This comment underscores the central reason for withdrawal of Notice No. 95–1. The FAA is involved in eliminating unnecessary differences between the Federal Aviation Regulations and the Joint Aviation Requirements (JAR) used in European countries, through an ongoing cooperative harmonization process that includes Joint Aviation Authorities (JAA) and Transport Canada. JAR–25 is the code of standards adopted by the airworthiness authorities of a number of European countries for type certification of transport category airplanes. It is based on, and is generally similar to, part 25; however, there are detail differences. The FAA's desire to harmonize the two codes has dictated their efforts in many areas of current regulatory activity. ARAC's Occupant Safety Issues Area, formerly known as the Emergency Evacuation Issues Area, is working on a recommendation for a harmonized proposal on the issues addressed by Notice No. 95–1. ARAC will make its recommendation after completion of a FAA research program to study access to Type III exits.

Subsequent to the close of the comment period and analysis of the timely comments, comments were received from three additional consumer advocacy groups and two labor organizations. Each opposed requiring the minimum passageway width to be only 13 inches. Like the consumer advocate that had commented earlier, two of the consumer advocacy groups claimed that requiring a minimum passageway width of 13 inches would be detrimental to safety and would offer no demonstrable benefits. Those commenters offered no evidence to support those opinions; and, as discussed above, they are contradicted by evidence outlined in the preamble of Notice No. 95–1.

The third late commenter also opposed requiring passageways to be only 13 inches wide for essentially the same reasons as those given by earlier dissenting commenters. Many of the points raised by that commenter are addressed in response to the timely comments; however, that commenter did raise additional issues.

The commenter questioned the effectiveness of adjacent Type III exits. Although not directly related to this rulemaking, the FAA has initiated separate rulemaking to reduce the combined passenger rating of such exits when they are located within three passenger seat rows of each other.

The commenter characterized the CAMI tests as ''manipulating research data to suggest that 13 inches would produce the same benefit.'' Contrary to the commenter's characterization, the tests do not represent ''manipulation'' of the earlier research data on which Amendment 25–76 was based. In fact, the CAMI tests confirm the results of the first test series '' passageways that are 20 inches wide do provide egress capability superior to that provided by passageways that are 10 inches wide. (This refers, of course, to installations of three-seat rows. Ten-inch passageways were found during the earlier testing to provide the same superior egress capability when two-seat rows are installed. No change was proposed in Notice No. 95–1 to the standards for access when two-seat rows are provided.) Since no testing of intermediate passageway widths was conducted during the first series, there were no data pertaining to those widths from the first series to ''manipulate.'' The egress capability provided by intermediate passageway widths was unknown at the time Amendment 25–76 was adopted, and the CAMI tests merely provided data for those intermediate passageway widths.

Finally, the commenter asserted that data from the testing conducted both in this country by CAMI and in the United Kingdom at Cranfield show that 20-inch passageways provide superior egress capability. Contrary to the commenter's assertion, the data from the recent CAMI tests do, in fact, show that 13-inch passageways provide egress capability equal to that provided by 20-inch passageways. Also contrary to the commenter's assertion, the competitive behavior tests conducted at Cranfield do not show that 20-inch passageways provide superior egress capability to those 13 inches in width.

The fourth late commenter opposed requiring passageways only 13 inches in width and questioned the validity of the test procedures. Most of the points raised by the commenter were raised by other dissenting commenters and addressed above. There were, however, a number of additional points raised.

The commenter noted that Advisory Circular 25–17 describes the Latin Square test method and implies that the inclusion of that test method in the advisory circular means other test methods are invalid. Advisory Circulars describe acceptable methods, but not the only acceptable methods, for complying with regulations. Contrary to the commenter's implication, the method used in the CAMI tests is also an established and highly respected scientific method to ensure that the test results are not clouded by variations in test subject performance. The Latin Square test method was not used in the CAMI tests primarily because it would have required almost twice as many test subjects to test the same configurations.

The commenter also quoted a statement made by the National Transportation Safety Board (NTSB) and asserts the statement means the NTSB opposes requiring these passageways to only be 13 inches wide. According to the commenter, the NTSB states in the accident investigation report for the USAir accident at Los Angeles in 1991, ''The Safety Board believes that a continuous access path of no less than 20 inches, as demonstrated by tests, is preferable to removing the seat adjacent to the exit or removing the seat and having a 20-inch or less access path.'' The NTSB was actually referring to the relative merits of the two proposed configurations that were later adopted in Amendment 25–76. The NTSB would not have commented on the merits of a passageway 13 inches in width because that was not one of the configurations proposed then and there were no applicable test data available then to prove or disprove its merits. As noted above, there were no specific standards for access to Type III exits at the time of the USAir accident; however, the passageways of that airplane were

approximately 6 to 6½ inches in width. The NTSB did not submit any comments concerning the changes proposed in Notice No. 95–1 and has not made any formal recommendations concerning the width of passageways leading to Type III exits.

