

Environmental Protection Agency

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to have been violated, the activity alleged to constitute a violation, the person or persons responsible for the alleged violation, the location of the alleged violation, the date or dates of such violation and the full name, address, and telephone number of the person giving notice.

(b) *Failure to act.* Notice regarding an alleged failure of the Administrator of the Environmental Protection Agency to perform any act or duty under the Noise Control Act which is not discretionary with such Administrator or notice regarding an alleged failure of the Administrator of the Federal Aviation Administration to perform any act or duty under section 611 of the Federal Aviation Act which is not discretionary with such Administrator shall identify the statutory provision which requires such act or creates such duty, shall describe with reasonable specificity the action taken or not taken by such Administrator which is alleged to constitute a failure to perform such act or duty, and shall state the full name, address, and telephone number of the person giving the notice.

(c) *Identification of Counsel.* The notice shall state the name, address, and telephone number of the legal counsel, if any, representing the person giving the notice.

PART 211—PRODUCT NOISE LABELING

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APPENDIX A TO PART 211—COMPLIANCE AUDIT TESTING REPORT

SOURCE: 44 FR 56127, Sept. 28, 1979, unless otherwise noted.

Subpart A—General Provisions

AUTHORITY: Sec. 8, Noise Control Act of 1972, (42 U.S.C. 4907), and other authority as specified.

§ 211.101 Applicability.

The provisions of subpart A apply to all products for which regulations are published under part 211 and manufactured after the effective date of this regulation, unless they are made inapplicable by product-specific regulations.

§ 211.102 Definitions.

(a) All terms that are not defined in this subpart will have the meaning given them in the Act.

(b) *Act* means the Noise Control Act of 1972 (Pub. L. 92-574, 86 Stat. 1234).

(c) *Administrator* means the Administrator of the Environmental Protection

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Agency or his authorized representative.

(d) *Agency* means the United States Environmental Protection Agency.

(e) *Acoustic descriptor* means the numeric, symbolic, or narrative information describing a product's acoustic properties as they are determined according to the test methodology that the Agency prescribes.

(f) *Export exemption* means an exemption from the prohibitions of section 10(a) (3) and (4) of the Act; this type of exemption is granted by statute under section 10(b)(2) of the Act for the purpose of exporting regulated products.

(g) *National security exemption* means an exemption from the prohibitions of section 10(a) (3) and (5) of the Act, which may be granted under section 10(b)(1) of the Act in cases involving national security.

(h) *Product* means any noise-producing or noise-reducing product for which regulations have been promulgated under part 211; the term includes "test product".

(i) *Regulations published under this part* means all subparts to part 211.

(j) *Testing exemption* means an exemption from the prohibitions of section 10(a) (1), (2), (3), and (5) of the Act, which may be granted under section 10(b)(1) of the Act for research, investigations, studies, demonstrations, or training, but not for national security.

(k) *Test product* means any product that must be tested according to regulations published under part 211.

§211.103 Number and gender.

In this part, words in the singular will be understood to include the plural, and words in the masculine gender will be understood to include the feminine, and vice versa, as the case may require.

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§211.104 Label content.

The following data and information must be on the label of all products for which regulations have been published under this part:

(a) The term "Noise Rating" if the product produces noise, or the term "Noise Reduction Rating" if the product reduces noise;

(b) The acoustic rating descriptor that is determined according to procedures specified in the regulations that will be published under this part;

(c) Comparative acoustic rating information, which EPA will specify in the regulations published under this part;

(d) A product manufacturer identification consisting of: (1) The Company name, and (2) The City and State of the principal office;

(e) A product model number or type identification;

(f) The phrase "Federal law prohibits removal of this label prior to purchase";

(g) The U.S. Environmental Protection Agency logo, as shown in Figure 1;

(h) The phrase "Label Required by U.S. EPA regulation 40 CFR part 211, subpart ____."



FIGURE 1

§211.105 Label format.

(a) Unless specified otherwise in other regulations published under this part, the format of the label must be as shown in Figure 2. The label must include all data and information required under §211.104.

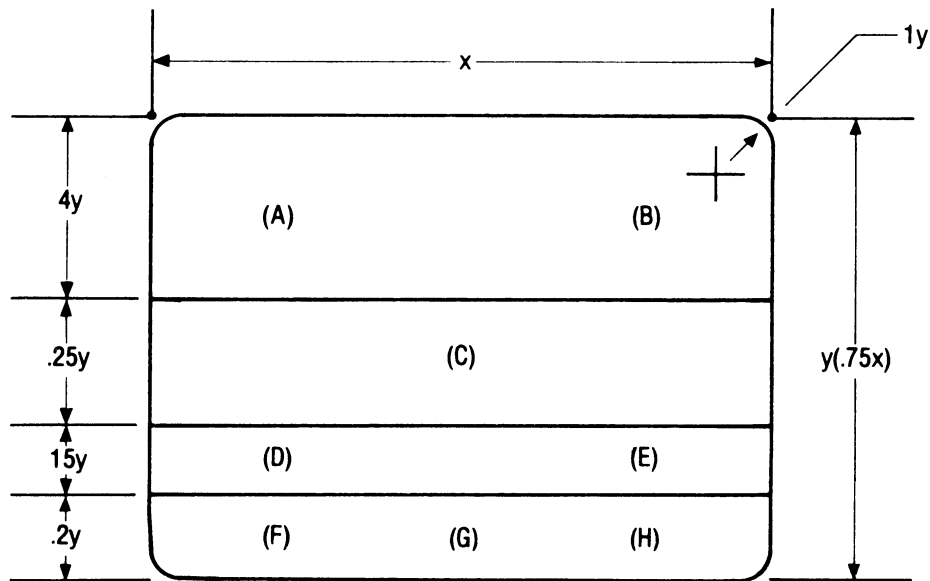


FIGURE - 2

(b) Unless EPA specifies otherwise in regulations published under this part, the required data and information specified in § 211.104 (a) through (h) must be located in the following areas of the prescribed label (see Figure 2 of this section):

- (1) Section 211.104 (a)—Area A.
- (2) Section 211.104 (b)—Area B.
- (3) Section 211.104 (c)—Area C.
- (4) Section 211.104 (d)—Area D.
- (5) Section 211.104 (e)—Area E.
- (6) Section 211.104 (f)—Area F.
- (7) Section 211.104 (g)—Area G.
- (8) Section 211.104 (h)—Area H.

