Product Noise Labeling of Hearing Protection Devices (Proposed Rule for Reporting of Test Data Reports)

Supporting Statement Part A

1. Identification of the Information Collection

a. Title: Product Noise Labeling of Hearing Protection Devices, EPA ICR No. 2341.01, OMB Control Number 2060-NEW

b. Short Characterization:

The EPA promulgated the regulation at 40 CFR Part 211, Subpart B, in September 1979 for the labeling of hearing protection devices (HPD). The said regulation requires all manufacturers of HPDs, that are entered into commerce in the United States, to provide the purchaser and ultimate user with information regarding the products effectiveness in reducing the level of noise (unwanted sound) entering a user's ears. The regulation requires that such information be presented on a label(s) that is readily visible at the point of purchase or distribution to users.

The regulation requires manufacturers to test each product according to the American National Standards Institute (ANSI) test methodologies and present the resultant numeric effectiveness rating (i.e., Noise Reduction Rating (NRR)) on the EPA mandated label. The NRR is a rating scheme that quantitatively rate the effectiveness (i.e., the sound attenuation or sound reduction) offered by a hearing protection device when used as instructed by its manufacturer. Presently, manufacturers are required to test their product for the resultant NRR once prior to entry into commerce and never test the product again, unless there are substantial changes in the product design or material. EPA recognizes that "one-time" testing is not suitable for an industry that is now comprised of HPDs that were not envisioned at the time the rule was promulgated. Many manufacturers have single or multiple HPD product lines with various performance functions, designs, and diverse testing protocols. The plethora of products in today's marketplace has warranted the need for recurrent testing to ensure the continuing validity of the effectiveness rating (i.e., NRR) that manufacturers place on their products and to provide a comparison of effectiveness ratings of a product over a period of time. Therefore, EPA is proposing that manufacturers conduct recurrent testing of their products once, every five (5) years, after the initial transition test.

In order to establish reliable baseline performance information for each device against which future performance can be compared, the EPA is proposing that manufacturers provide the Agency with their test information following each required product test. The 1979 regulation required manufacturers to establish and retain adequately organized and indexed records of the test information that provide the basis for the claimed Noise Reduction Ratings (NRR) that is placed on the mandated label. The regulation also required manufacturers to submit hearing protector test data reports for the attendant NRR to the EPA. However, under the agency's "sunset" policy for

reporting requirements in regulations, the reporting requirements expired five (5) years from the date of promulgation. EPA is again proposing to reinstitute the submittal of test data reports following each required product test, which include measurement information, test results, and calculated lesser and greater NRRs obtained from the testing laboratory for each product or products category to the Agency. Manufacturers will continue to retain such records until their next testing period, which is every 5 years or when a manufacturer elects to alter the product design or material. If such alterations are made to a product prior to the 5 year recurrent testing period, the manufacturer will be required to submit the new test data report to the EPA.

The manufacturer will be required to submit their test data report that is obtained from the testing laboratory for each product or product category, within ten (10) business days of completion of the required test, in electronic format or via postage mail to the EPA. These test data reports will be maintained by the EPA in the docket for this regulation at EPA-HQ-OAR-2003-0024, as well as in a tracking database.

2. Need for and use of the Collection

a. Need/Authority for the Collection

The Noise Control Act (NCA), Section 13, "*Records, Reports and Information*," states that manufacturers of products which emits noise capable of adversely affecting the public health or welfare; or which is sold wholly or in part on the basis of its effectiveness in reducing noise shall establish and maintain such records, make such reports, provide such information, and make such tests, as the Administrator may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with the Act.

b. Practical Utility/Uses of the Data

The recordkeeping and reporting requirements of this regulation will allow the EPA to use test data reports from manufacturers to establish a reliable baseline performance of each product in order to compare such information against future performance test results. The EPA believes that the collection of test data will establish quality assurance of the product design, product testing process, and the resultant Noise Reduction Rating (NRR) that is required for each HPD. In addition, the collection of test data reports will establish a reliable and collective resources database of HPD manufacturers and categories of products and will allow the EPA to use such information to assess the industry's operations, with respect to the establishment of new enterprises and products.