The issues raised by the last late commenter were all addressed in response to other commenters; however, that commenter questioned the use of the term ''clear path'' in the graph of pathway widths versus egress time contained in the preamble to Notice No. 95–1. ''Clear path'' was used in the preliminary graph of the results of the second test series to denote a configuration in which the forward-most edge of the unobstructed passageway was no farther forward than the forward-most edge of the emergency exit. It was recognized that the term could cause confusion, so the test configurations were described in terms of centerline offset or seat encroachment in the final reports.

**Reason for Withdrawal**

CAMI is presently doing further studies on access to Type III exits. The withdrawal of Notice No. 95–1 enables future rulemaking action that will be able to benefit from this ongoing research and produce a more accurate, fresh perspective on the issues.

In addition, the FAA is involved in eliminating unnecessary differences between the Federal Aviation Regulations and the Joint Aviation Requirements used in European countries. This is an ongoing process of aligning its regulations with those of the Joint Aviation Authorities (JAA) known as harmonization. Our desire to harmonize the two codes has dictated our efforts in many areas of current regulatory activity. ARAC's Occupant Safety Issues Area, formerly known as the Emergency Evacuation Issues Area, is working on a recommendation for a harmonized proposal on the issues addressed by Notice No. 95–1. ARAC will make its recommendation after completion of a FAA research program to study access to Type III exits. Continuing industry input through the ARAC process will contribute to a more complete analysis of the issues. Therefore, we have determined that it would be better to wait and see if some future regulatory action including the broader scope of this harmonized proposal would better serve the public interest.

**Withdrawal of Proposed Rule**

Withdrawal of Notice No. 95–1 does not preclude the FAA from issuing another NPRM on the subject matter in the future or committing the agency to any future course of action. To achieve harmonization goals, we will make any necessary changes to the Code of Federal Regulations through a future NPRM with opportunity for public comment. Therefore, the FAA withdraws Notice No. 95–1, published on January 30, 1995 (60 FR 5794).

Issued in Washington, DC, on April 26, 2002.

**John Hickey,**

*Director, Aircraft Certification Service (AIR–1).*

[FR Doc. 02–10947 Filed 5–2–02; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Airspace Docket No. 02–AEA–01]**

## Establishment of Class E Airspace; Lee Airport, Annapolis, MD

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to establish Class E airspace at Lee Airport (ANP), Annapolis, MD. The development of a Standard Instrument Approach Procedure (SIAP) to serve flights operating into the Lee Airport during Instrument Flight Rules (IFR) conditions make this action necessary. Controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain aircraft executing an approach. The area would be depicted on aeronautical charts for pilot reference.

**DATES:** Comments must be received on or before June 3, 2002.

**ADDRESSES:** Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 02–AEA–01 FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

The official docket may be examined in the Office of the Regional Counsel, AEA–7, FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

**FOR FURTHER INFORMATION CONTACT:** Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520 FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809: telephone: (718) 553–4521.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 02–AEA–01''. The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket closing both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

**Availability of NPRMs**

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Regional Counsel, AEA–7, FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809. Communications must identify the notice number of this NRPM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

**The Proposal**

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace area at Annapolis, MD. The development of a SIAP to serve flights operating into the airport under Instrument Flight Rules (IFR) make this action necessary. Controlled airspace extending upward

from 700 feet AGL is needed to accommodate the SIAP. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedure and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

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

## PART 71—[AMENDED]

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

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

**§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, is proposed to be amended as follows:

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

**AEA MD E5, Annapolis [New]**

Lee Airport

(Lat. 38°56′34″ N., long. 76°34′06″ W.)

That airspace extending upward from 700 feet above the surface within a 6.2 mile radius of the Lee Airport, Annapolis, MD.

Issued in Jamaica, New York, on March 28, 2002.

