Request for Office of Management and Budget Review and Approval for Federally Sponsored Data Collection

**OMB APPROVAL OF A COLLECTION OF INFORMATION**

**UNDER THE PAPERWORK REDUCTION ACT OF 1995**

# INFORMATION COLLECTION PROVISIONS IN 42 CFR, Part 84-

# TESTS AND REQUIREMENTS FOR CERTIFICATION AND APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

**(0920-0109)**

**SUPPORTING STATEMENT**

**PART A.**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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National Personal Protective Technology Laboratory
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March 31, 2008

Note regarding change in burden-hour estimate:

This data collection is consistent with the terms and conditions set forth in the previous OMB approval. The burden hour estimate has been updated based upon the latest information available including estimates of burden hours by applicants, current number of applications, and current number of applicants. While the mode of collection has not changed, an effort has been made to refine the burden-hour estimate based upon all currently available data. On average, hours reported per response changed slightly in regard to where the hours are spent, but not in the total per response; however, respondents submitted two less applications per year over the observed time frame. The drop in the number of responses was responsible for the decrease in estimated burden hours. The total number of burden hours estimated dropped from 98,470 in 2004 to 78,776 in 2007.

Note regarding terms cited in the previous OMB approval:

All Standard Test Procedures have been made available via the internet in accordance with user comments received. Attempts to establish electronic funds transmission, however, have not been successful due to the inability to capture funds locally within the FMO electronic funds system.

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The regulatory authority for the National Institute for Occupational Safety and Health (NIOSH or the Institute) certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 3, 5, 7, 811, 842(h), 844) and the Occupational Safety and Health Act of 1970 (29 U.S.C. 657(g)) (Attachment 1). These regulations mandate the performance tests and criteria for approval of respirators used by millions of American construction workers, miners, painters, asbestos removal workers, fabric mill workers, and fire fighters. In addition to benefiting industrial workers, the improved testing requirements also benefit health care workers implementing the current draft *CDC Guidelines for Preventing the Transmission of Tuberculosis*. Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH-approved respirators.

In accordance with implementing regulation 42 CFR, Part 84 (Attachment 2), NIOSH (1) issues certificates of approval for respirators which have met improved construction, performance, and protection requirements; (2) establishes procedures and requirements to be met in filing applications for approval; (3) specifies minimum

requirements and methods to be employed by NIOSH and by applicants in conducting inspections, examinations, and tests to determine effectiveness of respirators; (4) establishes a schedule of fees to be charged applicants for testing and certification; and (5) establishes approval labeling requirements.

Under 42 CFR, Part 84, certification applicants are required to submit detailed parts lists, drawings, and inspection instructions. The following lists the citation from 42 CFR, Part 84 on information collection:

Subpart B 84.11 - Reporting

Specifies necessary content of application for certification approval of respirators (drawings, specifications, drawing lists)

Subpart D 84.33 - Reporting

Specifies general requirements for content, format, and locations of approval labels and markings placed on devices and displayed in product literature. This requires submission of instructions for the use and maintenance of the respirator.

Subpart D 84.35 - Reporting

Specifies necessary content of application for modification of the existing certificate of approval to cover proposed changes (original certificate of approval, appropriate drawings and specifications, and proposed quality control plan meeting requirements of Subpart E)

Subpart E 84.41 - Reporting

Specifies necessary content of quality control plans (production quality requirements for data and record collection, engineering drawing control, test equipment calibration, purchased material incoming inspections, manufactured lot tracking systems, final inspections processes, and supporting organizational structure)

Subpart E 84.43 - Quality Control Records; Record keeping

Specifies that applicants shall keep quality control inspection records.

Subpart N 84.257 - Reporting

Specifies necessary content, format, and locations for approval labels mounted on special use respirators and displayed in product literature

Subpart KK 84.1103 - Reporting

Specifies necessary content, format, and locations for approval labels mounted on dust, fume, and mist; pesticide; paint spray; powered air-purifying high efficiency respirators and combination gas masks, and displayed in product literature.