3. Non duplication, Consultations, and Other Collection Criteria

a. Non duplication

Currently, HPD manufacturers are not required to submit test data results to the EPA, as that requirement was suspended. However, the manufacturer is required to maintain and retain test results pertaining to the attendant NRR for each of his products.

The Agency conducted interviews with several HPD manufacturers to discuss recordkeeping practices and associated costs to report data to the EPA. While these manufacturers noted that there are nominal administrative costs to retain their records, the cost to submit such records to the EPA is insignificant particularly if such reports can be submitted via electronic mail. In addition to interviews with HPD manufacturers, the EPA researched other channels such as trade associations and various publications for the availability of test data information and discovered that the manufacturer is the sole source of such information. There are some manufacturers that voluntarily provide the National Institute for Occupational Safety and Health (NIOSH) with product test information to be included in the NIOSH Compendium, but this database is not inclusive. Thus, the NIOSH database is not a duplication of this collection effort.

The EPA believes that requesting HPD test data reports directly from the HPD manufacturer versus any other avenues will result in authentic test data reporting and institute a reliable reporting process, as there are no existing comprehensive databases or collection procedures in place. Therefore, no duplication exists.

b. Public Notice Required Prior to ICR Submissions to OMB

The EPA has described the recordkeeping and reporting requirements in the notice of proposed rulemaking and will provide parties affected by this requirement the opportunity to comment on any potential burdens that this information collection may pose.

c. Consultations

The EPA sought detailed technical concerns, new information requirements, and other recommendations relevant to the current federal labeling requirements for hearing protection devices via a public workshop that was held in March 2003. After further considering comments and responses from the workshop, the agency held two informal meetings with the regulated community to further assess the industry and gather feedback to the preliminary revisions of the regulation. Additionally, EPA conducted a cost analysis that included consultations with 8 manufactures and 1 testing laboratory to solicit information about the proposed revisions to the regulation. During these meetings and consultations, the information collection requirement was briefly discussed and there were no major objections to the reporting of information with respect to burden or costs.

d. Effects of Less Frequent Collection

The information collection will be required upon the transition testing and again for the recurrent test, which is approximately every 5 years after the initial transition test has been completed. The collection of test data will establish quality assurance of the

product design, product testing process, and the resultant Noise Reduction Rating (NRR) that is required for each HPD. This process is necessary to ensure that manufacturers are reporting accurate information on the mandated label. The EPA believes that requiring test data reports will keep the industry honest and protect potential users from being exposed to harmful sounds based on inaccurate information that a manufacturer could potentially present on the label.

The agency has determined that recurrent testing of every 5 years would provide manufacturers with adequate time to plan tests, factor associated costs into their operating budget, and time-stream tests within the 5 year timeframe. The collection of information less frequently would make it impossible to maintain an authentic industry and impede on the primary purpose of the collection process.

e. General Guidelines

The reporting requirements do not violate any of the regulations established by OMB.

f. Confidentiality

The test data reports will not contain any data that should be considered as confidential business information. The required test data reports will contain the primary information that is presented on the mandated label, which is readily visible on all products. However, any information submitted to the EPA for which a claim of confidentiality is made will be safeguarded according to the Agency policies set forth in Title 40, Part 2, Subpart B – Confidentiality of Business Information (CBI).

g. Sensitive Questions

None of the reporting information of this collection will contain sensitive questions.

4. The Respondents and the Information Requested

a. Respondents/NAICS and SIC Codes

The respondents of the reporting requirements are hearing protection devices manufacturers. The North American Industry Classification System (NAICS) includes HPD manufacturing and other personal safety manufacturing under the general miscellaneous manufacturing category 339113, “Miscellaneous Manufacturing – Surgical Appliance and Supplies Manufacture.” Specifically, subcategory 3391136 within this category covers “Personal Industrial and Non-industrial Safety Equipment and Clothing,” including “personal noise protector manufacturing.” Similarly, the Standard Industrial Classification (SIC) identified HPD manufacturing under category 3842, “Orthopedic, Prosthetic, and Surgical Appliances and Supplies,” and subcategory 38423, “Personal Industrial Safety Devices.”

