Information Collection Request
Respiratory Protective Devices--42 CFR 84--Regulation

Revision (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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Attachments

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Institute for Occupational Safety and Health (NIOSH) is seeking a revision to the information collection activities described in 42 CFR Part 84. The current ICR Respiratory Protective Devices--42 CFR 84--Regulation expires on August 31, 2014. The nature of the collection activities are fundamentally unchanged, although the estimate for the number of responses has been updated (accounting for a decrease) to better match current respirator manufacturer practices. The regulatory authority for the 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 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 (Attachment 2), 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.

1.1 Privacy Impact Assessment

Overview of the Data Collection System

The majority of the covered data is transmitted electronically through mailed CD-ROM application disks or through electronic mail. Audits performed by the Institute or its agents at

respirator manufacturer sites also generate data for respirator approval certification functions. Data supporting respirator approvals is retained at least as long as the approval is maintained.

Items of Information to be Collected

Data collected through the Standard Application for the Approval of Respirators V7 (Attachment 6) support the respirator approval certification activities and have limited personal identifiable information. Respondents provide Information in Identifiable Form for general contact information, including name, business mailing address, business telephone numbers, business email address, and official title.

Information pertaining to factors likely to affect respirator performance and use is collected and retained. Such information includes, but is not necessarily limited to, respirator design, manufacturing methods and materials, quality assurance plans and procedures, and user instruction and draft labels, as specified in 42 CFR Part 84.

2. Purpose and Use of Information Collection

Information is collected to enable 42 CFR Part 84 respirator approval certification activities. Approved respirators used by millions of workers to facilitate the selection of appropriate high quality reliable respiratory personal protective equipment. Institute certification is required for satisfaction of Occupational Safety and Health Administration and Mine Safety and Health Administration regulations for respirator personal protective equipment. The removal of information collection authority would not allow the Institute to perform its certification activities and thereby endanger the health of millions of people. Certification of respirators allows purchasers and users to consistently assess the protective capabilities of respirators so

approved. Maintenance of respirator approvals ensures continual quality production and accountable response to problems discovered in the field.

2.1 Privacy Impact Assessment Information

Respondent personnel contact information will be retained with approval certification data in Institute files and databases accessible to personnel with relevant certification duties. Upon request by the identified person, contact information will be released to the public. Contact information for respondent personnel is unlikely to be considered sensitive, and the data collection will have little or no effect on the applicant's personal privacy.

Because proprietary (trade secret and company confidential) information is often 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, security 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 and on controlled electronic data servers. 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" may have additional protections from release under the Freedom of Information Act.

3. Use of Improved Information Technology and Burden Reduction

The main instrument for data collection for respirator approval functions is The Standard Application for the Approval of Respirators, currently Version 7, known as SAF V.7 (Attachment 6). SAF V.7 consists of a Microsoft Access database utility. An alternative format, The Standard Application for the Approval of Respirators, version 8, has been developed and is being made available for manufacturers lacking the correct Microsoft Access environment (Attachment 5). The version 8 software has been designed in Java to allow users much greater ease of use. It is anticipated that support for SAF V.7 will be dropped in as little as one year depending upon user feedback. Paper submission is deprecated, and has not been utilized for over 5 years.

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 CDs previously submitted in association with another approved respirator assembly that may have contained common components or parts. For any applicant who 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

There are 70 respirator manufacturers that hold NIOSH approvals. Of this group, 10 manufacturers are considered large companies; 35 are approval-holders based outside of the United States; and 25 are classified as small businesses as defined under the Small Business Act for this industry sector (NAICS 339113--Surgical Appliance and Supplies Manufacturing), employing fewer than 500 employees. The inform.ation 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 would likely 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,

(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), or

(4) seek approval of a change to the quality assurance procedures for a certified model.

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) conflicts with §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. 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 60-day Federal Register Notice was published in the Federal Register on April 7, 2014, vol. 79, No. 66, pp. 19086-19087 (see Attachment 3). There were no public comments.

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 2010.

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. Personally Identifiable Information is limited to name, title, and business telephone and address of the respondent's agent. Though business contact details 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 business sensitive) 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 secure 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 business sensitive information held by the Institute. However, confidential protections do not extend to laboratory test results from any application for certification. Based on a Department of Health and Human Services legal decision, information (such as a drawing) marked "Company Confidential" has additional protections from Freedom of Information Act release.

