Product _____
Critical Control Point _____

1. What is the hazard at this critical control point?
2. Describe your control measures.
3. What is your frequency of control?
4. What are your critical limits?
5. What records are kept of control measures?
6. What corrective action will you take when the product fails to meet the critical limits?

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Friday
January 28, 1994

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310, et al.

Amendment of Final Monograph for Over-the-Counter Antihistamine Drug Products; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 341, and 369

[Docket No. 76N–052H]

RIN 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for OTC Antihistamine Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph for over-the-counter (OTC) antihistamine drug products to include the ingredient doxylamine succinate. FDA is issuing this final rule after considering extensive information concerning this ingredient and the recommendations of its Nonprescription Drugs Advisory Committee (NDAC), which met on June 28, 1993, to consider potential labeling for doxylamine succinate regarding the results of toxicology testing conducted under the National Toxicology Program (NTP). This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: January 30, 1995.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. In that notice, the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) recommended that doxylamine succinate be generally recognized as safe and effective (Category I) as an OTC antihistamine at a dosage level of 7.5 to 12.5 milligrams (mg) (41 FR 38312 at 38385 through 38387). At that time, the agency concluded that doxylamine succinate should remain a prescription drug at dosage levels above 7.5 mg because it causes a high incidence of drowsiness compared to other OTC antihistamines (41 FR 38312 at 38313). Subsequently, after evaluating extensive data on the safety of doxylamine succinate, the agency determined that doxylamine succinate could be marketed OTC at the Panel's recommended dosage. In the **Federal Register** of August 24, 1987 (52 FR 31892 at 31893 through 31903), the agency proposed monograph status at dosages of 7.5 to 12.5 mg. No comments were received in response to this proposal.

In 1991, the agency received a report of a study on doxylamine succinate conducted by the National Center for Toxicological Research (NCTR) (Ref. 1). The results of this study were under consideration when the agency published the final monograph on OTC antihistamine drug products on December 9, 1992 (57 FR 58356). Accordingly, the agency deferred a decision on doxylamine succinate at that time.

The NCTR technical report concerns a 2-year carcinogenicity and chronic toxicity study of doxylamine succinate in Fischer 344 rats and B6C3F1 mice. The study was conducted under the auspices of the NTP. The study was prompted by the National Cancer Institute's finding that methapyrilene, a similar antihistamine, is a potent liver carcinogen in the rat (Ref. 2). Methapyrilene was removed from the market in 1979. The NCTR study on doxylamine succinate was reviewed by the agency's Pulmonary-Allergy Drugs Advisory Committee (the P-A Committee) on June 13 and 14, 1991 (Ref. 3).

In the NCTR study (Ref. 1), doxylamine succinate was administered, ad libitum, as an admixture in the feed to male and female rats at dose levels of 0, 500, 1,000, or 2,000 parts per million (ppm) for 2 years. Mice of both sexes received food containing dose levels of 0, 190, 375, or 750 ppm. Each group contained 48 weanling animals per sex; the animals were scheduled for sacrifice at the end of 104 weeks. An additional group of animals (9 rats and 12 mice per sex) in each dose group was sacrificed at the end of 65 weeks. There were no significant treatment-related differences in survival in either rats or mice. In rats, the highest doxylamine succinate dose group had final body weights that were 22.8 percent (females) and 8.4 percent (males) lower than controls. A number of nonneoplastic lesions was observed in rats, including fatty change, degeneration, and hyperplasia of the liver and increased cytoplasmic alteration in the salivary glands. In mice, there was evidence of hepatotoxicity including hypertrophy, clear and mixed cell foci, and, in females, fatty change. There also was a treatment-related increase in "atypical" hepatocytes in male mice. Both male and female mice had a dose-related increase in thyroid follicular cell hyperplasia. There was a positive trend for increased incidence with increasing dose for both hepatocellular adenomas and carcinomas in male rats. When the incidence of adenomas and carcinomas was combined, the statistical test was positive ($p < 0.01$) and the incidence in the highest dose group was significantly ($p < 0.05$) increased over that of controls. No treatment-related increase in neoplasms was found in female rats. Although not statistically significant, one rat in each of the high dose groups of male and female rats was found to have a pineal gland tumor, which is an extremely rare neoplasm in rats. In mice, doxylamine succinate administration produced an increased incidence of hepatocellular adenoma in both males ($p < 0.001$) and females ($p < 0.001$). Also, there was an increased incidence of follicular cell adenoma of the thyroid gland in male ($p < 0.05$) and female ($p < 0.0001$) mice.

Although the rodent tumorigenicity studies were positive, doxylamine succinate tested negative overall in in vitro tests for genotoxic activity (causing damage to deoxyribonucleic acid (DNA)). Based on the overall assessment, the tumorigenic responses observed in the rodent bioassays may relate to secondary mechanisms involving the induction of liver microsomal enzymes, cytotoxicity, cell proliferation, promotion of tumor potential in pre-existing susceptible cells, or other processes. Such mechanisms may represent species-specific effects or threshold phenomena applicable to rodents (under the conditions of the bioassay), but these mechanisms are considered of questionable significance in humans.

Due to uncertainty concerning the relevance of these findings to human use, the agency asked its P-A Committee and a number of consulting experts to evaluate the data and to advise the agency on whether doxylamine succinate should continue to be marketed OTC. By a vote of five to one, the P-A Committee concluded at its June 13 and 14, 1991, meeting that doxylamine succinate is not likely to have human carcinogenic potential. Again, by the same vote, the P-A Committee recommended that doxylamine succinate could remain OTC, but that consumers should be alerted that these data exist. The P-A Committee discussed labeling as a preferred means of providing this

information (Ref. 3, pp. 175 through 182).