## 2. Purpose and Use of the Information Collection

The information is used by NIOSH to fulfill its legislatively mandated responsibilities to evaluate and approve respirators submitted for certification actions (29 U.S.C. 657(g); 30 U.S.C. 3, 5, 7, 811, 842 (h), 844). Before NIOSH grants certification, it must have sufficient evidence of safety and required performance. Without the information specified in 42 CFR, Part 84, NIOSH would be unable to adequately evaluate respirator safety and efficacy, or to make subsequent evaluations of performance if material changes were made in the manufacture of certified products. Certified respirators are required by the Mine Health and Safety Administration (MSHA), the Occupational Safety and Health Administration (OSHA), EPA, and NRC whenever respirators are needed to reduce or prevent employee exposure to hazardous airborne contaminants.

## 3. Use of Information Technology and Burden Reduction

Beginning in July 1998, NIOSH instituted a policy within the Technical Evaluation Branch (then the Respirator Branch) for accepting approval applications electronically. The Technical Evaluation Branch worked with respirator manufacturers to develop a system whereby the application is submitted in a paperless format. NIOSH developed a self-loading application software program (developed in Microsoft Access) that is provided free-of-charge to respirator manufacturers. This program guides respirator manufacturers through the necessary steps in preparing an electronic application. When completed, the manufacturer submits a series of electronic files comprising the approval application and supporting documentation to the Technical Evaluation Branch. This is done via CD-ROM disc, ZIP-Disc, or other suitable electronic media. The result is a paperless application process that is the preferred method for receiving and processing an application. The Branch continuously evaluates information technology and seeks updated and current means and methods for use by applicants in transmitting the required data.

While NIOSH will still accept applications from those manufacturers not capable of preparing an electronic submission in any modern format that can be read by the Institute's data processing equipment (for example, aperture cards, computer printouts, typed, etc.), the preferred method, as stated in Technical Evaluation Branch policy is an electronic, paperless submission. Even with this option available, nearly 100% of the information received is provided in some electronic format. Since the last application for OMB approval, no one has sought to apply through a paper-based submission of information.

**4. Efforts to Identify Duplication and Use of Similar Information**

Since 42 CFR, Part 84 reporting requirements are legislatively mandated, respondents, who participate by their own choice, must provide a detailed description (engineering drawings, classification of defects (CDS), and complete parts lists) for each respirator submitted to NIOSH for certification evaluation. Most of the information that must be provided is proprietary and not available from any source other than the applicants themselves. To the greatest extent possible, NIOSH allows applicants to reference any other proprietary drawings, parts lists, or CD's previously submitted in association with another approved respirator assembly that may have contained common components or parts. For any applicant that submits multiple respirators with common parts, NIOSH will use, whenever possible, data and information previously submitted and suitably referenced by the applicant.

**5. Impact on Small Businesses or Other Small Entities**

About half of the 43 domestic respirator manufacturers are small businesses (i.e., with fewer than 500 employees). The information collection requirements within 42 CFR, Part 84 are uniformly applied regardless of the size of the applicant's business, and are the least burdensome necessary for the proper performance of the Institute's regulatory responsibilities and to achieve program objectives. NIOSH has made every effort to minimize the amount of information collected for the purpose of assessing and certifying the safety and efficacy of an applicant's respirator. These efforts have minimized the burden on small businesses. However, the minimum information needed by NIOSH to assess a respirator depends significantly on the type of respirator to be certified. Any further reductions in the amount or types of information collected from small respirator manufacturers could quite possibly compromise the usefulness and reliability of certificates of approval.