§ 211.106 Graphical requirements.

(a) *Color.* Unless EPA requires otherwise, the product manufacturer or supplier must determine the colors used for the label background, borders, and all included letters, numerals, and figures. However, the colors on the label must contrast sufficiently with each other and with any information or ma-

terial surrounding the label so that the label and the information within it are clearly visible and legible.

(b) *Label Size.* The prescribed label must be sized as specified in regulations published under this part.

(c) *Character Style.* Except when specified otherwise in this part, all letters and numerals that appear on the prescribed label must be Helvetica Medium.

(d) *Character Size.* All letters and numerals that appear on the prescribed label must be sized as specified in regulations published under this part.

§ 211.107 Label type and location.

The prescribed label must be of the type and in the location specified in regulations published under this part.

§ 211.108 Sample label.

Examples of labels conforming to the requirements of §§ 211.104, 211.105, and 211.106 are presented in Figure 3.

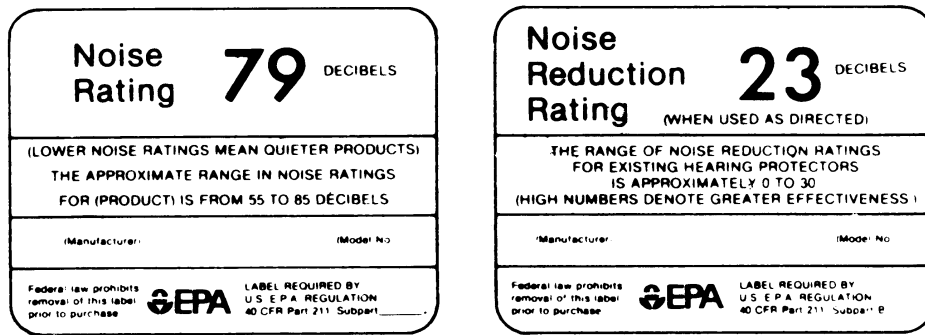


Figure - 3

§211.109 Inspection and monitoring.

(a) Any inspecting or monitoring activities that EPA conducts under this part with respect to the requirements set out in regulations published under this part, will be for the purpose of determining:

- (1) Whether test products are being selected and prepared for testing in accordance with the provisions of the regulations;
- (2) Whether test product testing is being conducted according to the provisions of those regulations; and
- (3) Whether products that are being produced and distributed into commerce comply with the provisions of those regulations.

(b) The Director of the Noise Enforcement Division may request that a manufacturer who is subject to this part admit an EPA Enforcement Officer during operating hours to any of the following:

- (1) Any facility or site where any product to be distributed into commerce is manufactured, assembled, or stored;
- (2) Any facility or site where the manufacturer performed or performs any tests conducted under this part or any procedures or activities connected with those tests;
- (3) Any facility or site where any test product is located.

(c)(1) Once an EPA Enforcement Officer has been admitted to a facility or site, that officer will not be authorized to do more than the following:

(i) Inspect and monitor the manufacture and assembly, selection, storage, preconditioning, noise testing, and maintenance of test products, and to verify the correlation or calibration of test equipment;

(ii) Inspect products before they are distributed in commerce;

(iii) Inspect and make copies of any records, reports, documents, or information that the manufacturer must maintain or provide to the Administrator under the Act or under any provision of this part;

(iv) Inspect and photograph any part or aspect of any product and any components used in manufacturing the product that is reasonably related to the purpose of this entry; and

(v) Obtain from those in charge of the facility or site any reasonable assistance that he may request to enable him to carry out any function listed in this section.

(2) The provisions of this section apply whether the facility or site is owned or controlled by the manufacturer, or by someone who acts for the manufacturer.

(d) For the purposes of this section:

(1) An "EPA Enforcement Officer" is an employee of the EPA Office of Enforcement. When he arrives at a facility or site, he must display the credentials that identify him as an employee of the EPA and a letter signed by the Director of the Noise Enforcement Division designating him to make the inspection.

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(2) Where test product storage areas or facilities are concerned, "operating hours" means all times during which personnel, other than custodial personnel, are at work in the vicinity of the area or facility and have access to it.

(3) Where other facilities or areas are concerned, "operating hours" means all times during which products are being manufactured or assembled; or all times during which products are being tested or maintained; or records are being compiled; or when any other procedure or activity related to labeling, selective enforcement auditing, or product manufacture or assembly being carried out.

(4) "Reasonable assistance" means providing timely and unobstructed access to test products or to products and records that are required by this part, and the means for copying those records or the opportunity to test the test products.

(e) The manufacturer must admit an EPA Enforcement Officer who presents a warrant authorizing entry to a facility or site. If the EPA officer does not have the warrant, he may enter a facility or site only if the manufacturer consents.

(1) It is not a violation of this regulation or the Act if anyone refuses to allow an officer without a warrant to enter the site.

(2) The Administrator or his designee may proceed *ex parte* (without the other party's knowledge) to obtain a warrant whether or not the manufacturer has refused entry to an EPA Enforcement Officer.

(Secs. 11 and 13, Pub. L. 92-574, 86 Stat. 1242, 1244 (42 U.S.C. 4910, 4912))

[44 FR 56127, Sept. 28, 1979, as amended at 47 FR 57716, Dec. 28, 1982]

§211.110 Exemptions.

§211.110-1 Testing exemption.

(a) A new product intended to be used solely for research, investigations, studies, demonstrations or training, and so labeled or marked on the outside of the container and on the produce itself, shall be exempt from the prohibitions of sections 10(a), (1), (2), (3), and (5) of the Act.

(b) No request for a testing exemption is required.

(c) For purposes of section 11(d) of the Act, any testing exemption shall be void ab initio with respect to each new product, originally intended for research, investigations, studies, demonstrations, or training, but distributed in commerce for other uses.

[47 FR 57716, Dec. 28, 1982]

§211.110-2 National security exemptions.