Most manufacturers of HPDs list category 339113 as their primary NAICS code. However, some manufacturers also manufacture other products, and determine their primary NAICS on the basis of these other products. For instance, many manufacturers of noise cancellation devices are also manufacturers of other electronic equipment. Similarly, some manufacturers of foam-based earplugs define their NAICS code based on the manufacture of polymer products. The table below lists the various NAICS and SIC codes used by HPD manufacturers and distributors.

The respondents to this information collection fall into the following list of NAICS/SIC codes given by manufacturers and wholesalers of Hearing Protection Devices:

NAICS code	SIC code	Description
Manufacturers		
339113	3842	Surgical Appliance and Supplies Manufacturing
334290	3669	Other Communications Equipment Manufacturing
334310	3651	Audio and Video Equipment Manufacturing
326112	3089	Plastics Packaging Film and Sheet (including Laminated) Manufacturing
325212	2822	Synthetic Rubber Manufacturing
334514	3824	Totalizing Fluid Meter and Counting Device Manufacturing
339932	3944	Game, Toy, and Children's Vehicle Manufacturing
334220	3663	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing
334419	3679	Other Electronic Component Manufacturing
339111	3821	Laboratory Apparatus and Furniture Manufacturing
325211	2821	Plastics Material and Resin Manufacturing
333514	3544	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing
339115	3851	Ophthalmic Goods Manufacturing
Wholesalers		
423450	5047	Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers
423990	5099	Other Miscellaneous Durable Goods Merchant Wholesalers
423860	5088	Transportation Equipment and Supplies (except Motor Vehicle) Merchant Wholesalers
423840	5085	Industrial Supplies Merchant Wholesalers
541710	8731	Research and Development in the Physical, Engineering, and Life Sciences
423	5065	Wholesalers of Electronic Parts and Equipment

b. Information Requested

None of these reporting requirements violate any of the regulations established by OMB established under 5 CFR Part 1320, section 1320.5.

i. Data Items:

Hearing Protection Devices (HPD) manufacturers who are regulated by 40 CFR Part 211 Subpart B must have their HPDs tested according to the testing methodologies identified §211-206 of the said regulation at a HPD testing laboratory of choice. The manufacturer will obtain their test data report(s) from the testing laboratory and will be required to submit their report(s) to the EPA. The report(s) must include the following.

- Identification and description by category/model parameters of protectors comprising the manufacturer's product line
- A complete record of all noise attenuation tests performed including all individual worksheets and other documentation relating to each test required by the Federal test procedure
- A description of any test procedures, other than those contained in this regulation, used to perform noise attenuation tests on any protector, and the results of those tests
- Testing Date
- Required signatures of both the manufacturer (acknowledging receipt of test data report) and an authorized representative of the testing laboratory (acknowledging test was performed, including any calibrations during testing, and test was completed)

ii. Respondent Activities:

Manufacturers of Hearing Protector Devices must perform the following.

- Review the revised reporting requirements in the regulation
- Complete the coversheet in the format identified in Annex A (e.g., product category, model, etc.) of the regulation.
- Convert test data report from testing laboratory format into PDF format, if necessary
- Submit coversheet and authorized test data reports electronically (in PDF format) or via postage mail to the EPA

5. The Information Collected–Agency Activities, Collection Methodology, and Information Management

a. Agency Activities

Upon receipt of the test data report submitted by manufacturers, the EPA will do the following.