FDA subsequently developed possible labeling that could be used. This labeling included the warning: "Use of this product may be hazardous to your health. This product contains doxylamine succinate which has been determined to produce tumors in laboratory animals." The agency requested the views of a national trade association of OTC drug manufacturers on this suggested warning (Ref. 4). In response, the association asserted that such a warning would be inappropriate (Ref. 5). The association stated that such a warning: (1) Would not ensure safe and effective product use by consumers; (2) is not based on sound scientific data known to be relevant to the human condition; (3) is not understood and actionable, in a meaningful way, by consumers; and (4) might reduce the impact of other warnings and occupy scarce label space.

The association argued that the proposed warning does not meet the criteria of section 502(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(c)). This part of the statute requires labeling information to be presented in "terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." The association contended that the proposed warning effectively shifts the burden of determining product safety from the agency to the consumer and then does not tell the consumer what action to take. In a subsequent communication (Ref. 6), the association further argued that a warning statement in the labeling of doxylamine products is not justified because the scientific data do not suggest a significant risk to humans, that such a warning would be unprecedented, and that a label warning is not the appropriate means for disclosing this information.

In 1992, the agency established a new advisory committee specifically for the review of OTC drugs, the Nonprescription Drugs Advisory Committee (NDAC). The agency asked NDAC to consider the issue of a tumor statement in the labeling of OTC drug products containing doxylamine succinate at its June 28, 1993, meeting. The agency presented a summary of the NCTR data, possible labeling, and legal and compliance issues (Ref. 7). Other interested parties presented their positions. The agency asked NDAC to consider the following questions: (1) Should a labeling statement be used to inform consumers in place of other alternative approaches (no warning, prescription only status, removal from all marketing, etc.)? (2) Is there a desirable risk-to-benefit relationship for labeling? (3) If the answer to both questions is yes, what information should be included in the labeling and what language should be used that would be easily understood by the average consumer? (4) How should information be presented to the consumer (i.e., under the "Warning" or some other heading, visible at the point of purchase, on the immediate container, or in a package insert) and should the information indicate that the product could be "hazardous" to health?

After considering the available evidence, NDAC voted unanimously (10 to 0) to reaffirm the P-A Committee's recommendation that doxylamine succinate remain OTC. NDAC also recommended (10 to 0) that there be no specific statement about tumors in the labeling and urged FDA to write a fully descriptive article on the subject in the "FDA Consumer" magazine.

The agency has considered the two advisory committees' recommendations and concludes that doxylamine succinate is safe and effective for OTC use as an antihistamine. Accordingly, the agency is including doxylamine succinate in the final monograph for OTC antihistamine drug products. The agency is also developing an "FDA Consumer" article and has issued a talk paper concerning the NCTR findings in animals to inform consumers of these data and the uncertainty of their relevance to humans.

References

(1) Department of Health and Human Services, NCTR, "Technical Report for Experiments 406 and 407; Chronic Study of Doxylamine in Fischer 344 Rats and B6C3F1 Mice," 1991, in OTC vol. 04HFM, Docket No. 76N–052H, Dockets Management Branch.

(2) Lijinsky, W., M. D. Reuber, and B. N. Blackwell, "Liver Tumors Induced in Rats by Chronic Oral Administration of the Common Antihistamine Methapyrilene Hydrochloride," Science, 209:817–819, 1980.

(3) Transcript of the June 13 and 14, 1991, meeting of the FDA Pulmonary–Allergy Drugs Advisory Committee, coded RPT 5, Docket No. 76N–052H, Dockets Management Branch.

(4) Letter from W. E. Gilbertson, FDA, to R. W. Soller, NDMA, coded LET 91, Docket No. 76N–052H, Dockets Management Branch.

(5) Letter from R. W. Soller, NDMA, to W. E. Gilbertson, FDA, coded C216, Docket No. 76N–052H, Dockets Management Branch.

(6) Letter from R. W. Soller, NDMA, to W. E. Gilbertson, FDA, coded C224, Docket No. 76N–052H, Dockets Management Branch.

(7) Transcript of the June 28, 1993, meeting of the FDA Nonprescription Drugs Advisory Committee, vol. I, pp. 6–89, coded TR 2, Docket No. 76N–052H, Dockets Management Branch.

The agency has examined the economic consequences of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rulemaking for OTC antihistamine drug products is not expected to have an impact on small businesses. Doxylamine succinate remains available OTC. No product reformulations will be required. Some minor relabeling will be necessary to meet the conditions of the final monograph. Manufacturers will have 1 year to implement this relabeling. Thus, the impact of the final rule appears to be minimal. Therefore, the agency concludes that the final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The agency is removing the exemption for certain drugs limited by new drug applications (NDA) to prescription sale in § 310.201(a)(13) (applicable to doxylamine succinate preparations) because most portions of that exemption are superseded by the requirements of the antihistamine final monograph (21 CFR part 341). Section 310.201(a)(13) does not apply to the use of doxylamine succinate as a nighttime sleep-aid, for which an NDA is required for marketing.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 341

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310, 341, and 369 are amended as follows:

PART 310—NEW DRUGS

2. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

§ 310.201 [Amended]

2. Section 310.201 *Exemption for certain drugs limited by new-drug applications to prescription sale* is amended by removing paragraph (a)(13) and reserving it.

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).4. Section 341.12 is amended by adding new paragraph (h) to read as follows:

§ 341.12 Antihistamine active ingredients.

* * * * *

(h) Doxylamine succinate.

* * * * *

5. Section 341.72 is amended by revising the heading of paragraphs (c)(4) and (c)(6)(iii) and by adding new paragraph (d)(8) to read as follows:

§ 341.72 Labeling of antihistamine drug products.