IRB Approval

The information collection is not research and IRB approval is not required (Attachment 7).

Privacy Impact Assessment Information

A. Data collected is not intended to be retrieved by contact information. Institute personnel use provided contact information solely in regards to respirator certification functions.

B. Documentation submitted by manufacturers is retained in secured areas including locked rooms and filing cabinets, as well as in limited access electronic data storage. Personnel working with the documentation must have Sensitive Data clearance.

Technical Controls

User Identification (Windows Login)

Firewall

Physical Controls

Security Guards

Identification Badges

Administrative Controls

Data is backed up in accordance with CDC policy. Currently encrypted nightly backups are retained offsite for four months.

C. Respondent consent for use of the data is implied. Submitted data is used for respirator approval functions. Data may be aggregated for Institute functional metrics (such as those used here) but are not used for exceptional research.

D. Application for Institute approval of a respirator is voluntary, and the benefits of applying are understood by the respondents. The Privacy Act does not apply.

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 related 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, 63 of 115 respirator companies with current approvals submitted applications.

b. The average number of applications (responses) per company, with or without current approval, in calendar year 2013 was 7.

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.

Respirator manufacturers are the respondents (an estimated 63 respondents are expected each year over the years 2014-2017). Upon submission of the SAF V.7, respondents' requests for approval are evaluated. Although there is no cost to respondents for consideration other than their time to participate, respondents requesting respirator approval evaluations are required to submit fees for necessary testing as specified in 42 CFR Parts 84.20-22, 84.66, 84.258 and 84.1102. In calendar year 2013 $449,610 was accepted, for an average fee of $1,019.52. Applicants are required to provide test data that show the respirator is capable of meeting the specified requirements in 42 CFR Part 84. The requirement for submitted test data is likely to be satisfied by standard testing performed by the manufacturer, and is not required to precisely follow the relevant NIOSH Standard Test Procedures.

Although 42 CFR Part 84 Subpart E prescribes certain quality standards, it is not expected that requiring quality systems which can be approved to this standard will impose an additional cost burden over similarly effective quality standards that may not meet the requirements of 42 CFR Part 84.

Manufacturers with current approvals are subject to site audits by the Institute or its agents. There is no fee or form associated with audits, which may occur periodically or as a result of a reported issue. An average of 61 site audits were completed annually over the calendar years 2008-2010. Audits take an average of 24 burden hours from the respondent.

Estimated Annualized Burden Hours:

An estimated 63 respirator manufacturers are expected to apply for an average of 7 respirator approvals each year from 2014-2017, and each application is expected to require an average of 229 hours to complete and maintain. For NIOSH certification of new respirators, an application can either be classified as a new application, an extension (for a change to an existing NIOSH certified respirator), or a QA Application. QA applications are for an extension limited to the manufacturing quality system of an existing NIOSH certified respirator (Attachment 4).

Form	Expected Annual Number of Respondents	Average Annual Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Standard Application for the Approval of Respirators	63	7	229	100,989
Audit	60	1	24	1,440
Total				102,429

Form	Total Burden Hours (from above)	Estimated Hourly Wage Rate	Total Cost of Hour Burden
Standard Application for the	100,989	$73.67	$7,439,860

Approval of Respirators			
Audit	1,440	$73.67	$106,085
Total			$7,652,029

Wage data is the average unspecified manufacturing industry engineer wage of $42.12 as reported in the 2012 National Sector NAICS Industry-Specific estimates multiplied by 1.06 inflation adjustment and 1.65 factor for overhead expenses.

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 $93,552/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 multiplied by 1.126 inflation factor). Thus NIOSH estimates an annual personnel cost for 42 CFR, Part 84 of:

($93,552/yr/position)(5.0 positions) = $467,763/yr.

In addition, based on past experience, NIOSH estimates an annual travel cost of $19,508/yr and an office supply cost of $3251/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:

$467,763/yr + $19,508/yr + $3251/yr = $490,522/yr.

15. Explanation for Program Changes or Adjustments

The decrease of 36,411 estimated total annual burden hours (from 138,840 total annual burden hours in 2010 to 102,429 total annual burden hours per year in 2014) occurred because the number of estimated respondents decreased from 75 to 63, including foreign and domestic respondents.

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.