**Richard J. Ducharme,**

*Assistant Manager, Air Traffic Division, Eastern Region.*

[FR Doc. 02–11055 Filed 5–2–02; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 314 and 601

**[Docket No. 00N–1652]**

**RIN 0910–AB91**

## Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations governing the format in which certain labeling is required to be submitted for review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The proposal would require that certain labeling content be submitted electronically in a form that FDA can process, review, and archive. Submitting the content of labeling in electronic format would simplify the drug labeling review process and speed up the approval of labeling changes.

**DATES:** Submit written or electronic comments by August 1, 2002. Submit written comments on the information collection requirements by June 3, 2002. See section X of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:**

Randy Levin, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

**SUPPLEMENTARY INFORMATION:**

### I. Background

*A. Current Labeling Submission Requirements*

Section § 314.50 (21 CFR 314.50) of our (FDA's) current regulations describes the content and format requirements for NDAs. Under § 314.50(e)(2)(ii), an applicant is required to submit, in the archival copy of an application, copies of the label and all labeling for the drug product. Under § 314.50(l)(1), information in the archival copy required under § 314.50(a) (i.e., the application form, including the signature of the applicant) and § 314.50(e) (i.e., samples and labeling) must be submitted to the agency on paper, while other required information may be submitted either on paper or on microfiche (or another suitable microform system, if FDA and the applicant agree). Under § 314.71(b) (21 CFR 314.71(b)), supplements to approved applications submitted to the agency under § 314.70 (21 CFR 314.70) must follow the procedures described in § 314.50. In addition, § 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)) requires that ''currently used professional labeling, patient brochures, or package inserts'' be submitted with annual reports.

Section § 314.94 (21 CFR 314.94) sets forth requirements for the content and format of ANDAs. Under § 314.94(a)(8)(ii), the archival copy of an ANDA must include copies of the label and all labeling for the drug product. Under § 314.94(d), an applicant may submit all or portions of the archival copy of an ANDA in any form that FDA and the applicant agree is acceptable. Under § 314.97 (21 CFR 314.97), supplements and other changes to approved ANDAs must be submitted to the agency under the requirements of §§ 314.70 and 314.71. As noted previously, under § 314.71(b), supplements to approved applications submitted to the agency under 314.70 must follow the procedures described in § 314.50. Finally, under § 314.98(c) (21 CFR 314.98(c)), ANDA applicants must submit annual reports as required in § 314.81(b)(2)(iii).

Section § 601.2 (21 CFR 601.2) describes the requirements for submission of a BLA, which include the

requirement that specimens of enclosures and Medication Guides for a product, if any, be submitted. Section 601.12 (21 CFR 601.12) describes the requirements to make changes to an approved BLA, including labeling changes. Under § 601.12(f), labeling changes to a biological product approved under a BLA may generally only be made after the approval of a labeling supplement to the BLA, although certain types of labeling changes may be made before FDA approval of a supplement or by reporting the change in an annual report. Neither § 601.2 nor § 601.12 specifies a format in which the labeling or other information required in BLAs, BLA supplements, or annual reports must be submitted to FDA.

The term ''labeling'' used in §§ 314.50, 314.94, 314.81, and 601.12 is defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(m)) to mean both labels[1] and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. Thus, requiring the submission of ''labeling'' entails submission of the label (i.e., the label on the immediate container) and labeling. Labeling consists of the comprehensive prescription drug labeling directed to health care practitioners (i.e., the labeling required under § 201.100(d)(3) (21 CFR 201.100(d)(3)), commonly referred to as the ''package insert'' or ''professional labeling'') and other labeling.[2]

*B. The Effect of the Proposed Rule on Current Submission Requirements*

Under this proposal, applicants would be required to submit to us in electronic format the *content* of the package insert or professional labeling, including all text, tables, and figures. As explained below, this submission should be formatted in the manner described in agency guidance on electronic submissions.

This proposed requirement would be in addition to existing requirements, described in section I.A of this document, that copies of the label and labeling and specimens of enclosures be submitted. For example, *copies* of the package insert must still be submitted to us in an NDA under § 314.50(e)(2)(ii). Copies submitted to us must be identical to the label and labeling and specimens of enclosures that appear in the package insert, on the immediate container, or in any other form distributed. Under this proposal, these copies may be submitted electronically or on paper.

*C. Electronic Format Submission Initiatives*

In the **Federal Register** of March 20, 1997 (62 FR 13430), we published a regulation on electronic records and electronic signatures (part 11 (21 CFR part 11)). Part 11 generally provides that in instances where records are required to be submitted to the agency, such records may be submitted in electronic format instead of paper format, provided the controls in part 11 are met and we have identified the submission in the public docket as the type of submission we are prepared to accept in electronic format.