(a) A new product which is produced to conform with specifications developed by national security agency, and so labeled or marked on the outside of the container and on the product itself, shall be exempt from the prohibitions of sections 10(a), (1), (2), (3), and (5) of the Act.

(b) No request for a national security exemption is required.

(c) For purposes of section 11(d) of the Act, any national security exemption shall be void ab initio with respect to each new product, originally intended for a national security agency, but distributed in commerce for other uses.

[47 FR 57716, Dec. 28, 1982]

§211.110-3 Export exemptions.

(a) A new product intended solely for export, and which has satisfied the requirements of other applicable regulations of this part, will be exempt from the prohibitions of section 10(a) (3) and (4) of the Act.

(b) Requests for an export exemption are not required.

(c) For purposes of section 11(d) of the Noise Control Act, the Administrator may consider any export exemption under section 10(b)(2) void from the beginning if a new product, intended only for export, is distributed in commerce in the United States.

(Sec. 10(b)(2), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(b)(2)))

[44 FR 56127, Sept. 28, 1979, as amended at 47 FR 57716, Dec. 28, 1982]

§211.111 Testing by the Administrator.

(a)(1) To determine whether products conform to applicable regulations under this part, the Administrator may require that any product that is to be

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tested under applicable regulations in this part, or any other products that are regulated under this part, be submitted to him, at a place and time that he designates, to conduct tests on them in accordance with the test procedures described in the regulations.

(2) The Administrator may specify that he will conduct the testing at the facility where the manufacturer conducted required testing. The Administrator will conduct the tests with his own equipment.

(b)(1) If, from the tests conducted by the Administrator, or other relevant information, the Administrator determines that the test facility used by the manufacturer(s) does not meet the requirements of this part for conducting the test required by this part, he will notify the manufacturer(s) in writing of his determination and the reasons for it.

(2) After the Administrator has notified the manufacturer, EPA will not accept any data from the subject test facility for the purposes of this part, and the Administrator may issue an order to the manufacturer(s) to cease to distribute in commerce products that come from the product categories in question. However, any such order shall be issued only after an opportunity for a hearing. Notification of this opportunity may be included in a notification under paragraph (b)(1) of this section. A manufacturer may request that the Administrator grant a hearing. He must make this request no later than fifteen (15) days (or any other period the Administrator allows) after the Administrator has notified the manufacturer that he intends to issue an order to cease to distribute.

(3) A manufacturer may request in writing that the Administrator reconsider his determination in paragraph (b)(1) of this section, if he can provide data or information which indicates that changes have been made to the test facility, and that those changes have remedied the reason for disqualification.

(4) The Administrator will notify a manufacturer of his decision concerning requalifying the test facility within 10 days of the time the manufacturer requested reconsideration under paragraph (b)(3) of this section.

(c)(1) The Administrator will assume all reasonable costs associated with shipment of products to the place designated pursuant to paragraph (a) of this section, except with respect to:

(i) [Reserved]

(ii) Testing of a reasonable number of products for purposes of compliance audit testing under the Section titled Compliance Audit Testing of the product-specific Subpart, or if the manufacturer has failed to establish that there is a correlation between his test facility and the EPA test facility or the Administrator has reason to believe, and provides the manufacturer with a statement or reasons, that the products to be tested would fail to meet their verification level if tested at the EPA test facility, but would meet the level if tested at the manufacturer's test facility;

(iii) Any testing performed during a period when a notice issued under paragraph (b) of this section, is in effect; and

(iv) Any testing performed at place other than the manufacturer's facility as a result of the manufacturer's failure to permit the Administrator to conduct or monitor testing as required by this part.

(Secs. 11 and 13, Pub. L. 92-574, 86 Stat. 1243 (42 U.S.C. 4910, 4912))

[44 FR 56127, Sept. 28, 1979, as amended at 47 FR 57716, Dec. 28, 1982]

Subpart B—Hearing Protective Devices

AUTHORITY: Sec. 8, Pub. L. 92-574, 86 Stat. 1241 (42 U.S.C. 4907), and additional authority as specified.

SOURCE: 44 FR 56139, Sept. 28, 1979, unless otherwise noted.

§211.201 Applicability.

Unless this regulation states otherwise, the provisions of this subpart apply to all hearing protective devices manufactured after the effective date of this regulation. (See §211.203(m) for definition of "hearing protective device.")

§211.202 Effective date.

Manufacturers of hearing protectors must comply with the requirements set

forth in this part for all hearing protective devices manufactured on or after September 27, 1980.

§ 211.203 Definitions.

(a) As used in subpart B, all terms not defined here have the meaning given them in the Act or in subpart A of Part 211.

(b) *ANSI Z24.22-1957*. A measurement procedure published by the American National Standards Institute (ANSI) for obtaining hearing protector attenuation values at nine of the one-third octave band center frequencies by using pure tone stimuli presented to ten different test subjects under anechoic conditions.

(c) *ANSI S3.19-1974*. A revision of the ANSI Z24.22-1957 measurement procedure using one-third octave band stimuli presented under diffuse (reverberant) acoustic field conditions.

(d) *Carrying Case*. The container used to store reusable hearing protectors.

(e) *Category*. A group of hearing protectors which are identical in all aspects to the parameters listed in § 211.210-2(c).

(f) *Claim*. An assertion made by a manufacturer regarding the effectiveness of his product.

(g) *Custom-molded device*. A hearing protective device that is made to conform to a specific ear canal. This is usually accomplished by using a moldable compound to obtain an impression of the ear and ear canal. The compound is subsequently permanently hardened to retain this shape.

(h) *Dispenser*. The permanent (intended to be refilled) or disposable (discarded when empty) container designed to hold more than one complete set of hearing protector(s) for the express purpose of display to promote sale or display to promote use or both.

(i) *Disposable Device*. A hearing protective device that is intended to be discarded after one period of use.

(j) *Ear Insert Device*. A hearing protective device that is designed to be inserted into the ear canal, and to be held in place principally by virtue of its fit inside the ear canal.

(k) *Ear Muff Device*. A hearing protective device that consists of two acoustic enclosures which fit over the ears and which are held in place by a spring-

like headband to which the enclosures are attached.

