

**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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Sep 22, 2020

A. Justification.....

A1. Circumstances Making the Collection of Information Necessary.....

A2. Purpose and Use of Information Collection.....

A3. Use of Improved Information Technology and Burden Reduction.....

A4. Efforts to Identify Duplication and Use of Similar Information.....

A5. Impact on Small Businesses or Other Small Entities.....

A6. Consequences of Collecting the Information Less Frequently.....

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....

A8. Comments in Response to the Federal Register Notice and Efforts to Consult
Outside the Agency.....

A9. Explanation of Any Payment or Gift to Respondents.....

A10. Assurance of Confidentiality Provided to Respondents.....

A11. Justification for Sensitive Questions.....

A12. Estimates of Annualized Burden Hours and Costs.....

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record
Keepers.....

A14. Annualized Cost to the Government.....

A15. Explanation for Program Changes or Adjustments.....

A16. Plans for Tabulation and Publication and Project Time Schedule.....

A17. Reason(s) Display of OMB Expiration Date is Inappropriate.....

A18. Exceptions to Certification for Paperwork Reduction Act Submissions.....

Attachments

- Attachment 1 - Occupational Safety and Health Act**
- Attachment 2 - 42 CFR, Part 84**
- Attachment 3 - IFR "Approval Tests and Standards for Air-Purifying Particulate
Respirators"**
- Attachment 3a - Reopening of comment period "Approval Tests and Standards for Air-
Purifying Particulate Respirators"**
- Attachment 3b - 60day Federal Register Notice**
- Attachment 4 - Standard Application for the Approval of Respirators (Full)**
- Attachment 5 - Standard Application for the Approval of Respirators (Request Code)**
- Attachment 6 - IRB**
- Attachment 7- Audit**

A. Justification

- This collection enables the submission of respirators for NIOSH evaluation under 42 C.F.R. 84 “Approval of Respiratory Devices” requirements
- The resulting data allows NIOSH to certify that qualifying respirators meet published criteria, allowing proper selection of respiratory protection
- Data is provided by applicants and includes information submitted on a standard form and NIOSH-directed audits of quality systems and manufacturing sites
- Approvals are only appropriate for applicants with control over the production of respirators for which NIOSH certification is desired
- Data for each project is evaluated against published, stable criteria, and is only combined for reporting and to improve the certification business process

1.

Circumstances Making the Collection of Information Necessary

The National Institute for Occupational Safety and Health (NIOSH) is requesting a Revision for the information collection activities described in 42 CFR Part 84. The most recent Information Collection Request for 0920-0109 was approved through an Emergency Revision on April 30, 2020 through October 31, 2020. Emergency approval was requested for reasons described in the associated interim final rulemaking entitled “Approval Tests and Standards for Air-Purifying Particulate Respirators” to allow for the approval of respirators in a new class, PAPR100, better suited to the needs of workers in the healthcare and public safety sectors currently experiencing a shortage of air-purifying particulate respirators due to Coronavirus Disease 2019 (COVID-19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The regulatory authority for the NIOSH 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, 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 Information Collection

Information collected will be used solely to support the 42 CFR 84 NIOSH respirator evaluation requirements established for NIOSH approval of respirators. The information collected under OMB collection number 0920-0109 since promulgation of 42 CFR 84 in 1995 has been used in over 24,200 projects involved in respirator certification activities, including 464 in 2020. These projects involve evaluations of new and modified respirators and audits of approved products

and established manufacturing processes to ensure currently certified respirators continue to meet the requirements. All evaluations are conducted by personnel at the National Personal Protective Technology Laboratory under the direction of the Conformity Verification and Standards Development Branch (CVSDB). The collected information is accessible only by personnel charged with 42 CFR 84 duties requiring the information, and is not used for research purposes.

NIOSH approval provides objective assurance that the respirators will provide the protection promised by the label. The use of NIOSH approved respirators is specified for workplaces covered by the Occupational Safety and Health Act requiring 29 CFR 134 respiratory protection plans. Mine Safety and Health Administration regulations require NIOSH approval of respirators. The FDA currently uses NIOSH approval as part of its medical device clearance process for surgical respirators. Without this collection, NIOSH approval of respirators would not be possible.

464 projects were accepted by the CVSDB in 2020, including requests for certification of new, improved respirator designs. Continuing the information collection will allow respirator manufacturers to improve the performance, comfort, availability and economy of their respirators, providing better protection for workers in hazardous atmospheres, as well as continued verification of approved respirator quality.

Over 10,300 models of respirators are currently approved by NIOSH. Up to approximately 6000 additional respirators have lost approval due to manufacturer closings, at the request of the manufacturer, or at NIOSH discretion due to respirator manufacturing quality issues.