Although we have not up to this time required regulatory submissions in electronic format, we have issued guidances describing how to submit NDAs, BLAs, and other types of regulatory submissions in electronic format. In the **Federal Register** of January 28, 1999 (64 FR 4432), we announced the availability of a guidance entitled ''Providing Regulatory Submissions in Electronic Format—NDA's'' (the NDA electronic submission guidance), which provided information on how to submit a complete archival copy of an NDA in electronic format. The guidance applies to the submission of original NDAs, as well as to the submission of supplements and amendments to NDAs. Among other things, the NDA electronic submission guidance provides recommendations on how to submit ''labeling text'' in electronic format. ''Labeling text'' is the term used in the NDA electronic submission guidance to mean labeling required under § 201.100(d)(3), including all text, tables, and figures required by or included under authority of those sections. The term ''content of labeling,'' as used in this rulemaking, is intended to mean the same as the term ''labeling text,'' as used in the guidance. The NDA electronic submission guidance recommends that labeling text be submitted as a portable document format (PDF) file and that the file be submitted in the following format:

- The print area (i.e., the area of the PDF file when printed) should fit on an 8 1/2- by 11-inch sheet of paper with 1-inch margins;
- The page orientation should be portrait;
- The file should not contain any columns, headers, or footers; and
- The files should be paginated, beginning with page 1. The guidance also describes recommended font types and minimum font sizes for the PDF file text.

In November 1999, we published a guidance to assist applicants in submitting documents in electronic format for review and archive purposes as part of a BLA, product license application (PLA), or establishment license application (ELA) (64 FR 61647, November 12, 1999).

In January 1999, we issued a guidance on general considerations for electronic submissions entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations'' (the general considerations guidance) (64 FR 4433, January 28, 1999). In the general considerations guidance, we include a description of the types of electronic file formats that we are able to accept to process, review, and archive electronic documents. The general considerations guidance states that documents submitted in electronic format should enable the user to: (1) Easily view a clear and legible copy of the information; (2) print each document page by page while maintaining fonts, special orientations, table formats, and page numbers; and (3) copy text and images electronically into common word processing documents. To achieve these and other goals, we recommend that all electronic documents be submitted as PDF files.

## II. Rationale for Requiring Electronic Submission of the Content of Labeling

As discussed in section I of this document, until now, the initiatives we have undertaken have been focused on permitting, but not requiring, applicants to submit required regulatory documents in electronic format. For a number of reasons, we believe that it is important to require that the content of labeling (i.e., the labeling required under § 201.100(d)(3), including all text, tables, and figures) be submitted to us electronically for prescription drugs and biological products that are subject to the requirements of § 201.100(d)(3).

*A. Why Is It Important for the Content of Labeling To Be Submitted Electronically?*

Each year, we receive more than 1,000 proposed labeling changes for approved NDAs and BLAs, and more than 2,600 proposed original and supplemental labeling changes for ANDAs. As part of the review process, we conduct a word-for-word comparison of the proposed labeling with the last approved labeling

[1] Under section 201(k) of the act, the term ''label'' means a display of written, printed, or graphic matter upon the immediate container of any article.

[2] Section 201.100(d) requires that any labeling distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use of the drug, or which prescribes, recommends, or suggests a dosage for the use of the drug, must meet the content and format requirements in 21 CFR 201.56 and 201.57.

to verify that all labeling changes have been identified. In addition, for ANDAs, we conduct a word-for-word comparison of the labeling for the proposed generic drug product and the reference listed drug to verify that any differences in labeling have been correctly annotated and explained by the ANDA applicant under § 314.94(a)(8)(iii). Currently, a reviewer must conduct these comparisons manually using two paper copies of the labeling. This manual comparison is slow and subject to error.

The proposed rule would require that the content of labeling be submitted in an electronic file in a form that we can process, review, and archive. The formatting of these submissions will allow electronic review and comparison of labeling files. We believe that the use of computer technology to identify changes in different versions of the labeling would greatly enhance the accuracy and speed of this part of the review. The ability to quickly identify changes in different versions of the labeling would shorten the time needed to approve labeling changes and reduce the amount of resources we need to devote to labeling review. Our ability to protect the public health will be enhanced because electronic review and comparison of labeling files will provide a higher degree of certainty that all portions of prescription drug labeling are appropriate. Furthermore, in certain circumstances (e.g., changes to NDA labeling made under § 314.70(c)), we review labeling changes after they have been implemented. We may find the revised labeling to be inappropriate. Our ability to quickly identify the changes and correct the labeling would minimize public exposure to the inappropriate labeling.