(l) *Headband*. The component of hearing protective device which applies force to, and holds in place on the head, the component which is intended to acoustically seal the ear canal.

(m) *Hearing Protective Device*. Any device or material, capable of being worn on the head or in the ear canal, that is sold wholly or in part on the basis of its ability to reduce the level of sound entering the ear. This includes devices of which hearing protection may not be the primary function, but which are nonetheless sold partially as providing hearing protection to the user. This term is used interchangeably with the terms, "hearing protector" and "device."

(n) *Impulsive Noise*. An acoustic event characterized by very short rise time and duration.

(o) *Label*. That item, as described in this regulation, which is inscribed on, affixed to or appended to a product, its packaging, or both for the purpose of giving noise reduction effectiveness information appropriate to the product.

(p) *Manufacturer*. As stated in the Act "means any person engaged in the manufacturing or assembling of new products, or the importing of new products for resale, or who acts for, and is controlled by, any such person in connection with the distribution of such products."

(q) *Noise Reduction Rating (NRR)*. A single number noise reduction factor in decibels, determined by an empirically derived technique which takes into account performance variation of protectors in noise reducing effectiveness due to differing noise spectra, fit variability and the mean attenuation of test stimuli at the one-third octave band test frequencies.

(r) *Octave Band Attenuation*. The amount of sound reduction determined according to the measurement procedure of § 211.206 for one-third octave bands of noise.

(s) *Over-the-Head Position*. The mode of use of a device with a headband, in which the headband is worn such that it passes over the user's head. This is contrast to the behind-the-head and under-the-chin positions.

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(t) *Package.* The container in which a hearing protective device is presented for purchase or use. The package in some cases may be the same as the carrying case.

(u) *Primary Panel.* The surface that is considered to be the front surface or that surface which is intended for initial viewing at the point of ultimate sale or the point of distribution for use.

(v) *Spectral uncertainty.* Possible variation in exposure to the noise spectra in the workplace. (To avoid the under-protection that would result from these variations relative to the assumed “Pink Noise” used to determine the NRR, an extra three decibel reduction is included when computing the NRR.)

(w) *Tag.* Stiff paper, metal or other hard material that is tied or otherwise affixed to the packaging of a protector.

(x) *Test Facility.* For this subpart, a laboratory that has been set up and calibrated to conduct ANSI Std S3.19–1974 tests on hearing protective devices. It must meet the applicable requirements of these regulations.

(y) *Test Hearing Protector.* A hearing protector that has been selected for testing to verify the value to be put on the label, or which has been designated for testing to determine compliance of the protector with the labeled value.

(z) *Test Request.* A request submitted to the manufacturer by the Administrator that will specify the hearing protector category, and test sample size to be tested according to §211.212–1, and other information regarding the audit.

(aa) *Random Incident Field.* A sound field in which the angle of arrival of sound at a given point in space is random in time.

(bb) *Real-Ear Protection at Threshold.* The mean value in decibels of the occluded threshold of audibility (hearing protector in place) minus the open threshold of audibility (ears open and uncovered) for all listeners on all trials under otherwise identical test conditions.

(cc) *Reverberation Time.* The time that would be required for the mean-square sound pressure level, originally in a steady state, to fall 60 dB after the source is stopped.

§211.204 Hearing protector labeling requirements.

All provisions of subpart A apply to this subpart except as otherwise noted.

§211.204–1 Information content of primary label.

The information to appear on the primary label must be according to §211.104 of subpart A except as stated here and shown in Figure 1 of §211.204–2:

(a) Area A must state “Noise Reduction Rating.”

(b)(1) Area B must state the value of the Noise Reduction Rating (NRR) in decibels for that model hearing protector. The value stated on the label must be no greater than the NRR value determined by using the computation method of §211.207 of this subpart.

(2) For devices with headbands that are intended for use with the headband in different positions, the worst case NRR must be specified. The top of Area B must state the position(s) associated with that NRR. The other positions and the respective NRRs must be included with the supporting information specified in §211.204–4.

(c) Area C must contain the statement “The range of Noise Reduction Ratings for existing hearing protectors is approximately 0 to 30 (higher numbers denote greater effectiveness).”

(d) At the bottom of Area A–B, there must be the phrase “(When used as directed).”

[44 FR 56127, Sept. 28, 1979, as amended at 45 FR 8275, Feb. 6, 1980]

§211.204–2 Primary label size, print and color.

The primary label characteristics are the same as those specified in §§211.105 and 211.106 of subpart A except as stated here.

(a) The label must be no smaller than 3.8 centimeters by 5.0 centimeters (cm) (approximately 1.5 inches by 2.0 inches).

(b) The minimum type face size for each area shall be as follows, based upon a scale of 72 points = 1 inch:

(1) Area A—2.8 millimeters (mm) or 8 point.

(2) Area B—7.6 mm or 22 point for the Rating;—1.7 mm or 5 point for “Decibels”.

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- (3) Area A-B—1.5 mm or 4 point.
- (4) Area C—1.5 mm or 4 point.
- (5) Area D—0.7 mm or 2 point.
- (6) Area E—0.7 mm or 2 point.
- (7) Area F—0.7 mm or 2 point.
- (8) Area H—0.7 mm or 2 point.

These type face sizes apply to the 3.8 cm × 5.0 cm label; type face sizes for larger labels must be in the same approximate proportion to the label as those specified for the 3.8 cm × 5.0 cm label.

(c) The use of upper and lower case letters and the general appearance of the label must be similar to the example in Figure (1).

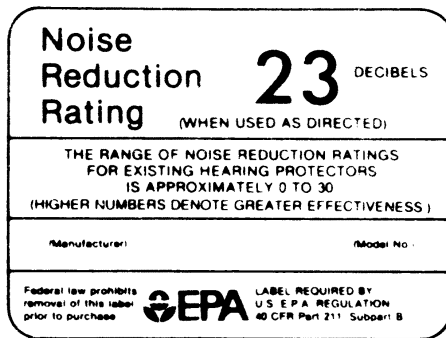


Figure - 1

(d) The color of the label must be as specified in subpart A.

[44 FR 56127, Sept. 28, 1979, as amended at 45 FR 8275, Feb. 6, 1980]

§211.204-3 Label location and type.

