## II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web on the CDRH home page at ''http://www.fda.gov/cdrh'' or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

## III. Petitions

FDA has received a petition requesting an exemption from premarket notification for the audiometer (21 CFR 874.1050).

In the **Federal Register** of November 18, 1998 (63 FR 64091), FDA published a notice announcing that this petition had been received and providing an opportunity for interested persons to submit comments on the petition by December 18, 1998. FDA received one comment that supported the proposal. FDA has reviewed the petition and has determined that this device meets the criteria for exemption described previously, provided that certain conditions are met. The petitioner stated that manufacturers of audiometers voluntarily comply with a consensus standard for audiometers, American National Standards Institute (ANSI), S3.6 (R1996)[1]. FDA believes that compliance with this standard obviates the need for premarket notifications and is, therefore, issuing this order exempting these devices from the requirements of premarket notification, provided that they are in compliance with this standard, and is codifying this order in the Code of Federal Regulations. Audiometers that do not comply with this standard are not exempt from the premarket notification requirements. FDA also notes that otoacoustic emissions test devices are not exempt from the the premarket notification requirements. Because the otoacoustic emissions test device is not a type of audiometer, it is not completely covered by the ANSI standard and, therefore, is not subject to the exemption.

[1] The standard is available from the American National Standards Institute, Standards Secretariat, Acoustical Society of America, 120 Wall St., 32d Floor, New York, NY 10005–3993.

## IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

## V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

## VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

## PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 874.1050 is amended by revising paragraph (b) to read as follows:

**§ 874.1050 Audiometer.**

* * * * *

(b) *Classification*. Class II. Except for the otoacoustic emission device, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, if it is in compliance with American National Standard Institute S3.6–1996, ''Specification for Audiometers,'' and subject to the limitations in § 874.9.

Dated: March 24, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 99–7746 Filed 3–26–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Part 882

**[Docket No. FR–4054–C–05]**

**RIN 2577–AB63**

### Section 8 Certificate and Voucher Programs Conforming Rule; Technical Amendment

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

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

**SUMMARY:** This document makes one technical amendment to the final rule that was published April 30, 1998 (63 FR 23826), which combined and conformed program regulations for the Section 8 certificate and voucher programs.

**EFFECTIVE DATE:** March 29, 1999.

**FOR FURTHER INFORMATION CONTACT:** Gloria Cousar, Deputy Assistant Secretary for Public and Assisted Housing Delivery, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4204, 451 7th Street, SW, Washington, DC 20410. Her telephone numbers are (202) 708–2841 (voice) and (202) 708–0850 (TTY). (These are not toll-free numbers.)

**SUPPLEMENTARY INFORMATION:**

### Need for Amendment

The Section 8 Certificate and Vouchers Programs Conforming Rule,

published on April 30, 1998 (63 FR 23826), was corrected by a document published on June 10, 1998 (63 FR 31624). A final rule was published on March 16, 1999 (64 FR 13056) correcting additional errors in the final rule. However, an additional erroneous cross-reference has been detected and HUD wants to make this correction immediately.

In § 882.401(a), there is a reference to ''moderate rehabilitation as defined in § 882.402.'' That reference should have been to the actual location of definitions in part 882, which is § 882.102.

**List of Subjects in 24 CFR Part 882**

Grant programs—housing and community development, Homeless, Housing, Lead poisoning, Low- and moderate-income housing, Rent subsidies, Reporting and recordkeeping requirements.

For the reasons stated above, part 882 of title 24 of the Code of Federal Regulations is amended as follows:

## PART 882—SECTION 8 MODERATE REHABILITATION PROGRAMS

1. The authority citation for part 882 continues to read as follows:

**Authority:** 42 U.S.C. 1437f and 3535(d).

**§ 882.401 [Amended]**

2. In § 882.401(a), the reference to ''§ 882.402'' is removed and a reference to ''§ 882.102'' is added in its place.

Dated: March 23, 1999.

**Harold Lucas,**

*Assistant Secretary for Public and Indian Housing.*

[FR Doc. 99–7613 Filed 3–26–99; 8:45 am]

**BILLING CODE 4210–33–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[Region 2 Docket No. NJ31–2–189, FRL–6313–9]**

## Approval and Promulgation of Implementation Plans; Reasonably Available Control Technology for Oxides of Nitrogen for the State of New Jersey

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

**ACTION:** Final rule.

**SUMMARY:** The EPA is approving revisions to the New Jersey State Implementation Plan (SIP) for ozone. The State submitted this SIP revision as an amendment to New Jersey's statewide rule for the application of reasonably available control technology (RACT) to sources that emit oxides of nitrogen ($NO_X$). The intended affect of this SIP revision is to reduce emissions of $NO_X$ in order to help attain the national ambient air quality standard for ozone.

**EFFECTIVE DATE:** This rule will become effective April 28, 1999.

**ADDRESSES:** Copies of the State submittal and other information are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th floor, New York, New York 10007–1866.

New Jersey Department of Environmental Protection, Office of Air Quality Management, Bureau of Air Quality Planning, 401 East State Street, CN418, Trenton, New Jersey 08625.

Environmental Protection Agency, Air and Radiation Docket and Information Center, Air Docket (6102), 401 M Street, SW, Washington, DC 20460.

**FOR FURTHER INFORMATION CONTACT:** Ted Gardella, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th floor, New York, New York 10007–1866, (212) 637–4249.

**SUPPLEMENTARY INFORMATION:** On November 15, 1993, New Jersey submitted to EPA, as a revision to the SIP, Subchapter 19 of Chapter 27, Title 7 of the New Jersey Administrative Code. Subchapter 19 is entitled ''Control and Prohibition of Air Pollution From Oxides of Nitrogen.'' This Subchapter provides the $NO_X$ RACT requirements for New Jersey and became effective on December 20, 1993. On January 27, 1997 (62 FR 3804), EPA published approval of Subchapter 19 as part of the SIP.

On June 21, 1996, New Jersey submitted to EPA, as a revision to the SIP, the revisions to Subchapter 19. The June 1996 SIP submittal from New Jersey includes new provisions and amendments to Subchapter 19. The revisions apply to major stationary sources of $NO_X$ and allow a facility to comply with Subchapter 19 with any of the following new provisions: seasonal fuel switching; the emergency use of fuel oil; an exemption for electric generating facilities during a maximum emergency generating alert; and phased compliance for facilities choosing to repower, facilities actively pursuing innovative control technology, or facilities that made a good faith effort to comply by May 31, 1995. On August 31, 1998, EPA published in the **Federal Register** (63 FR 46209) a Notice of Proposed Rulemaking (NPR) proposing to approve the June 21, 1996 revisions to Subchapter 19 and providing for a 30-day public comment period. EPA received no comments regarding the NPR. For a more detailed discussion of New Jersey's SIP submittal and EPA's action, the reader is referred to the NPR.

**Conclusion**

The EPA has evaluated the June 21, 1996 revision to Subchapter 19 for consistency with the Act's provisions, EPA regulations and policy and has determined that the revisions to this regulation are fully approvable. Therefore, this rule makes final the action proposed at 63 FR 46209.

**Administrative Requirements**

*Executive Order 12866*

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

*Executive Order 12875*

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

**Executive Order 13045**

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically