10S2

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

John Sporrer
National Personal Protective Technology Laboratory
P.O. Box 18070
626 Cochrans Mill Road, Mail Stop P-05
Pittsburgh, PA 15236
(412) 386-6435
eyi0@cdc.gov

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Attachments

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Attachment 2 - 42 CFR, Part 84
Attachment 3 - 60-day Federal Register Notice
Attachment 4 - Standard Application for the Approval of Respirators (Full)
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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. Data is also collected from individuals who consent to participate when testing respirators to NIOSH performance requirements.
- Approvals are only appropriate for applicants with control over the production of respirators for which NIOSH certification is desired. Human participants during performance testing are recruited from the community surrounding the NIOSH test facility.
- 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. These revisions are necessary to (1) more comprehensively reflect the burden associated testing human participants and (2) incorporate new information elements identified as necessary during the COVID-19 pandemic.

The regulatory authority for the NIOSH approval 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. 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 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.

Additionally, throughout the regulation, testing and evaluation using human participants to assess the performance and capacity of various respirator types is described. Please refer to **Table 1** below for specific areas within the regulation that call for human participant testing along with a link to the publicly available testing procedures. The participant serves as a "living test fixture" with the data collected during the tests themselves not pertaining to the participant. However, participant payment does require information about the individual to be collected, which is described in the next section.

Table 1. Specific test procedures within 42 CFR Part 84 that require that the respirator be tested and evaluated using a human participant.

NIOSH Test Requiring Human Participant	Federal Regulation
Isoamyl Acetate Test – STP-0005-05a-06	84.63, 84.124, 84.176, 84.205
Facepiece Fit Test, quantitatively using corn oil aerosol for full facepiece – CVB-APR-STP-0009	84.176
Facepiece Fit Test, quantitatively using corn oil aerosol for hoods/helmets – CVB-APR-STP-0010	84.176

Powered Air-Purifying Respirator Sound Level Test - RCT-APR-0030	84.63, 84.202, 84.177
Saccharin/Bitrex Test - RCT-APR-0067	84.63
Supplied-Air Isoamyl Acetate Test - RCT-ASR-0110.rev1.1	84.63, 84.159
Supplied-Air Sound Level Test -RCT-ASRS-STP-0111	84.140
Abrasive Blast Supplied Air Quantitative Corn Oil Test - RCT-ASR-0112.rev1.1	84.63
SCBA/CCSCBA Cold Temperature Test - RCT-ASR-0118.rev1.1 ; RCT-ASR-0143.rev1.1	84.63, 84.98
SCBA Isoamyl Acetate Test - RCT-ASR-0125.rev1.1. ; RCT-ASR-0125A.rev1.1	84.63, 84.104
SCBA Man Test #1-4 - RCT-ASR-0140.rev1.1	84.63, 84.99, 84.100
SCBA Man Test #5 - RCT-ASR-0141.rev1.1	84.63, 84.101, 84.102
SCBA Mode of Transfer Test - RCT-ASR-0147.rev1.1	84.63
SCBA Man Test #6 RCT-ASR-0155.rev1.1	84.63, 84.102, 84.103
Communications Test – TEB-CBRN-APR-STP-0313 Rev 2.0	84.63
Fogging Test - CET-APRS-STP-CBRN-0314	84.63
LRPL Quantitative Corn Oil Test - TEB-CBRN-APR-STP-0352 ; TEB-CBRN-APR-STP-0452-508. ; TEB-CBRN-APR-STP-0552 ; TEB-CBRN-APR-STP-0352	84.63
LRPL Donning - Microsoft Word - CET-APRS-STP-CBRN-0499.rev1.1	84.63
CCER Wearability - TEB-CCER-STP-0610	84.303(d), 84.306
CCER Donning - TEB-CCER-STP-0611	84.306(b)(1)(2)
CCER Capacity - TEB-CCER-STP-0612	84.303, 84.304
CCER Performance - TEB-CCER-STP-0613	84.303, 84.305
CCER Assessment of Stressors - TEB-CCER-STP-0614	84.303, 84.304, 84.305(a)(3), 84.306
CCER Man Test #4 - TEB-CCER-STP-0615	84.304(a)(5)
CCER Human Participant Work Rate - TEB-CCER-SOP-0616	84.304(a)(4), 84.305(a)(3)

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 (Attachments 7 a-c) 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.

To evaluate the performance requirements in 42 CFR 84, human participants are used as test fixture surrogates to perform tests while wearing the respirator being evaluated. The purpose of the data collection is to assess the performance of the respirator, not the human participant. The data collected is used to make informed program decisions based on the outcome of the tests. Data is collected via computer programs and is stored electronically within the Respirator Approval Program data system.

Participants provide their name and contact information (Attachment 8), provide their consent (Attachment 9), complete health and wellness screenings depending on the type of test (Attachments 10-12), and have various types of other information collected from them such as their initial and final weight, facial dimensions, and respiration (Attachments 13-26). Every application received by NIOSH's Respirator Approval Program is a new "project" – participant name and contact information is used for scheduling throughout the year. Consent and health and wellness screenings are necessary for participant safety. The other data collected is necessary to evaluate the performance of the respirator itself.

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.

Hundreds of projects are accepted by the CVSDB each year, including requests for certification of new, improved respirator designs. This data 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. Forms are received using CDC authorized systems that currently include Outlook, NIOSH's Division Electronic Information Management System (DEIMS), and will eventually be received using the Respirator Approval System that is currently under development by NIOSH.

Respirator performance test data and human participant data is collected electronically via instrumentation and computer software that is authorized by use by the CDC. These data are then

electronically stored on CDC MUST drives. In the future, these data are expected to be stored within NIOSH's Edge Computing Platform.

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.

Human participants may be recruited to participate multiple times as applications and the need for testing arises. While some data must be collected with each "project," NIOSH is able to allow some information to be collected only once every 12 months (e.g., some of the health and wellness data).

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 approved, or until the approval of the unit is invalidated. These records must be retained for the duration of the approval, 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 60-day Federal Register Notice was published November 28, 2022 (Attachment 3). No comments were received. Additionally, 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 those respondents who are applicants; however, human participants are compensated for their time at a rate ranging from (1) $50/hour for tests that require the participant to move their head and mouth in specific patterns to (2) $75/hour for tests that require the participant to withstand cold temperatures, to (3) a maximum of $100/hour for tests that require a certain level of physical exertion that limits the population of participants capable of doing the tests (e.g. the types of testing necessary to evaluate respirators that are used by physically fit firefighters). The participant payment values are the minimum amount that NIOSH

has been able to offer while still providing sufficient incentive for individuals travel to its more rural Pittsburgh campus where no public transportation routes to the facility exist.

NIOSH is not able to issue IRS 1099 forms to participants who earn $600 or more in a single tax year. Therefore, NIOSH additionally tracks payments to participants to ensure that no individual exceeds $599 in a given tax year. Payment will be issued to participants using gift cards – i.e., no additional information such as SS# or banking information is necessary.

10. Assurance of Confidentiality Provided to Respondents

ISSO determined in conjunction with the CDC Privacy Office that Privacy Act is applicable. The collection contains PII with demographic information in the survey (i.e., Name, Contact information, Sensitive health information, and Two-dimensional facial dimensions).

The collection methods will include phone calls and in-person conversations. The data will be stored in NIOSH Edge Computing Platform (NCEP), which includes the in-place technical, physical, or administrative controls (safeguards).

NIOSH Edge Computing Platform (NCEP) System Security Plan (SSP) defines the process for handling security incidents. The system's team and the Cybersecurity Program Office (CSPO) share the responsibilities for event monitoring and incident response. Direct reports of suspicious security or adverse privacy related events to the component's Information Systems Security Officer (ISSO), CDC helpdesk, or to the CDC Security Incident Response Team (CSIRT). The CDC CSPO reports to the HHS Computer Security Incident Response Center (CSIRC), which reports incidents to US-CERT as appropriate."

For the applicants, personally identifiable information includes 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. Data collected is not intended to be retrieved by contact information. Institute personnel use provided contact information solely in regard 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 (CDC MUST drives, CDC NIOSH's DEIMS, and eventually CDC NIOSH's Respirator Approval System). Personnel working with the documentation must have Sensitive Data clearance.