(a) The manufacturer labeling the product for ultimate sale or use selects the type of label and must locate it as follows:

- (1) Affixed to the device or its carrying case; and
- (2) Affixed to primary panel of the product packaging if the label complying with §211.204-3(a)(1) is not visible at the point of ultimate purchase or the point of distribution to users.

(b) Labeling with a minimum sized label will occur as follows:

(1) If the protector is individually packaged and so displayed at the point of ultimate purchase or distribution to the prospective user, the package must be labeled as follows:

(i) If the primary panel of the package has dimensions greater than 3.8 × 5.0 cm (approximately 1½ × 2 in) the label must be presented on the primary panel.

(ii) If the primary panel of the package is equal to or smaller than 3.8 × 5.0 centimeters, a label at least 3.8 × 5.0 centimeters must be affixed to the package by means of a tag.

(2) If the protector is displayed at the point of ultimate purchase or distribution to prospective users in a permanent or disposable bulk container or dispenser, even if the protector is individually packaged within the dispenser and labeled as above, the container or dispenser itself must be labeled. The label must be readily visible to the ultimate purchaser or prospective user.

§211.204-4 Supporting information.

The following minimum supporting information must accompany the device in a manner that insures its availability to the prospective user. In the case of bulk packaging and dispensing, such supporting information must be affixed to the bulk container or dispenser in the same manner as the label, and in a readily visible location.

(a) The mean attenuation and standard deviation values obtained for each test frequency according to §211.206, and the NRR calculated from those values. For “muff” type protectors with various use positions, the positions providing higher NRR values shall be identified, and their associated NRR values listed in bold type.

(b) The following statement, example and cautionary note: “The level of noise entering a person’s ear, when hearing protector is worn as directed, is closely approximated by the difference between the A-weighted environmental noise level and the NRR.

Example

- 1. The environmental noise level as measured at the ear is 92 dBA.
- 2. The NRR is (value on label) decibels (dB).
- 3. The level of noise entering the ear is approximately equal to [92 dB(A)—NRR] dB(A).

CAUTION: For noise environments dominated by frequencies below 500 Hz the C-weighted environmental noise level should be used.”

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(c) The month and year of production, which may be in the form of a serial number or a code in those instances where the records specified in § 211.209(a)(1)(iv) are maintained;

(d) The following statement: "Improper fit of this device will reduce its effectiveness in attenuating noise. Consult the enclosed instructions for proper fit";

(e) Instructions as to the proper insertion or placement of the device; and

(f) The following statement: "Although hearing protectors can be recommended for protection against the harmful effects of impulsive noise, the Noise Reduction Rating (NRR) is based on the attenuation of *continuous* noise and may not be an accurate indicator of the protection attainable against *impulsive* noise such as gunfire."

[44 FR 56127, Sept. 28, 1979, as amended at 45 FR 8275, Feb. 6, 1980]

§ 211.205 Special claims.

(a) Any manufacturer wishing to make claims regarding the acoustic effectiveness of a device, other than the Noise Reduction Rating, must be prepared to demonstrate the validity of such claims.

(b) [Reserved]

[44 FR 56139, Sept. 28, 1979, as amended at 47 FR 57716, Dec. 28, 1982]

§ 211.206 Methods for measurement of sound attenuation.

§ 211.206-1 Real ear method.

(a) The value of sound attenuation to be used in the calculation of the Noise Reduction Rating must be determined according to the "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs." This standard is approved as the American National Standards Institute Standard (ANSI STD) S3.19-1974. The provisions of this standard, with the modifications indicated below, are included by reference in this section. Copies of this standard may be obtained from: American National Standards Institute, Sales Department, 1430 Broadway, New York, New York 10018.

(b) For the purpose of this subpart only, sections 1, 2, 3 and appendix A of the standard, as modified below, shall

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be applicable. These sections describe the "Real Ear Method." Other portions of the standard are not applicable in this section.

(1) The sound field characteristics described in paragraph 3.1.1.3 are "required."

(2) Sections 3.3.2 and 3.3.3 shall be accomplished in this order during the same testing session. Any breaks in testing should not allow the subject to engage in any activity that may cause a Temporary Threshold Shift.

(3) Section 3.3.3.1(1) shall not apply. Only "Experimenter fit" described in Section 3.3.3.1(2) is permitted.

(4) Section 3.3.3.3 applies to all devices except custom-molded devices. When testing custom-molded devices, each test subject must receive his own device molded to fit his ear canal.

[44 FR 56139, Sept. 28, 1979, as amended at 45 FR 8275, Feb. 6, 1980]

§ 211.206-2 Alternative test data.

(a) In lieu of testing according to § 211.206-1, manufacturers may use the latest available test data obtained according to ANSI STD Z24.22-1957 or ANSI STD S3.19-1974 to determine the mean attenuation and standard deviation for each test frequency and the NRR calculated from those values. Manufacturers whose data is based on the ANSI STD Z24.22-1957 measurement procedure must state in the supporting information required by § 211.204-4 that the mean attenuation and standard deviation values used to calculate the NRR are based on ANSI STD Z24.22-1957.

(b) Manufacturers who initially use available data based on ANSI STD Z24.22-1957 must retest within one year of the effective date of this regulation (by September 27, 1981) the affected categories of hearing protectors in accordance with § 211.206-1 of the regulation, and must relabel those categories as necessary.

(c) Manufacturers who use available data based on ANSI STD S3.19-1974 are not required to retest the affected categories of hearing protectors.

(d) If a manufacturer has both ANSI STD S3.19-1974 test data and ANSI STD Z24.22-1957 test data on a hearing protector category, that manufacturer

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must use the data obtained according to ANSI STD S3.19-1974.

[45 FR 8275, Feb. 6, 1980]

§§ 211.206-3—211.206-10 Alternative test methods. [Reserved]

§ 211.207 Computation of the noise reduction rating (NRR).

Calculate the NRR for hearing protective devices by substituting the average attenuation values and standard deviations for the pertinent protector category for the sample data used in

steps #6 and #7 in Figure 2. The values of $-.2, 0, 0, 0, -.2, -.8, -3.0$ in Step 2 and $-16.1, -8.6, -3.2, 0, +1.2, +1.0, -1.1$ in Step 4 of Figure 2 represent the standard "C"- and "A"-weighting relative response corrections applied to any sound levels at the indicated octave band center frequencies. (NOTE: The manufacturer may label the protector at values lower than indicated by the test results and this computation procedure, e.g. lower NRR from lower attenuation values. (Ref. §211.211(b).))

FIGURE 2—COMPUTATION OF THE NOISE REDUCTION RATING

Octave band center frequency (Hz)	125	250	500	1000	2000	3000	4000	6000	8000
1 Assumed Pink noise (dB)	100	100	100	100	100	100	100	100	100
2 "C" weighting corrections (dB)	-.2	0	0	0	-.2	-.8	-.8	-.8	-3.0
3 Unprotected ear "C"-weighted level (dB)	99.8	100	100	100	99.8	99.2	99.2	99.2	97.0
(The seven logarithmically added "C"-weighted sound pressure levels of Step #3 = 107.9 dS)									
4 "A"-weighting corrections (dB)	-16.1	-8.6	-3.2	0	+1.2	+1.0	-1.1
5 Unprotected ear "A"-weighted level (step #1-step #4) (dB)	83.9	91.4	96.8	100	101.2	101	98.9
6 Average attenuation in dB at frequency	21	22	23	29	41	$(43 + 47)/2 = 45$	$(41 + 36)/2 = 38.5$
7 Standard deviation in dB at frequency	3.7	3.3	3.8	4.7	3.3	$(3.3 + 3.4) = 6.7$	$(6.1 + 6.5) = 12.6$
	× 2	× 2	× 2	× 2	× 2
	7.4	6.6	7.6	9.4	6.6
8 Step #5-(step #6-step #7) develops the protected ear "A" weighted levels (dB)	70.3	76.0	81.4	80.4	66.8	62.7	73.0
(The seven logarithmically added "A"-weighted sound pressure levels of Step #8 using this sample data = 85.1 dB)									
9 NRR = Step #3—Step #8—3 dB*; = 107.9 dB—85.1 dB—3 dB*; = 19.8 dB (or 20) (Round values ending in .5 to next lower whole number).									
*Spectral uncertainty (as defined in § 211.203).									

The value for #3 is constant. Use Logarithmic mathematics to determine the combined value of protected ear levels (Step #8) which is used in Step #9 to exactly derive the NRR; or use the following table as a substitute for logarithmic mathematics to determine the value of Step #8 and thus very closely approximate the NRR.

Difference between any two sound pressure levels being combined (dB)	Add this level to the higher of the two levels (dB)
0 to less than 1.5	3
1.5 to less than 4.5	2
4.5 to 9	1

Difference between any two sound pressure levels being combined (dB)	Add this level to the higher of the two levels (dB)
Greater than 9	0

§ 211.208 Export provisions.

(a) The outside of each package or container containing a hearing protective device intended solely for export must be so labeled or marked. This will include all packages or containers that are used for shipping, transporting, or dispersing the hearing protective device along with any individual packaging.

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(b) In addition, the manufacturer of a hearing protective device intended solely for export is subject to the export exemption requirements of §211.110-3 of subpart A.

(Sec. 10(b)(2), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(b)(2)))

§211.210 Requirements.

§211.210-1 General requirements.

(a) Every hearing protector manufactured for distribution in commerce in the United States, and which is subject to this regulation:

(1) Must be labeled at the point of ultimate purchase or distribution to the prospective user according to the requirements of §211.204 of this subpart; and

(2) Must meet or exceed the mean attenuation values determined by the procedure in §211.206 and explained in §211.211(b).

(b) Manufacturers who distribute protectors in commerce to another manufacturer for packaging for ultimate purchase or use must provide to that manufacturer the mean attenuation values and standard deviations at each of the one-third octave band center frequencies as determined by the test procedure in §211.206. He must also provide the Noise Reduction Rating calculated according to §211.207.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

[44 FR 56139, Sept. 28, 1979, as amended at 45 FR 8275, Feb. 6, 1980; 47 FR 57716, Dec. 28, 1982]

§211.210-2 Labeling requirements.

(a)(1) A manufacturer responsible for labeling must satisfy the requirements of this subpart for a category of hearing protectors before distributing that category of hearing protectors in commerce.

(2) A manufacturer may apply to the Administrator for an extension of time to comply with the labeling requirements for a category of protectors before he distributes any protectors in commerce. The Administrator may grant the manufacturer an extension of up to 20 days from the date of distribution. The manufacturer must provide reasonable assurance that the protec-

tors equal or exceed their mean attenuation values, and that labeling requirements will be satisfied before the extension expires. Requests for extension should go to the Administrator, U.S. Environment Protection Agency, Washington, DC 20460. The Administrator must respond to a request within 2 business days. Responses may be either written or oral.

(3) A manufacturer, receiving hearing protectors through the chain of distribution that were labeled by a previous manufacturer, may use that previous manufacturer's data when labeling the protectors for ultimate sale or use, but is responsible for the accuracy of the information on the label. The manufacturer may elect to retest the protectors.

(b) Labeling requirements regarding each hearing protector category in a manufacturer's product line consist of:

(1) Testing hearing protectors according to §211.206 and the hearing protectors must have been assembled by the manufacturer's normal production process; and it must have been intended for distribution in commerce.

(c) Each category of hearing protectors is determined by the combination of at least the following parameters. Manufacturers may use additional parameters as needed to create and identify additional categories of protectors.

(1) *Ear muffs.* (i) Head band tension (spring constant);

(ii) Ear cup volume or shape;

(iii) Mounting of ear cup on head band;

(iv) Ear cushion;

(v) Material composition.

(2) *Ear inserts.* (i) Shape;

(ii) Material composition.

(3) *Ear caps.* (i) Head band tension (spring constant);

(ii) Mounting of plug on head band;

(iii) Shape of plug;

(iv) Material composition.

If an ear insert or ear cap is manufactured in more than one size (small, medium, large, etc.) each size does not constitute a separate category and is not required to be separately label verified. However, each size must be used when conducting the required test

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to determine the labeled values for the specified category.