* * * * *

(c) * * *

(4) *For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in § 341.12(f), (g), and (h).* * * *

* * * * *

(6) * * *

(iii) *For products containing diphenhydramine citrate, diphenhydramine hydrochloride, or doxylamine succinate identified in § 341.12(f), (g), and (h).* * * *

(d) * * *

(8) *For products containing doxylamine succinate identified in § 341.12(h).* Adults and children 12 years of age and over: oral dosage is 7.5 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 3.75 to 6.25 milligrams every 4 to 6 hours, not to exceed 37.5 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

* * * * *

6. Section 341.90 is amended by adding new paragraph (l) to read as follows:

§ 341.90 Professional labeling.

* * * * *

(l) *For products containing doxylamine succinate identified in § 341.12(h).* Children 2 to under 6 years of age: oral dosage is 1.9 to 3.125 milligrams every 4 to 6 hours, not to exceed 18.75 milligrams in 24 hours.

* * * * *

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

7. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.21 [Amended]

8. Section 369.21 Drugs; warning and caution statements required by regulations is amended by revising the introductory text of the entry for "ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE, DOXYLAMINE SUCCINATE, AND CHLOROTHEN CITRATE PREPARATIONS)" to read "ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE AND CHLOROTHEN CITRATE PREPARATIONS). (See § 310.201(a)(4) and (a)(24) of this chapter.)"

* * * * *

Dated: January 24, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1792 Filed 1–27–94; 8:45 am]

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federal register

Friday
January 28, 1994

Part IV

Department of Education

34 CFR Part 692

State Student Incentive Grant Program; Rule

DEPARTMENT OF EDUCATION

34 CFR Part 692

RIN 1840–AB72

State Student Incentive Grant Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the State Student Incentive Grant (SSIG) Program regulations to clarify them, to make minor technical changes, and to implement statutory changes made by the Higher Education Amendments of 1992 to the Higher Education Act of 1965, as amended (HEA).

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Dan Sullivan, U.S. Department of Education, 400 Maryland Avenue, SW., room 4018, ROB–3, Washington, DC 20202–5447. Telephone: (202) 708–4607. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Secretary is revising the existing SSIG Program regulations to implement statutory changes required by the Higher Education Amendments of 1992, enacted July 23, 1992 (Pub. L. 102–325) (1992 amendments), which amend the HEA. These revised regulations also change the SSIG Program regulations to reduce burden and clarify existing rules.

The SSIG Program provides financial incentives for States to establish and to maintain financial assistance programs that make grants and provide work-study assistance to students with substantial financial need.

The SSIG Program supports National Education Goal 5, which calls for every adult American to be literate and possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

On July 2, 1993, the Secretary published a notice of proposed rulemaking (NPRM) for this program in the **Federal Register** (58 FR 36110). The major issues addressed by the proposed regulations are discussed in the preamble to the NPRM. There are two major differences between the NPRM and the final regulations. The first change is to revise the allotment formula above the "hold-harmless" allotment of Federal funds each State received in fiscal year 1979 under the SSIG Program. The "hold-harmless" amount of Federal funds is the SSIG Program allotment each State received in fiscal year 1979. Under section 415B(a)(1) of the program statute, if an appropriation exceeds the fiscal year 1979 appropriation, each State still would continue to receive at least its "hold-harmless" amount regardless of the results of the allotment formula. Based on the comments received, a change was made in the final regulations to revise the allotment formula above the "hold-harmless" level by redefining the term "deemed eligible." The Secretary determines the number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of each State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotment and the State-appropriated funds matching the allotment. In making this determination, the Secretary uses the most recently available data reported by each State. The Secretary will allot additional SSIG funds to States above their "hold-harmless" amounts by using the following steps:

(1) Calculate the States' number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of each State's SSIG funds expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States.

(2) Calculate the States' projected allotments by dividing each State's number of students "deemed eligible" by the total number of students "deemed eligible" for all States, and then multiply that number by the appropriation.

(3) Compare each State's projected allotment calculated in step 2 to its "hold-harmless" amount and select only States where the projected allotment exceeds the "hold-harmless" amount.

(4) For the States selected in step 3, calculate the amount the Secretary will allot above the "hold-harmless" amount to each of these States by dividing each of the selected State's number of students "deemed eligible" by the total "deemed eligible" students for all of the selected States and then multiply that number by the amount of the appropriation above the total "hold-harmless" amount.

The other change under § 692.41(b) provides that, upon a showing of good cause, the Secretary may approve a State's definition for "independent student" that varies from that term as defined in section 480(d) of the HEA.

Analysis of Comments and Changes

Fifteen commenters responded to the Secretary's invitation to comment on the NPRM. The following is an analysis of comments and changes in the regulations since publication of the NPRM. Substantative issues are discussed under the section of the regulations to which they pertain. Technical and other minor changes to the language published in the NPRM—and requests for changes the Secretary is not legally authorized to make under the applicable statutory authority—may not be addressed.

Section 692.10 How Does the Secretary Allot Funds to the States?

Comment: Three commenters agreed with the revision in § 692.10(b) of the proposed regulations to redefine students who are "deemed eligible" to participate in the SSIG Program as students who were reported by the State as SSIG recipients in the most recently available performance report data.

Several commenters objected to the use of State-reported SSIG recipients in the most recently available performance report data as students who are "deemed eligible" to participate in the SSIG Program. These commenters believed that the number of recipients could be easily manipulated by States by inflating the number of awards to students. Rather than provide substantial awards to the most needy students, States could inflate the number of students deemed eligible by providing smaller awards to a larger number of students in order to receive a larger share of program funding above the hold-harmless amount.