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, known as the Standard Application Form (SAF). Forms are returned electronically. Paper submission is deprecated, and has not been utilized for over 8 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

A 2010 analysis of respirator manufacturers classified 60 certified approval holders as 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 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. The 60 Day FRN published in the Federal Register on July 20, 2020, vol. 85, No. 139, pp. 43840-43841 (see Attachment 3b). An interim final rule Federal Register Notice was published in the Federal Register on April 14, 2020, vol. 85, No. 72, pp. 20598-20611 (see Attachment 3). There were no public comments. A reopening of comment period Federal Notice was published in the Federal Register on August 26, 2020, vol. 85, No. 166. p. 52488, extending the comment period to September 25, 2020. (see Attachment 3a).

B. NIOSH is taking comment on its interim final rulemaking entitled "Approval Tests and Standards for Air-Purifying Particulate Respirators." NIOSH will respond to comments, if any

are received, on the burden estimates associated with this rule, when the package is next renewed.

C. 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 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 were:

(Domestic):

Mr. Klaus Wilkens

Principle Certification Engineer

3M Scott Fire & Safety

4320 Goldmine Road, Monroe, NC 28110

Ph. 704-291-8395

(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:

Wesley Allen Shumaker, P.E.

Chief, Applied Engineering Division

MSHA Technical Support, Approval & Certification Center

765 Technology Drive

Triadelphia, WV 26059

Ph: (304)547-2081 Fax: (304)547-2044

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 9 was completed in April 2019.

9. Explanation of Any Payment or Gift to Respondents

No payments are made to respondents.

10. Assurance of Confidentiality Provided to Respondents

The ICR has been reviewed by NIOSH's Information System Security Officer, who determined that the privacy act doesn't apply. 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.

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

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. Institutional Review Board (IRB) and Justification for Sensitive Questions

The information collection is not research and IRB approval is not required (Attachment 6).

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. Initial applicants must complete the Standard Application Form (SAF) (see attachment 5) to apply for a manufacturer code. Once a code has been issued, applicants must then complete the full version of the SAF (see attachment 4) to submit projects for review by the Respirator Approval Program before being granted an approval.

a. In 2019, 102 respirator companies submitted applications. So far in 2020, 150 respirator companies have submitted applications.

b. The average number of applications (responses) per company, with or without current approval, in calendar year 2019 was 4.

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.

d. NIOSH estimates that 5 respirator companies may submit applications for the approval of PAPR class PAPR100 respirators from April 2020 through April 2021.

e. The expected average number of applications (responses) per companies expected to submit applications for the approval of PAPR class PAPR100 devices from April 2020 through April 2021 is 4.

f. 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 140 respondents are expected each year over the years 2020-2023). Upon submission of the SAF, respondents' requests for approval are evaluated. Respondents requesting respirator approval evaluations are required to submit fees for necessary testing and evaluation as specified in 42 CFR Parts 84.20-22, 84.66, 84.258 and 84.1102. So far in calendar year 2020, \$3,629,5322.00 was accepted, for an average fee of \$25,925.

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 associated with audits, which may occur periodically or as a result of a reported issue. 53 site audits were completed during the fiscal year 2019. Audits take an average of 23.5 burden hours from the respondent.

Estimated Annualized Burden Hours:

An estimated 140 respirator manufacturers are expected to apply for an average of 4 respirator approvals each year from 2020-2023, and each application is expected to require an average of 229 hours to complete and maintain. An estimated 5 manufacturers are expected to apply for an average of 4 approvals for PAPR class PAPR100 approvals from April 2020 through April 2021, and each application is expected to require an average of 229 hours to complete and maintain.

| Type of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|------------------------------|----------------------|-----------------------|------------------------------------|--|-------------------------|
| Business or other for-profit | Standard Application | 140 | 4 | 229 | 128,240 |

| | | | | | |
|---------------------------------|--|----|---|----|---------|
| | Form for the Approval of Respirators | | | | |
| Business or other for-profit | Audit | 70 | 1 | 24 | 1680 |
| Total | | | | | 129,920 |

| Form | Total Burden Hours (from above) | Estimated Hourly Wage Rate | Total Cost of Hour Burden |
|---|------------------------------------|----------------------------------|------------------------------|
| Standard Application for the Approval of Respirators | 128,240 | \$79.89 | \$10,245,093.6 |
| Audit | 1,680 | \$79.89 | \$134,215.2 |
| Total | | | \$10,379,308.8 |

Wage data is the average unspecified manufacturing industry engineer wage of \$45.68 as reported in the 2016 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 seven 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:

$$(\$93,552/\text{yr}/\text{position})(5.0 \text{ positions}) = \$467,763/\text{yr}.$$

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:

$$\$467,763/\text{yr} + \$19,508/\text{yr} + \$3251/\text{yr} = \$490,522/\text{yr}.$$

15. Explanation for Program Changes or Adjustments

The increase of 6,218 estimated total annual burden hours (from 123,702 total annual burden hours per year in 2017 to 129,920 total annual burden hours in 2020) occurred because NIOSH issued an interim final rulemaking entitled “Approval Tests and Standards for Air-Purifying Particulate Respirators” to allow for the approval of respirators in a new class, PAPR100, better suited to the needs of workers in the healthcare and public safety sectors currently experiencing a shortage of air-purifying particulate respirators.

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

There are no exceptions to the certification.