[44 FR 56139, Sept. 28, 1979, as amended at 47 FR 57717, Dec. 28, 1982]

§ 211.211 Compliance with labeling requirement.

(a) All hearing protective devices manufactured after the effective date of this regulation, and meeting the applicability requirements of § 211.201, must be labeled according to this subpart, and must comply with the Labeled Values of mean attenuation.

(b) A manufacturer must take into account both product variability and test-to-test variability when labeling his devices in order to meet the requirements of paragraph (a) of this section. A specific category is considered when the attenuation value at the tested one-third octave band is equal to or greater than the Labeled Value, or mean attenuation value, stated in the supporting information required by § 211.204-4, for that tested frequency. The attenuation value must be determined according to the test procedures of § 211.206. The Noise Reduction Rating for the label must be calculated using the Labeled Values of mean attenuation that will be included in the supporting information required by § 211.204-4.

[47 FR 57717, Dec. 28, 1982]

§ 211.212 Compliance audit testing.

§ 211.212-1 Test request.

(a) The Administrator will request all testing under this section by means of a test request addressed to the manufacturer.

(b) The test request will be signed by the Assistant Administrator for Enforcement or his designee. The test request will be delivered by an EPA Enforcement Officer or sent by certified mail to the plant manager or other responsible official as designated by the manufacturer.

(c) In the test request, the Administrator must specify the following:

(1) The hearing protector category selected for testing;

(2) The manufacturer's plant or storage facility from which the protectors must be selected;

(3) The selection procedure the manufacturer will use to select test protectors;

(4) The test facility where the manufacturer is required to have the protectors tested;

(5) The number of protectors to be forwarded to the designated test facility and the number of those protectors which must be tested by the facility.

(6) The time period allowed for the manufacturer to initiate testing; and

(7) Any other information that will be necessary to conduct testing under this section.

(d) The test request may provide for situations in which the selected category is unavailable for testing. It may include an alternative category to be selected for testing in the event that protectors of the first specified category are not available because the protectors are not being manufactured at the specified plant, at the specified time, and are not being stored at the specified plant or storage facility.

(e)(1) Any testing conducted by the manufacturer under a test request must commence within the period specified within the test request. The Administrator may extend the time period on request by the manufacturer, if a test facility is not available to conduct the testing.

(2) The manufacturer must complete the required testing within one week following commencement of the testing.

(3) The manufacturer will be allowed 1 calendar week to send test hearing protectors from the assembly plant to the testing facility. The Administrator may approve more time based upon a request by the manufacturer. The request must be accompanied by a satisfactory justification.

(f) Failure to comply with any of the requirements of this section will not be considered a violation of these regulations if conditions and circumstances outside the control of the manufacturer render it impossible for him to comply. These conditions and circumstances include, but are not limited to, the temporary unavailability of equipment and personnel needed to

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conduct the required tests. The manufacturer bears the burden of establishing the presence of the conditions and circumstances.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

[44 FR 56139, Sept. 23, 1979, as amended at 45 FR 8275, Feb. 6, 1980; 47 FR 57717, Dec. 28, 1982]

§211.212-2 Test hearing protector selection.

(a) The test request will specify the number of test protectors which will be selected for testing from the number of protectors delivered to the test facility in accordance with §211.212-1(c)(5). The remainder may be used as replacement protectors if replacement is necessary. The test request will also specify that the protectors be selected from the next batch scheduled for production after receipt of the test request.

(b) If random selection is specified, it must be achieved by sequentially numbering all the protectors in the group and then using a table of random numbers to select the test hearing protectors. The manufacturer may use an alternative random selection plan when it is approved by the Administrator.

(c) Each test protector of the category selected for testing must have been assembled, by the manufacturer, for distribution in commerce using the manufacturer's normal production process.

(d) At their discretion, EPA Enforcement Officers, rather than the manufacturer, may select the protectors designated in the test request.

(e) The manufacturer must keep on hand the test protectors designated for testing until such time as the category is determined to be in compliance. Hearing protectors actually tested and found to be in compliance with these regulations may be distributed in commerce.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

[44 FR 56139, Sept. 23, 1979, as amended at 45 FR 8275, Feb. 6, 1980]

§211.212-3 Test hearing protector preparation.

The manufacturer must select the test hearing protector according to

§211.212-2 before the official test, and must comply with the test protector preparation requirements described in this subpart:

(a) A test hearing protector selected according to §211.212-2 must not be tested, modified, or adjusted in any manner before the official test unless the adjustments, modifications and/or tests are part of the manufacturer's prescribed manufacturing and inspection procedures.

(b) Quality controls, testing, assembly or selection procedures must not be, used on the completed protector or any portion of the protector, including parts, that will not normally be used during the production and assembly of all other protectors of that category to be distributed in commerce.

[47 FR 57717, Dec. 28, 1982]

§211.212-4 Testing procedures.

(a) The manufacturer must conduct one valid test according to the test procedures specified in §211.206 for each hearing protector selected for testing under §211.212-2.

(b) The manufacturer must not repair or adjust the test hearing protectors once compliance testing has been initiated. In the event a hearing protector is unable to complete the test, the manufacturer may replace the protector. Any replacement protector will be of the same category as the protector being replaced. It will be selected from the remaining designated test protectors and will be subject to all the provisions of these regulations. Any replacement and the reason for replacement must be reported in the compliance audit test report.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§211.212-5 Reporting of test results.

(a)(1) The manufacturer must submit to the Administrator a copy of the Compliance Audit Test report for all testing conducted under §211.212. It must be submitted within 5 days after completion of testing. A suggested compliance audit test report form is included as appendix B.

(2) The manufacturer must provide the following test information:

- (i) Category identification;

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(ii) Production date, and model of hearing protector;

(iii) The name and location of the test facility used;

(iv) The completed data sheet in the form specified for all tests including, for each invalid test, the reason for invalidation; and

(v) The reason for the replacement where a replacement protector was necessary.