A few commenters believed that the current allotment formula for awarding SSIG funds above the hold-harmless amount should not be amended. These commenters felt that the current allotment formula based on the enrollment data for each State is more objective and meaningful in distributing funds for the SSIG Program.

Two commenters recommended that the allotment formula above the hold-

harmless level should be based on the amount of funds actually expended by each State to match its Federal allotment.

Discussion: The Secretary is amending the current allotment formula for awarding funds above the hold-harmless level because it does not conform to section 415B(a)(1) of the HEA. Section 415B(a)(1) was amended by the Higher Education Amendments of 1986 (Pub. L. 99–498), but the SSIG Program regulations were not amended to conform with this statutory change.

The Secretary is changing the allotment formula for funds above the hold-harmless level to one that counts, for purposes of making allotments to States, the number of students "deemed eligible" to participate in a State's SSIG Program as determined by the following formula. The Secretary divides the amount of each State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States in the most recent award year as reported by the State. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotment and the State-appropriated funds matching the allotment.

In the past, the Secretary has provided extreme flexibility to States in implementing the SSIG Program statute. It is the Secretary's experience that mere head counts do not accurately reflect the participation of States in the joint Federal-State SSIG Program. Moreover, this change responds to the concerns raised by some commenters that States might manipulate a head-count of recipients and the concerns raised by other commenters that funding should be based on the actual matching expenditures of the States. Furthermore, the Secretary collects the Federal and State SSIG funding data and average grant award per student from each State's most recent SSIG Program performance report. By using the most recently available performance report data, the States will not be required to conduct a new data collection.

Under section 415B(a)(1) of the program statute, this formula would be used only if an appropriation exceeds the fiscal year 1979 appropriation. Each State still receives at least its "hold-harmless" amount. The Secretary believes that by considering the amount of State SSIG expenditures in the calculation of the number of students "deemed eligible," States are provided with incentive to increase the amount of funds they allocate to their SSIG Programs. In this way, States that provide more State dollars will receive more Federal SSIG funds above the "hold-harmless" amount, the allotment each State received in fiscal year 1979 under the SSIG Program. For States to exceed the allotment of funds beyond the "hold harmless" amount, States would have to elect to include more of their State grant funds under the SSIG Program in their calculation under § 692.10(b).

The Secretary believes that the change encourages the inclusion of additional State funds in the SSIG Program and, as a result, would stabilize the grant funds available to students from the States. The Secretary also believes that the revised formula provides for the best use of Federal funds under the program by: (1) Rewarding States that have made a strong commitment of their State grant funds to the SSIG Program as reflected by the States' amount of State grant funds; and (2) encouraging States to maintain or expand their commitment of their level of expenditures for State grant programs.

Changes: A change has been made. The Secretary has amended § 692.10(b) to provide that the Secretary determines the number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of each State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotment and the State-appropriated funds matching the allotment. In making this determination, the Secretary uses the most recently available data reported by each State.

Section 692.21 What Requirements Must Be Met by a State Program?

Comment: One commenter stated that the Secretary should clarify § 692.21(e) concerning whether fees may or may not be collected in the case of decentralized State grant programs under which institutions award State grant funds as well as institutional aid.

Discussion: If there is a fee for submitting and processing the State information on a form to make a determination of financial need under the SSIG Program, the fee must be payable to the State regardless of whether the information may also be used for institutional aid. In the case of a decentralized State grant program under which institutions participating in the State's SSIG Program award State grant funds, funds awarded under these programs are still considered to be State aid and not institutional aid. It is the responsibility of each State to ensure that institutions participating in the State's SSIG Program conform with this requirement.

Changes: None.

Comment: Two commenters stated that the term "reasonable" as listed in § 692.21(g) should be clearly defined by the Secretary with some specific parameters provided.

Discussion: Section 692.21(g) provides that, if a State awards grants to independent students or to students who are less-than-full-time students enrolled in an institution of higher education, a reasonable portion of the State's allocation must be awarded to those students. The Secretary believes that in order to provide the States with the maximum amount of flexibility under this provision, no specific parameters for the term "reasonable" should be provided. The Secretary on a case-by-case basis, if necessary, will determine the reasonableness of the allocation.

Changes: None.

Comment: A few commenters believed that under § 692.21(g), the Secretary requires that a State must award SSIG Program grants to independent students or to students who are less-than-full-time students in reasonable proportion to the State's allocation of SSIG Program funds.

One commenter believed it was unwise to reserve a portion of very limited need-based grant aid for less-than-full-time students because of the overwhelming numbers of very needy full-time students who cannot be served due to lack of adequate funding.

Discussion: Section 692.21(g) provides that, if a State awards grants to independent students or to students who are less-than-full-time students enrolled in an institution of higher education, a reasonable portion of the State's allocation must be awarded to those students. Neither the program statute nor § 692.21(g) requires a State to award grants to independent students or students who are less-than-full-time. If the State's allocation from the Secretary is based on a formula that includes the financial need of students who are independent or attend an institution less-than-full-time, then the State must ensure that those students receive a reasonable proportion of SSIG funds.

Changes: None.

Section 692.21 What Requirements Must be met by a State Program? and Section 692.41 What Standards May a State Use to Determine Substantial Financial Need?

Comment: Several commenters objected to the proposed requirement in § 692.41(b) that States use the term "independent student" as defined by section 480(d) of the HEA in a State's own need-analysis system or a need-analysis system combining the State's system with the Federal system under part F of title IV of the HEA in order to obtain the Secretary's approval of the State's system.

Some commenters believed that the use of the Federal definition infringes upon the State's right to set priorities for administering State grant funds and would limit the State's flexibility in awarding these funds.

Some commenters also believed that they should have the flexibility to use their own State statutory or regulatory definition of "independent student" and report any variance with the Federal definition on the State's annual application to participate in the program.