- Review report for completeness (i.e., required information according to Annex A and attenuation test results)
- Submit all reports to the EPA docket
- Input test data report results into the Microsoft Access database
- Verify that the test data match the reported NRR values

b. Collection Methodology and Management

The agency believes that receiving data electronically will simplify the process and reduce any burdens to the regulated parties and EPA personnel with respect to time and level of effort needed to report and maintain such records. However, the agency will also accept a hard copy of the test data reports via postage mail. The submission of test data information will be submitted in a secured fashion via the Agency's network. Once the information is collected, it will be maintained in the Agency's docket and via internal tracking system (Microsoft Access). The preamble of the regulation provides information on the associated docket, including access instructions and contact information.

c. Small Entity Flexibility

The HPD industry is collectively a small entity based on the Small Business Administration's size standards. The entire industry has been allotted the same amount of time to submit their test data reports to the EPA, which is within 30 months for the initial compliance test and every 5 years, thereafter. Because the industry is so small, the agency has proposed a uniform testing schedule, as mentioned below, and will not offer exemptions or differing reporting requirements.

d. Collection Schedule

Manufacturers will be required to submit the test data reports for the initial transition test within 30 months after the effective date of the rule. After the initial transition test, manufacturers will be required to retest their product(s) every 5 years and submit the test results to the EPA. There may be additional reporting prior to the 5 year recurrent test period, which will occur if a manufacturer makes substantial changes in a product's design or material. If this occurs, the manufacturer will be required to submit the resultant test data report to the EPA at that time.

6. Estimating The Burden and Cost of the Collection

a. Estimating Respondent Burden

A cost analysis was conducted to assess the impact of significant regulatory revisions on the HPD industry and the costs of recordkeeping and reporting are outlined in the notice of proposed rulemaking (Table C-4). The cost analysis estimated approximately 1,029 hearing protection devices will be tested in accordance to §211-206 and each test will yield a report for the attendant NRR values that must be presented on

the mandated label in accordance to §211.204. Manufacturers will have 30 months from the effective date of the regulation to comply with the testing and labeling requirements and must submit their initial transition test data reports for each of his products to the EPA. At the conclusion of the transition test, manufacturers will be require to retest their product every five (5) years and submit their test results to the EPA. Since the maximum amount of time that OMB will approve an information collection is three (3) years, the estimates for the burden and cost reflect the initial transition test data reports only.

Based on the 1,029 products that will be tested within a 3 year collection period, the EPA estimates that the total burden on manufacturers will be approximately 555 hours (Table I), which is185 hours a year.

Table I. ESTIMATED ANNUAL RESPONDENT BURDENS AND COSTS

Type of Response	Activities	Burden per Response	Cost per Response	Number of Responses	Total Burden Hours	Total Cost
Reading applicable section of the regulation	1. Read revised regulation for "reinstated" reporting requirements	0.50	$15.50	81	40.5	$1,255.50
Submittal of Test Data Reports **(passive: earplugs and semi-aural inserts)**	2 Complete the coversheet in the format identified in Annex A of the regulation 3 Convert test data report from testing laboratory format into PDF format 4 Submit coversheet and authorized test data reports (in PDF format) to the EPA electronically or via postage mail	0.50 (all tasks)	$15.50	403	201.50	$6,246.50
Submittal of Test Data Reports **(passive: earmuffs)**	2 Complete the coversheet in the format identified in Annex A of the regulation 3 Convert test data report from testing laboratory format into PDF format 4 Submit coversheet and authorized test data reports (in PDF format) to the EPA electronically or via postage mail	0.50 (all tasks)	$15.50	572	286	$8,866.00
Submittal of Test Data Reports **(Active: earplugs and earmuffs**	2 Complete the coversheet in the format identified in Annex A of the regulation 3 Convert test data report from testing laboratory format into PDF format 4 Submit coversheet and authorized test data reports (in PDF format) to the EPA electronically or via postage mail	0.50 (all tasks)	$15.50	54	27	$837.00
Total					**555**	**$17,205**
* This information collection represents 81 manufacturers for the initial transition test data reports of approximately 1,029 Hearing Protection Devices.						

b. Estimating Respondent Costs

i. Estimating Labor Costs

The cost analysis estimates for recordkeeping and reporting are based on Bureau of Labor Statistics information for the medical supplies manufacturing industry and hourly rates include an overhead factor (including benefits) of 100%. The EPA believes that the responsibility of reporting test data reports to the agency will most likely be that of an administrative (clerical) staff person. The labor category involved in the reporting process for this collection is clerical (administrative) at $31 per hour for an estimated .50 hours (30 minutes) per activity, resulting in an overall project cost of $17,205 (see Table I).