**6. Consequences of Collecting the Information Less Frequently**

The 42 CFR, Part 84 regulations do not specify data collection frequencies in terms of fixed time intervals (e.g., monthly, yearly). However, as stated in Item 5, the amount of required information collected from any given manufacturer over any given period (e.g., annually) is regarded as the minimum necessary for NIOSH to be able to adequately evaluate respirator safety and efficacy thereby protecting the health and safety of respirator users. The data collection frequency of §84.11 depends upon the voluntary actions of a certification applicant. Respirator manufacturers will submit applications for approval whenever they:

(1) seek approval of a new model,
(2) seek an extension of approval to accommodate a change or modification to a certified model; that is a modification that affects the respirator's form, fit, or function, or
(3) seek approval of a minor change or modification to a certified model that does

not affect form, fit or function (e.g. color of a screw changes from black to silver).

A sample of the data collection instrument used to fulfill the purposes of §84.11, is attached. (Attachment 3 – 3 parts)

For other provisions (e.g., §84.33(f), 84.42(b), 84.43(c), 84.65(e)), the data collection frequency is a function of the production frequency of defective or nonconforming respirators from a respirator manufacturer. The frequency of these collection activities is determined largely by the activities of the applicants, however, any reductions in the amount of information collected or frequency of collection, as stated in item 5, could quite possibly compromise the reliability of certificates of approval.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The provisions of 42 CFR, Part 84 as implemented by NIOSH require information collection to be conducted in a manner inconsistent with the following two guidelines of 5 CFR 1320.5:

§1320.5d(2)(ii): "Requiring respondents to prepare a written response to an information collection request or requirement in fewer than 30 days after receipt of it."

§1320.5d(2)(iv): "Requiring respondents to retain records, other than health, medical or tax records, for more than three years."

First, NIOSH response to critical defects (§84.41(d)(1)) identified in certified respirators deployed in industrial and mining workplaces contradicts §1320.5d(2)(ii). When NIOSH becomes aware that a certified respirator problem or defect exists and that "…judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator," NIOSH will: "Notify the Manufacturer in writing describing the problem and requesting that the Manufacturer immediately Stop Sale of the respirator(s)... as a NIOSH certified device. The Manufacturer is asked to investigate the problem and submit a report to NIOSH within a specified time period (usually 2 weeks)."

Second, §84.31(c) contradicts §1320.5d(2)(iv) since it requires the manufacturer to maintain certificates of approval, and drawings and specifications incorporated by reference, as long as the unit is sold as NIOSH or NIOSH/MSHA certified, or until the certification of the unit is invalidated (approximately 5 to 25 years). These records must be retained for the duration of the certification, which generally exceeds three years, to enable NIOSH to review a series of minor respirator changes and determine if the aggregate effect of the changes compromise the safety and performance of the affected device. CDC requests a waiver from §1320.5d(2)(ii) and (f) to enable NIOSH to adequately protect the health and safety of respirator users.

**8. Consultation Outside the Agency**

**A.** A notice of this proposed project was published in the Federal Register, Vol. 72, No. 162 on August 22, 2007, page 47044-47045, as required by 5 CFR 1320.8(d) (Attachment 4). No public comments were received.

**B.** Since 1994, NIOSH and the International Safety Equipment Association have held joint meetings with all approval-holding manufacturers to address clarifications and accommodations with manufacturer record systems needed to improve the approval application process. On average these meetings have occurred on roughly a yearly basis. The International Safety Equipment Association, formerly known as the Industrial Safety Equipment Association, represents well over 80% of 7949 NIOSH respirator approvals currently listed in the Certified Equipment List. This meeting is always attended by more than 40 representatives from 25 plus domestic and foreign respirator manufacturers. Two representatives are:

(Domestic):

Mr. Craig Colton
Senior Specialist - Technical Service
3M Company
OH & ES Division
Building 235-2E-91
St. Paul, MN 55144-1000
Ph. (651) 733-6297

(Foreign):

Mr. Klaus-Michael Rück
Chemical Engineer
Research & Development
Dräger Safety AG & Co. KGaA
Revalstraße 1
Luebeck, D-23560
GERMANY