One commenter was concerned that, if the regulations are adopted as proposed, the States should be given an opportunity to amend their statutory or regulatory definitions of "independent student" to conform with the Federal definition by making the effective date of the provision begin with the 1995–96 award year. This effective date would provide the States with time to amend their statutory or regulatory independent student definitions to conform with the Federal definition.

One commenter was concerned regarding whether the students selected for SSIG matching purposes by a State would reflect the proportion of independent students in the State program. The commenter believed that the Secretary could achieve the intent of the Higher Education Amendments of 1992 by allowing States to submit changes to their applications and programs. Each State's application would specify the proportion of independent students as defined in the State's approved need-analysis system which are in the base used to allocate funds and the means by which the State would ensure a proportionate distribution of SSIG Program funds to independent students.

Discussion: The Secretary agrees with the concerns raised by commenters who believed that the proposed requirement in § 692.41(b) would create difficulties for some States in administering the SSIG Program. The Secretary, therefore, is revising § 692.41(b) to provide that, upon the review and approval of the Secretary, a State may use its own definition for "independent student" that varies from the Federal definition of the term as defined in section 480(d) of the HEA. The Secretary will approve a variant definition on a case-by-case basis. States that wish to use a variant definition of "independent student," other than the Federal definition, must provide information concerning their "independent student" definition at the time of application for program funds that includes a justification, with accompanying supporting documentation, demonstrating "good cause" as to why the Secretary should approve the variant definition.

The Secretary believes that States that have a valid reason to use a different independent student definition should be accommodated, as long as the use of a different definition is reasonably justified and does not place significant additional reporting burdens on applicants. The Secretary believes that a valid reason for requesting a variance might include that excessive costs to the State are incurred in implementing the Federal definition. The Secretary will also take into consideration in approving a definition the extent to which the new definition imposes additional data requirements beyond those provided for by the Federal definition and the Federal Need Analysis Methodology authorized under part F of title IV of the HEA. For example, a State, rather than adopt a new definition, may decide, with the Secretary's approval, to use the Federal definition except for the professional judgment provision in section 480(d)(7) of the HEA.

The Secretary also agrees with the concerns raised by a commenter regarding whether a State, in selecting students for the SSIG Program matching purposes, would accurately reflect the proportion of independent students to all students in the State program. The Secretary believes that the State SSIG Program student funding should be comparable to the overall State program, if the entire State program is not contained in the State SSIG Program. However, the Secretary does not wish to place any unnecessary burdens on States. Therefore, the Secretary is providing a new paragraph (j) in § 692.21. Under § 692.21(j) the proportion of SSIG Program funds awarded to independent students, including both the Federal allotment and the State funds matching the allotment, must be, to the extent practicable, the same proportion of funds awarded independent students as is in the State program or programs of which the State's SSIG Program is a part.

Changes: Two changes have been made. The Secretary amends § 692.41(b) to provide that he may approve, on a case-by-case basis, the use of a definition of "independent student" that varies from the term defined in section 480(d) of the HEA if a State demonstrates "good cause" as to why a variance should be approved.

The Secretary also amends § 692.21 by adding a new paragraph (j) to provide that, to the extent practicable, the proportion of the funds awarded to independent students in the SSIG Program shall be the same proportion of funds awarded to independent students as is in the State program or programs of which the State's SSIG Program is a part.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed regulations and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 692

Grant programs—education, Postsecondary education, State administered—education, Student Aid—education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number 84.096, State Student Incentive Grant Program)

Dated: January 14, 1994.

Richard W. Riley,

Secretary of Education.

The Secretary amends part 692 of title 34 of the Code of Federal Regulations as follows:

PART 692—STATE STUDENT INCENTIVE GRANT PROGRAM

1. The authority citation for part 692 is revised to read as follows:

Authority: 20 U.S.C. 1070c through 1070c–4, unless otherwise noted.

* * * * *

2. Section 692.3 is amended by revising paragraphs (b) and (d) to read as follows:

§ 692.3 What regulations apply to the State Student Incentive Grant Program?

* * * * *

(b) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR 75.60–75.62 (Ineligibility of Certain Individuals to Receive Assistance).

(2) 34 CFR part 76 (State-Administered Programs).

(3) 34 CFR part 77 (Definitions That Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments).

(6) 34 CFR part 82 (New Restrictions on Lobbying).

(7) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(8) 34 CFR part 86 (Drug-Free Schools and Campuses).

* * * * *

(d) The Student Assistance General Provisions in 34 CFR part 668.

(Authority: 20 U.S.C. 1070c–1070c–4)

3. In § 692.4, paragraph (a) is amended by removing the terms, "Academic year (§ 668.2)", "Campus-based programs (§ 668.2)", "Guaranteed Student Loan Program (§ 668.2)", "Income Contingent Loan Program (§ 668.2)", "Pell Grant Program (§ 668.2)", "PLUS Program (§ 668.2)", and "Postsecondary vocational institution (§ 668.5)"; by redesignating paragraph (b) as paragraph (c); and by adding a new paragraph (b) to read as follows:

§ 692.4 What definitions apply to the State Student Incentive Grant Program?

* * * * *

(b) *Definitions in the HEA.* The following terms used in this part are defined in section 481(a), (b), (c), and (d) of the HEA:

Academic year
Institution of higher education
Postsecondary vocational institution
Proprietary institution of higher education

* * * * *

4. Section 692.10 is amended by revising paragraph (b) to read as follows:

§ 692.10 How does the Secretary allot funds to the States?