ii. Estimating Capital and Operations and Maintenance Costs

There are no capital and operating & management (O&M) costs associated with this collection.

iii. Capital/Start-ups and Operating and Maintenance Costs

There are no one-time capital/start-ups and operating & management (O&M) costs associated with this collection

iv. Annualizing Capital Costs

There are no annual capital costs.

c. Estimating Agency Burden and Cost

EPA has provided guidance in the regulation with respect to the format in which the test data reports must be submitted. The agency's level of effort is based on the completeness of the reports that are submitted from the manufacturer. Once the test data reports are received, the EPA will:

1) review the report for completeness
2) submit the report to the EPA docket
3) input test data report information into the tracking database; and
4) verify that the test data match the reported NRR values.

We anticipate that the related tasks (#1-3) will be performed by an EPA clerical person at the GS-9[1] level, with an hourly rate of $24, and task #4 will be performed by a technical person at the GS-13 level, with an hourly rate of $41. A technical person will possess a level of understanding with respect to the attenuation test data and its correlation to the resultant NRR values. These two positions are full-time personnel but the activities of this collection will be less than 10% of time for the year for approximately 1,029 test data reports that will be submitted to the agency. The EPA estimates the burden hours to be 926 and total cost to be $26,600 for this collection.

[1] 2009 General Schedule (GS) Locality Pay Table, Office of Personnel Management

TABLE II. ESTIMATED AGENCY BURDENS AND COSTS

Agency Activity Per Activity	Cost Per Activity	Burden Hour Hours	Burden Hour Cost	Total Burden	Total Burden
1. Review report for completeness		0.20	(0.20 x $24= $4.80)	205.80	$4,939.20
2. Submit report to the EPA docket		0.25	(0.25 x $24= $6.00)	257.25	$6,174.00
3. Input test data report results into the database		0.20	(0.20 x $24= $4.80)	205.80	$4,939.20
4. Verify that the test data match the reported NRR values		0.25	(0.25 x $41= $10.25)	257.25	$10,547.25
TOTAL		**0.90**	**$25.85**	**926.10**	**$26,599.65**

The agency believes that there are no other agency costs associated with this collection activity. With respect to maintaining and tracking test data reports, the agency will not incur additional costs, because the federal docket system is available government-wide and Microsoft Access is agency standard software. All tasks that require IT performance are easily accessible and agency personnel are knowledgeable with both programs. For these reasons, the agency burden and cost will be minimal.

d. Estimating Respondent Universe and Total Burden and Costs

The EPA expects to receive approximately 1,029 test data reports. The total burden expected on industry 555 hours, and the total labor cost of $17,205 for all respondents over the three year period of this ICR.

e. Bottom Line Burden Hours and Cost Tables

Table 3 summarizes the total burdens and costs that the HPD industry and Agency will incur as a result of the information collection.

TABLE III. TOTAL ESTIMATED RESPONDANT AND AGENCY BURDEN AND COST SUMMARY

	Number of Respondents	Total Burden Hours	Total Labor Cost
HPD Industry	81	555	$17,205
EPA		926	$26,600
TOTAL	**81**	**1,481**	**$43,805**

Total Respondents: 81
Total Responses to the EPA: 1,029
Total Burden Hours: 1,481
Total Cost to Respondents: $43,805

f. Reasons for Change in Burden

The change in burden is due to revisions to the said regulation, which is now reinstituting the reporting requirements of test data reports in an effort to maintain a level of quality assurance and to keep the industry honest.

g. Burden Statement

The annual public reporting burden for this collection of information is estimated to be less than one hour per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID number EPA-HQ-OAR-2003-0024, which is available for online viewing at www.regulations.gov, or in person viewing at the Air Docket in the EPA Docket Center in Washington, DC (EPA/DC). The docket is located in the EPA West Building, 1301 Constitution Avenue, NW, Room 3334, and is open from 8:30 a.m. to 4:30 p.m., Eastern Standard Time, Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OAR-2003-0024 and OMB Control Number 2060-NEW in any correspondence.