Ph. (+49) 451 882 4513

Since MSHA has co-approval authority on respirators used in mining applications, MSHA representatives participate in the annual NIOSH meeting with all manufacturers and always have an opportunity to discuss the data collected in each application. NIOSH requires documentation of MSHA intrinsic safety approval as a prerequisite and major section of the respirator approval application. The MSHA agency representative on this project is:

Mr. Jeff Kravitz
MSHA Pittsburgh Safety and Health Technology Center
Cochrans Mill Road

P. O. Box 18233
Pittsburgh, Pennsylvania 15236
412/386-6923 / 412-386-6964 FAX

The NIOSH application form has been modified several times over the years in response to, and in cooperation with, respirator manufacturers. This is done to ensure all necessary data would be collected from manufacturers during the approval process, while working to continuously improve the application process. The most recent revision was completed in November 2006.

**9. Explanation of Any Payment or Gift to Respondents**

No payments are made to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

The Privacy Act is not applicable. No personal information is being collected. Even if full names of those completing information collection documents are furnished, the primary method of retrieval for this information collection will not be performed by this field. Individuals would be providing data relating only to respirators and the production methods used to manufacture them, and not related to themselves or other persons. Therefore, the Privacy Act does not apply to the data collection.

Because proprietary (trade secret and confidential) information may be furnished as part of the application, the following information on the applicable Freedom of Information Act exemption enabling withholding of such information is provided to clarify the extent to which the confidential nature of documents might be protected for respondents who choose to participate in this data collection. The most recent revision of the DHHS regulation (45 CFR 5) implementing the Freedom of Information Act (5 U.S.C. 552) was issued on November 13, 1987 (52 FR 43575). Specifically, 45 CFR 5.65 covers the limits and details of the exemption to mandatory disclosure granted to trade secrets and confidential information held by the Institute. However, confidential protections do not extend to laboratory test results from any application for certification. Documentation submitted by manufacturers is retained in secured areas including locked rooms and filing cabinets. Personnel working with the documentation must have Sensitive Data clearance. Based on a Department of Health and Human Services legal decision, information such as a drawing marked "Company Confidential", will not be released upon Freedom of Information requests unless the applicant involved gives explicit permission.

**11. Justification for Sensitive Questions**

This data collection contains no sensitive questions (e.g. gender, sexual behavior and attitudes, religious beliefs, health information, or other personal matters that are commonly considered personal and private).

**12. Estimates of Annualized Burden Hour and Costs**

A. The number of hours per response has been estimated from an informal telephone survey of five applicants representing both large and small business. Information regarding the average number of responses has been calculated from NIOSH records of submissions.

a. Last year, 62 of 81 respirator companies submitted applications.

b. The average number of applications (responses) per company last year was 8.

c. NIOSH assumes an equal time distribution between manufacturer's clerical and quality control support staff to arrive at a burden hour estimate per manufacturer of 229 hours per response, including record keeping.

12A. Estimated Annualized Burden to Respondents

| Type of Respondents | Type of Forms | | No. of Respondents | No. Responses Per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|---|---|---|---|---|---|---|
| Respirator Manufacturers | 84.11 | Applications | 43 | 8 | 86 | 29,584 |
| | 84.33 | Labeling | 43 | 8 | 2 | 688 |
| | 84.35 | Modifications | 43 | 8 | 66 | 22,704 |
| | 84.41 | Reporting | 43 | 8 | 23 | 7912 |
| | 84.43 | Record Keeping | 43 | 8 | 46 | 15,824 |
| | 84.257 | Labeling | 43 | 8 | 3 | 1032 |
| | 84.1103 | Labeling | 43 | 8 | 3 | 1032 |
| | TOTAL | | | | | 78,776 |

*Past estimates from applicants indicated the burden due to the various provisions in 42 CFR, Part 84 breaks down into:

**B.** The primary cost burden associated with preparing a certification application is the compilation of the proper documentation for a specific respirator. The costs of preparing source documents (e.g., user guides, engineering drawings, quality control plans, material specification lists by §84.11) are excluded by NIOSH using the definition of burden given in 5 CFR 1320.3(b)(1). These documents are compiled by the manufacturers "in the normal course of their activities," since the required documents are "usual and customary" in this industry. Reproduction equipment required by the manufacturer is available from their normal operations.