* * * * *

(b) For the purpose of paragraph (a)(1) of this section, the Secretary determines the number of students "deemed eligible" to participate in a State's SSIG Program by dividing the amount of that State's SSIG expenditures, including both its Federal allotment and the State-appropriated funds matching the allotment, by the average grant award per student of all participating States. The Secretary determines the "average grant award per student" by dividing the total number of student recipients for all States into the total amount of SSIG expenditures for all States, including both the Federal allotments and the State-appropriated funds matching those allotments. In making this determination, the Secretary uses the most current available data reported by each State.

5. Section 692.21 is amended by removing the periods after paragraphs (a) and (d); adding semi-colons after paragraphs (a) and (d); redesignating paragraphs (e), (f), (g), (h), and (i) as paragraphs (f), (g), (h), (i), and (k), respectively; adding new paragraphs (e) and (j); revising paragraphs (b), (c), and redesignated pargraphs (g), and (i); and revising the Office of Management and Budget control number at the end of the section to read as follows:

§ 692.21 What requirements must be met by a State program?

* * * * *

(b) Provides assistance only to students who meet the eligibility requirements in § 692.40;

(c) Provides that assistance under this program to a full-time student will not be more than $5,000 for each academic year;

* * * * *

(e) Provides that no student or parent shall be charged a fee that is payable to an organization other than the State for the purpose of collecting data to make a determination of financial need in accordance with paragraph (d) of this section;

* * * * *

(g) Provides that, if a State awards grants to independent students or to students who are less-than-full-time students enrolled in an institution of higher education, a reasonable portion of the State's allocation must be awarded to those students;

* * * * *

(i) Provides for State expenditures under the State program of an amount that is not less than—

(1) The average annual aggregate expenditures for the preceding three fiscal years; or

(2) The average annual expenditure per full-time equivalent student for those years;

(j) Provides that, to the extent practicable, the proportion of the funds awarded to independent students in the SSIG Program shall be the same proportion of funds awarded to independent students as is in the State program or programs of which the State's SSIG Program is a part; and

* * * * *

(Approved by the Office of Management and Budget under control number 1840–0660)

* * * * *

6. Section 692.30 is amended by removing the first of the duplicate paragraphs (e)(2).

7. Section 692.41 is amended by redesignating paragraphs (a), (b), and (c) as paragraphs (a) (1), (2), and (3), respectively; by designating the introductory text as the introductory text of paragraph (a); by revising paragraph (a)(1); and by adding a new paragraph (b), to read as follows:

§ 692.41 What standards may a State use to determine substantial financial need?

(a) * * *

(1) A system for determining a student's financial need under part F of title IV of the HEA;

* * * * *

(b) The Secretary generally approves a need-analysis system under paragraph (a) (2) or (3) of this section only if the need-analysis system applies the term "independent student" as defined under section 480(d) of the HEA. However, for good cause shown, the Secretary may approve, on a case-by-case basis, a State's need analysis system that uses a definition for "independent student" that varies from that term as defined in section 480(d) of the HEA.

* * * * *

[FR Doc. 94–1692 Filed 1–27–94; 8:45 am]
BILLING CODE 4000–01–P

federal register

Friday
January 28, 1994

Part V

Department of Defense

Department of the Army

Corps of Engineers

33 CFR Part 334
Restricted Area, Pacific Ocean Offshore of Camp Pendleton, CA; Rule

DEPARTMENT OF DEFENSE

Department of the Army

Corps of Engineers

33 CFR Part 334

Restricted Area, Pacific Ocean Offshore of Camp Pendleton, San Diego County, CA

AGENCY: Army Corps of Engineers, DoD.
ACTION: Final rule.

SUMMARY: This rule adopts as final, the Corps regulations contained in 33 CFR 334.905 Pacific Ocean, offshore of Camp Pendleton, California, Fallbrook restricted area, which were published in the **Federal Register** as an interim final rule on October 15, 1993.

EFFECTIVE DATE: October 15, 1993.

ADDRESSES: HQUSACE, CECW–OR, Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth White at (619) 455–9422 or Mr. Ralph Eppard at (202) 272–1783.

SUPPLEMENTARY INFORMATION: The Commanding Officer of the Naval Weapons Station requested the Corps to establish a restricted anchorage area (identified as Fallbrook), offshore of Camp Pendleton, San Diego County, California. In accordance with Naval Sea Systems Command, OPS Volume 1 Manual, Ammunition and Explosives Ashore Safety Regulations for Handling, Storing, Production, Renovation, and Shipping, a safety distance of 9,000 feet to inhabited structures is required for the anticipated net explosive weight of 5,500,000 pounds. During loading/unloading, vessel traffic and anchorage would be restricted to a distance not closer than 5,400 feet from the vessel. The Fallbrook anchorage site has been intermittently utilized in the past and its use needs to be continued in support of replenishment operations associated with the transfer of ordnance from the Fallbrook Annex to and from naval combatants and ammunition ships. The Navy's utilization of this anchorage is expected to grow to a maximum of 10 days per month. This planned long-term utilization for replenishment operations necessitates establishment of the restricted anchorage. The Corps Los Angeles District Engineer issued a public notice on June 2, 1993, which solicited comments on this proposed restricted area to all known interested parties. The District did not receive any objections to the establishment of the restricted anchorage area. There also were no comments received in response to the interim final rule and accordingly, the rule is adopted without change.

Economic Assessment and Certification

This final rule is issued with respect to a military function of the Defense Department and the provisions of E.O. 12866 do not apply. These rules have been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354), which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small businesses (i.e., small businesses and small government) jurisdictions. There is no anticipated navigational hazard or interference with existing waterway traffic. There are no recreational or commercial fishery operations presently in or using the waters within this area because of ongoing military operations. Therefore, no loss of resources or use of resources would be borne by the public. Therefore, it has been determined that this rule will not have a significant economic impact on a substantial number of small entities and that preparation of a regulatory flexibility analysis is not warranted.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Transportation.