(3) The manufacturer must provide the following statement and endorsement:

This report is submitted under section 8 and section 13 of the Noise Control Act of 1972. All testing, for which data are reported here, was conducted in strict conformance with applicable regulations under 40 CFR Part 211 *et seq.* All the data reported are true and accurate representations of this testing. All other information reported here is, to the best of (company name) and (test laboratory name) knowledge, true and accurate. I am aware of the penalties associated with violation of the Noise Control Act of 1972 and the regulations published under it. (authorized representative)

If the testing is conducted by an outside laboratory the manufacturer must require an authorized representative of the laboratory to cosign both the statement and the endorsement.

(b) In the case where an EPA Enforcement Officer is present during testing required by this subpart, the written reports required in paragraph (a) of this section may be given directly to the Enforcement Officer.

(c) The reporting requirements of this regulation will no longer be effective after five (5) years from the date of publication; however, the requirements will remain in effect if the Administrator is taking appropriate steps to repromulgate or modify the reporting requirements at that time.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

§211.212-6 Determination of compliance.

(a) A category will be in compliance with these requirements if the results of the test conducted under the test request show that:

(1) The mean attenuation value, at each one-third octave band center frequency as determined from the Compli-

ance Audit Test values plus 3 dB(A), is equal to or greater than the mean attenuation value at the same one-third octave band as stated in the Supporting Information required by §211.204-4; and

(2) The Noise Reduction Rating, when calculated from the mean attenuation values determined by Compliance Audit Testing, equals or exceeds the Noise Reduction Rating as stated on the label required by §211.204.

(b) If a category is not in compliance, as determined in paragraph (a) of this section, the manufacturer must satisfy the continued testing requirements of §211.212-7, and the relabeling requirements of §211.212-8 before further distributing hearing protectors of that category in commerce.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

[44 FR 56139, Sept. 28, 1979, as amended at 47 FR 57717, Dec. 28, 1982]

§211.212-7 Continued compliance testing.

If a category is not in compliance as determined under §211.212-6, the manufacturer must satisfy the requirements of paragraph (a) or (b) of this section.

(a) The manufacturer must continue to conduct additional tests until the mean attenuation values from the last test at each octave band equal or exceed the lowest attenuation values obtained from all previous compliance tests.

(b) Upon approval by the Administrator, the manufacturer may relabel at a lower level in compliance with §211.212-8 in lieu of testing under paragraph (a) of this section. The manufacturer must obtain approval by showing that the relabeled values adequately take into account results achieved from the Compliance Audit Testing and product variability. The Administrator is to exercise his discretion in light of factors including the prior compliance record of the manufacturer, the adequacy of the proposed new labeling value, the amount of deviation of test results from the labeled values, and any other relevant information.

(c) When the manufacturer can show that the non-compliance under §211.212-6 was caused by a quality control failure and that the failure has

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been remedied, he may, with the Administrator's approval, conduct an additional test and relabel using the mean attenuation values no higher than those obtained in that test.

(d) The manufacturer may request a hearing on the issue of whether the compliance audit testing was conducted properly and whether the criteria for non-compliance in §211.212-6 have been met; and the appropriateness or scope of a continued testing order. In the event that a hearing is requested, the hearing shall begin no later than 15 days after the date on which the Administrator received the hearing request. Neither the request for a hearing, nor the fact that a hearing is in progress, shall affect the responsibility of the manufacturer to commence and continue testing required by the Administrator pursuant to paragraph (a) of this section.

(Sec. 13, Pub. L. 92-574, 86 Stat. 1244 (42 U.S.C. 4912))

[44 FR 56139, Sept. 28, 1979, as amended at 45 FR 8275, Feb. 6, 1980]

§211.212-8 Relabeling requirements.

(a) Any manufacturer who is found to not conform with §211.212-6, and who has met the requirement of §211.212-7, must relabel all protectors of the specified category already in his possession according to §211.211 before distributing them in commerce. The manufacturer shall relabel at values no greater than any mean attenuation values received from Compliance Audit Testing. Any manufacturer who proceeds with §211.212-7(a) or (b) must relabel his product line with the lowest mean attenuation value at each octave band received from testing; or he may take into account product variability under §211.211(b) and label with a lower mean attenuation value than the worst case values obtained from Compliance Audit Testing.

(b) [Reserved]

(Sec. 10(a)(3), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(a)(3)))

§211.213 Remedial orders for violations of these regulations.

(a) The Administrator may issue an order under section 11(d)(1) of the Act

when any person is in violation of these regulations.

(b) A remedial order will be issued only after the violator has been notified of the violation and given an opportunity for a hearing according to section 554 of title 5 of the United States Code.

(c) All costs associated with a remedial order shall be borne by the violator.

(Sec. 11(d) Pub. L. 92-574, 86 Stat. 1243 (42 U.S.C. 4910(d)))

§211.214 Removal of label.

Section 10(a)(4) of the Act prohibits any person from removing, prior to sale, any label required by this subpart, by either physical removal or defacing or any other physical act making the label and its contents not accessible to the ultimate purchaser prior to sale.

(Sec. 10(a)(4), Pub. L. 92-574, 86 Stat. 1242 (42 U.S.C. 4909(a)(4)))

APPENDIX A TO PART 211—COMPLIANCE AUDIT TESTING REPORT

Data Sheet

Company name: _____
Address: _____
Test laboratory: _____
Address: _____
Model number of hearing protector: _____
Category designation: _____
Production date: _____

Test Results—Frequency, Mean Attenuation, and Standard Deviation

125 _____
250 _____
500 _____
1000 _____
2000 _____
3150 _____
4000 _____
6300 _____
8000 _____

Noise Reduction Rating: _____

If replacement hearing protector was necessary to conduct test, reason for replacement:

This report is submitted under sections 8 and 13 of the Noise Control Act of 1972. All testing, for which data are reported here, was conducted in strict conformance with applicable regulations under 40 CFR Part 211, *et seq.* All the data reported here are true and

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accurate representations of this testing. All other information reported here is, to the best of (company name) and (test laboratory name) knowledge, true and accurate. I am aware of the penalties associated with violation of the Noise Control Act of 1972 and the regulations published under it.

(Authorized representative of company)

(Authorized representative of test laboratory)

[44 FR 56139, Sept. 28, 1979. Redesignated at 47 FR 57717, Dec. 28, 1982]