Based upon an informal survey conducted in 2000, four domestic manufacturer

applicants estimated that the mean cost for "total aggregate cost of certification" had remained about $83,770/year/manufacturer under 42 CFR, Part 84 regulations. Adjusting for inflation since 2000 using CPI values compiled by the Bureau of Labor Statistics (BLS) over the years since then yields a current value of approximately 1.210 times that amount or:

($83,770/year/manufacturer) x (1.210) = $101,424/year/manufacturer

NIOSH will use the $101,424/year/manufacturer estimate and add a 4.7% inflation factor to establish the mean value over the next three years. Thus for respirator manufacturers NIOSH estimates an *annual mean cost* for 42 CFR, Part 84 of:

($101,424/year/manufacturer) x (1.047) = $106,191/year/manufacturer

For the purposes of 5 CFR 1320, the *total annual cost burden* averaged over the next three years of 42 CFR, Part 84 for the 43 domestic respirator manufacturers is then estimated as:

($106,191/year/ manufacturer) x (43 manufacturers) = $4,566,213/year

12B Estimated Annualized Cost to Respondents

| Type of Activity | Estimated Number of Respondents | Estimated Cost per Respondent | Total Annual Cost |
|---|---|---|---|
| Requirements of 42 CFR, Part 84 | 43 | $106,191 | $4,566,213 |

**13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There are no costs outside of those estimated in item 12.

**14. Annualized Cost to the Federal Government**

Based on twenty four year's experience since the promulgation of the paperwork reduction act and working under the present 42 CFR, Part 84 regulations, previously codified under 30 CFR 11, NIOSH estimates that the Institute program that will review and maintain the information collected from respirator manufacturers will annually require 5.0 person-years of effort. The average personnel cost is $83,084/year (average 2006 salary plus fringe benefits for the Technology Evaluation Branch at the National Personal Protective Technology Laboratory (NPPTL), NIOSH in the Centers for Disease Control and Prevention). Thus NIOSH estimates an annual personnel cost for 42 CFR, Part 84 of:

($83,084/yr/position)(5.0 positions) = $415,420/yr.

In addition, based on past experience, NIOSH estimates an annual travel cost of $17,325/yr and an office supply cost of $2,887/yr. Then the total annual cost to the Federal Government for information collected under 42 CFR, Part 84 is estimated as the annual personnel cost plus travel and supply costs:

$415,420/yr + $17,325/yr + $2,887/yr = $435,632/yr.

**15. Explanation for Program Changes or Adjustments**

The decrease of 19,694 total annual burden hours (from 98,470 total annual burden hours in 2003 to 78,776 total annual burden hours per year in 2006) occurred because the average number of applications voluntarily submitted per applicant decreased from 10 in 2003 to 8 in 2006.

**16. Plans for Tabulation and Publication and Project Time Schedule**

The requirements for collecting information under 42 CFR, Part 84 are derived solely from its established provisions to evaluate the performance of the respirator, and the compliance of the applicants' quality assurance systems with the regulatory requirements. Affirmative evaluations result in the issuance of certificate(s) of approval, negative evaluations result in denial of the applicants' requests for certification. No compilation, or results of information collection will be published other than lists of respirators to which approval has been granted. These lists are updated on a regular basis and are available on a broad distribution basis via the Internet.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

No exemption is requested.

**18. Exceptions to Certification for *Paperwork Reduction Act* Submissions**

No exception is identified or requested.