In consideration of the above, the Corps is amending part 334 of title 33 to read as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266; (33 U.S.C. 1) and 40 Stat. 892; (33 U.S.C. 3)

2. Accordingly, the interim final rule amending 33 CFR part 334 which was published at 58 FR 53426 on October 15, 1993, is adopted as a final rule without change.

Dated: January 14, 1994.

Stanley G. Genega,

Major General, USA, Director of Civil Works.

[FR Doc. 94–1838 Filed 1–27–94; 8:45 am]
BILLING CODE 3710–92–M

federal register

Friday
January 28, 1994

Part VI

Environmental Protection Agency

National Emission Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Operated by the Department of Energy; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–4830–7]

RIN 2060–AE39

National Emissions Standards for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Operated by the Department of Energy

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: This notice confirms that 40 CFR part 61, subpart I, is presently in effect for two categories: (1) Facilities licensed by the Nuclear Regulatory Commission (NRC) or NRC Agreement States except for commercial nuclear power reactors and (2) all federal facilities not operated by the Department of Energy (DOE). The effectiveness of Subpart I is presently stayed for commercial nuclear power reactors. The previous stay of Subpart I for NRC and Agreement State licensees other than nuclear power reactors expired on November 15, 1992, and has not been extended or renewed. All NRC and Agreement State licensees other than nuclear power reactors, as well as federal facilities not operated by DOE, are now subject to all applicable provisions of subpart I. Each affected facility must demonstrate compliance for calendar year 1993 with the annual emission standard set forth in 40 CFR 61.102, utilizing the procedures specified in 40 CFR 61.103. Those facilities which are not exempt from reporting requirements under 40 CFR 61.104(b) must submit the annual report concerning emissions for calendar year 1993 required by 40 CFR 61.104(a) to EPA by March 31, 1994. Facilities that are unable to gather the necessary information and report to EPA by March 31, 1994 should request an extension from the appropriate EPA regional office. EPA will consider extensions of up to 60 days.

DATES: 40 CFR part 61, subpart I became effective for NRC and Agreement State licensees other than commercial nuclear power reactors on November 16, 1992. Those facilities which are not exempt from reporting requirements under 40 CFR 61.104(b) must submit the annual report concerning emissions required by 40 CFR 61.104(a) for calendar year 1993 to EPA by March 31, 1994. Facilities that are unable to gather the necessary information and report to EPA by March 31, 1994 should request an extension from the appropriate EPA regional office. EPA will consider extensions of up to 60 days.

FOR FURTHER INFORMATION CONTACT: David P. O'Very, Air Standards and Economic Branch, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, DC 20460, (202) 233–9762.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1989, EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPS) to control radionuclide emissions to the ambient air from several source categories. This rule was published in the **Federal Register** on December 15, 1989 (54 FR 51654).

Subpart I limits radionuclide emissions to the ambient air from NRC-licensed facilities to that amount which would cause any member of the public to receive in any year an effective dose equivalent (ede) of 10 millirem, of which no more than 3 millirem ede may be from radioiodines. These limits involved application to radionuclide emissions of the Agency's policy for regulating section 112 pollutants which was first announced in the benzene NESHAP (54 FR 38044 September 14, 1989), and utilized the two-step process outlined in *NRDC* v. *EPA*, 824 F.2d at 1146 (1987) (the *Vinyl Chloride* decision).

At the time of promulgation of the radionuclide NESHAPS rule, EPA granted reconsideration of subpart I based on information received late in the rulemaking from the NRC and the National Institutes of Health (NIH). The NRC was concerned about duplicative regulation of its licensees by NRC and EPA, while the NIH was concerned with the potential negative effects of the standard on the use of nuclear medicine in patient treatment. EPA subsequently extended the stay of the effective date of subpart I on several occasions, pursuant to the authority provided by section 10(d) of the Administrative Procedure Act (APA), 5 U.S.C. 705, and section 301(a) of the Clean Air Act, 42 U.S.C. 7601(a). (55 FR 10455, March 21, 1990; 55 FR 29205, July 18, 1990; and 55 FR 38057, September 17, 1990).

In 1990, Congress enacted legislation comprehensively amending the Clean Air Act, which included a section addressing the issue of regulatory duplication between EPA and NRC. Section 112(d)(9) of the CAA provides, that no standard for radionuclide emissions from any category or subcategory of facilities licensed by the Nuclear Regulatory Commission (or an Agreement State) is required to be promulgated under Section 112 if the Administrator determines, by rule, and after consultation with the Nuclear Regulatory Commission, that the regulatory program established by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act for such category or subcategory provides an ample margin of safety to protect the public health. This provision enables EPA to eliminate duplication of effort between EPA and NRC so long as public health is protected with an ample margin of safety.

On April 24, 1991, EPA issued a final rule staying until November 15, 1992 the effectiveness of subpart I for all categories of facilities licensed by the NRC or NRC Agreement States except nuclear power reactors (56 FR 18735). The purpose of this stay was to avoid the costs and disruption associated with formal implementation of subpart I while EPA was collecting additional information necessary to make the substantive determination for these facilities contemplated by CAA Section 112(d)(9). NESHAPS Rulemaking on Nuclear Regulatory Commission and Agreement State Licensees Other Than Nuclear Power Reactors, EPA 430–R–92–011 (November 1992). (On August 5, 1991, EPA proposed to rescind subpart I for commercial nuclear power reactors (56 FR 37196) and issued a final rule staying the effectiveness of subpart I for nuclear power reactors during the pendency of the substantive rulemaking on rescission (56 FR 37158)).