*B. Why Should the Content of Labeling Be Submitted in PDF?*

For the agency to efficiently use computer technology to identify changes between different versions of labeling, we need to receive labeling in an electronic file format that supports word-for-word comparisons of files and in a form we can process, review, and archive. Although there are several file formats and computer software applications capable of providing the functions necessary for review purposes, it would not be cost effective to purchase many different types or versions of software and train our employees to use them, or to archive many different file formats. At this time, PDF is the only type of electronic file format that we have the ability to use to process, review, and archive submissions.

We believe that of the file formats and software applications currently available, PDF best meets our needs while keeping costs to applicants low. Using commercially available software, an electronic source document created by any number of programs (e.g., word processors, spreadsheets, desktop publishing programs) can be converted to a PDF file, preserving the fonts, formatting, colors, and graphics of the source document, regardless of the application and platform used to create it. The PDF file can be copied onto a floppy disk or CD–ROM and shared with other users who may use PDF reading software to view, navigate through, and print the document exactly as it appears in its original form. Once we receive a PDF document, we can use our current software to compare the text of the file received with other PDF files and view, search, annotate, and print the file. Available software also allows us to copy text, tables, and figures from the file. Software to convert electronic files to PDF format is commercially available at a cost of approximately $100 to $300. Additionally, the technology necessary to create PDF documents is publicly available, and applicants that choose to do so may use their own software to create PDF documents for submission.

Although we believe that PDF is currently the best file format in which to submit labeling electronically, future advancements in computer technology and computer software design may result in new types of file formats and software to better meet our needs and those of industry. Therefore, we believe it is important to evaluate these new technologies as they become available. If we determine that a new technology provides important benefits over PDF, we need the flexibility to identify new or additional formats for electronic labeling submissions. For this reason, we are not proposing to require specifically that PDF be used to submit labeling content electronically. Rather, we are proposing that the content of labeling be submitted in a form that we can process, review, and archive. This language will provide us the flexibility to recommend file formats or software other than PDF in future guidance, to make electronic submissions easier.

*C. Why Does the Agency Make Specific Recommendations for Electronic Labeling Submissions?*

After the agency receives the labeling, we compare it to the last-submitted labeling and look for differences in text, figures, and other changes. In the process of review, we frequently copy, paste, and print portions of the labeling. These functions are most easily performed using PDF when: (1) There are no headers or footers (other than page numbers) to compare or copy; (2) there are no columns to interfere with the copy and paste function or with navigation through the labeling; (3) the font size is sufficiently large to be easily read; (4) the page orientation is portrait; (5) the pagination starts with page one to avoid confusion when referring to changes; and (6) the page size is not too large to be printed on a standard page and not too small to print efficiently. Therefore, electronic files submitted to us should be prepared, organized, and sent to us in accordance with the recommendations in the most recent agency guidance so that they may be easily reviewed and used. Submitting documents according to these recommendations will ensure a uniformity of submissions that will improve the efficiency and speed of agency reviews.

**III. Description of the Proposed Rule**

The proposal would revise our regulations to require electronic submission of the content of labeling for NDAs, certain BLAs, ANDAs, supplements, and annual reports. This requirement would be in addition to existing requirements, found elsewhere in our regulations, that copies of labeling be submitted. The proposal would also make minor changes to reformat and modernize certain regulatory provisions.

*A. Electronic Submission of the Content of Labeling*

Under the proposal, §§ 314.50(l), 314.81(b)(2)(iii), and 314.94(d)(1) would be revised to require applicants to submit the content of labeling in NDAs, ANDAs, supplements, and annual reports electronically in a form that we can process, review, and archive. Under proposed § 314.94(d)(1), ANDA applicants would be required to submit in electronic format the content of labeling for the proposed drug product (i.e., the content of the generic drug product labeling). ANDA applicants would not be required to submit in electronic format the content of labeling for the reference listed drug product. Under proposed § 601.14, applicants for biological products subject to the requirements of § 201.100(d)(3) would be required to submit the content of labeling in BLAs, supplements, and annual reports electronically in a form that we can process, review, and archive.

As discussed in section II of this document, the only type of electronic file format that we have the ability to