The Natural Resources Defense Council (NRDC) petitioned for judicial review of the rule staying subpart I for NRC and Agreement State licensees other than nuclear power reactors. On September 25, 1992, the DC Circuit Court of Appeals issued a decision holding that EPA had exceeded its authority by staying subpart I while it was collecting the information required to make a finding under CAA section 112(d)(9). *NRDC* v. *Reilly*, 976 F.2d 36 (DC Cir. 1992).

EPA completed its investigation of radionuclide emissions by NRC and Agreement State licensees other than nuclear power reactors while the litigation in the DC Circuit Court concerning the rule staying subpart I for these facilities was still pending. On September 18, 1992, EPA announced that it intended to propose rescission of subpart I for these facilities and proposed a rule which would further stay subpart I during the pendency of the substantive rulemaking on rescission (57 FR 43173). Although EPA did propose to rescind subpart I for NRC and Agreement State licensees other

than nuclear power reactors on December 1, 1992 (57 FR 56877), EPA did not adopt the proposed stay. EPA concluded that the Court's ruling in *NRDC* v. *Reilly* had left substantial doubt concerning the legality of any further stay of subpart I for these facilities and decided not to issue any further stay. As a result, the rule staying subpart I for NRC and Agreement State licensees other than nuclear power reactors expired by its own terms on November 15, 1992, and subpart I took effect for these facilities on November 16, 1992 (the official mandate implementing the DC Circuit Court's decision in *NRDC* v. *Reilly* was not transmitted until after the stay had already expired).

II. Implementation of Subpart I as Applied to NRC-Licensed Facilities Other Than Nuclear Power Reactors

Subpart I became effective on November 16, 1992 for all categories of facilities licensed by NRC or Agreement States except for commercial nuclear power reactors. Subpart I was already in effect prior to that time for federal facilities not operated by DOE.

At this time, EPA has not taken final administrative action concerning the rule to rescind subpart I for NRC and Agreement State licensees other than commercial nuclear power reactors which it proposed on December 1, 1992. EPA is recommending that NRC make certain changes in its regulatory program in order to fully support the substantive finding which is required by CAA Section 112(d)(9) before EPA may rescind subpart I for NRC licensees other than commercial nuclear power reactors. EPA and NRC are presently engaged in consultations concerning specific actions which would strengthen the basis for rescission of subpart I for this category, but it is unlikely that any agreement between EPA and NRC concerning additional measures could be implemented quickly. While the rulemaking concerning rescission is still pending, EPA advises all facilities not to presume that EPA will take any particular action in that rulemaking and to proceed in the meantime with all legally required compliance activities.

Because subpart I first took effect for NRC and Agreement State licensees other than nuclear power reactors near the end of 1992, EPA has determined that affected facilities were not required to demonstrate compliance with subpart I for calendar year 1992. However, each NRC or Agreement State licensee, as well as each federal facility not operated by DOE, is now subject to all provisions of subpart I. Each affected facility must demonstrate compliance for calendar year 1993 with the annual emission standard set forth in 40 CFR 61.102, utilizing the procedures specified in 40 CFR 61.103. Those facilities which are not exempt from reporting requirements under 40 CFR 61.104(b) must submit the annual report concerning emissions for calendar year 1993 required by 40 CFR 61.104(a) to EPA by March 31, 1994. Facilities that are unable to gather the necessary information and report to EPA by March 31, 1994 should request an extension from the appropriate EPA regional office listed below. EPA will consider extensions of up to 60 days.

As required by 40 CFR 61.04, all requests, reports, applications, submittals, and other communications to EPA pursuant to the standards in subpart I should be submitted in duplicate to the appropriate Regional Office of the EPA to the attention of the Director of the Division indicated in the following list of EPA Regional Offices:

Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont), Director, Air, Pesticides, and Toxics Management Division, U.S. Environmental Protection Agency, John F. Kennedy Federal Building, Boston, MA 02203.

Region II (New Jersey, New York, Puerto Rico, Virgin Islands), Director, Air and Waste Management Division, U.S. Environmental Protection Agency, Federal Office Building, 26 Federal Plaza, New York, NY 10278.

Region III (Delaware, District of Columbia, Maryland, Pennsylvania, West Virginia), Director, Air, Toxics and Radiation Management Division, U.S. Environmental Protection Agency, 841 Chestnut St., Philadelphia, PA 19107.

Region IV (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee), Director, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, 345 Courtland Street NE, Atlanta, GA 30365.

Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin), Director, Air and Radiation Division, U.S. Environmental Protection Agency, 77 West Jackson Blvd., Chicago, IL 60604–3590.

Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas), Director, Air, Pesticides, and Toxics Division, U.S. Environmental Protection Agency, 1443 Ross Avenue, Dallas, TX 75202.

Region VII (Iowa, Kansas, Missouri, Nebraska), Director, Air and Toxics Division, U.S. Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, KS 66101.

Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming), Director, Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, 999 18th Street, Suite 500, Denver, CO 80202–2460.

Region IX (American Samoa, Arizona, California, Guam, Hawaii, Nevada), Director, Air & Toxics Division, U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105.

Region X (Alaska, Oregon, Idaho, Washington), Director, Air & Toxics Division, U.S. Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101.

Facility operators and owners desiring further information should write to Eleanor Thornton, Air Standards and Economic Branch, Criteria and Standards Division (6602J), Office of Radiation and Indoor Air, Environmental Protection Agency, Washington, DC 20460 to obtain a copy of EPA's Guide for Determining Compliance with the Clean Air Act Standards for Radionuclide Emissions from NRC-Licensed and Non-DOE Federal Facilities, the COMPLY computer code, and the User's Guide for the COMPLY Computer Code.

Dated: January 20, 1994.

Carol M. Browner,

Administrator.

[FR Doc. 94–1960 Filed 1–27–94; 8:45 am]

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