For human participants, personally identifiable information includes their name, contact information, sensitive health information, and two-dimensional facial dimensions. The facial dimension information is used to place individuals into one of ten face size categories (categories 1 to 10). Because all face size categories must be represented for the application to be completed, NIOSH routinely contacts past participants with known face sizes to inquire about their interest in participating again. Thus, when human participants are needed to complete an application, NIOSH staff first contact individuals who routinely participate and are demonstrated to be reliable. As the face size categories begin to be populated, NIOSH staff then look at the face size category variable in their spreadsheet of past participants to identify who to call next to inquire about participation. Recruitment of potential test participants is ongoing as the approach just described is one that relies upon a "test participant bank" that is maintained over time.

Health and wellness screening information is kept in a locked, fire-resistant cabinet with restricted access. All other human participant information is kept on CDC MUST drives and will eventually be kept on the CDC NIOSH Edge Computing Platform with access restricted to only those involved in routine testing of these individuals. *"Data will be kept private to the extent allowed by law"*

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.

<u>Technical Controls</u>

User Identification (Windows Login)

Firewall

<u>Physical Controls</u>

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. For those respondents who are applicants, 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.

For those respondents who are human participants, consent is obtained during each day of testing. Data is used to make respirator approval decisions only. Data is not used for research.

D. Application for Institute approval of a respirator is voluntary, and the benefits of applying are understood by the respondents.

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

The information collection received a non-research determination—IRB approval is not required (Attachment 6). This data collection contains no sensitive questions related to gender, sexual behavior and attitudes, religious beliefs, or other related matters that are commonly considered personal and private. Health and wellness information is collected from the human participants – this information is necessary to ensure participant safety.

12. Estimates of Annualized Burden Hour and Costs

The prior submission acknowledged the use of human participants with the inclusion of the IRB determination as an appendix. However, the specific burden to these individuals was not

catalogued in the package. The revision below provides a comprehensive description of the burden to these individuals.

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) (Attachment 5) to apply for a manufacturer code. Once a code has been issued, applicants must then complete the full version of the SAF (Attachment 4) to submit projects for review by the Respirator Approval Program before being granted an approval. NIOSH is using 2019 numbers to justify its burden estimates as 2019 was prior to the COVID-19 pandemic and represents a more realistic year-to-year expectation.

a. In 2019, 102 respirator companies 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.

e. 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.

f. Human participant time and costs are tracked annually. From 2017 – 2019, an average of 1,700 human participant hours per year were expended for respirator testing.

Respirator manufacturers are the respondents (an estimated 140 respondents are expected each year). 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. Historically data estimates the average fee at $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 (Attachment 7a-c). There is no fee associated with audits, which may occur periodically or as a result of a reported issue. 81 site audits were completed during the fiscal year 2022 (2022 is

being used because existing manufacturing sites must be audited and it is the most recent year of reference). Audits take up to 16 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, 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, 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	Attachment 4 – Standard application form	140	4	229	128,240
	Attachment 5 – Request manufacturing code	10	1	30/60	5
	Attachment 7a – Site audits, Part 1	85	1	30/60	43
	Attachment 7b – Site audits, Part 2	85	1	9/60	13
	Attachment 7c – Site audits (completed for each corrective action)	70	2	16	2,240
Member of general public	Attachment 8 – Information sheet (initial participant visit only – contact info)	10	1	9/60	2
	Attachment 9 – Informed consent (annually, all test participants)	40	1	15/60	10
	Attachment 10 – Health and wellness screening (annually, all test participants)	40	1	15/60	10
	Attachment 11 – Health and wellness screening (each test, fit testing)	40	20	6/60	80
	Attachment 12 – Health and wellness screening (each test, man testing)	10	10	15/60	25
	Attachment 13 – Data collection form (man testing)	10	10	45/60	75
	Attachment 14 – Capacity test	10	1	6/60	1
	Attachment 15 –	10	1	2	20

	Communication Tests				
	Attachment 16 – Donning test	10	1	1	10
	Attachment 17 – Fit test STP 5_5.1_6	14	20	9/60	42
	Attachment 18 - Fit tests STP-9 and 10	14	20	9/60	42
	Attachment 19 – Fogging test	10	1	30/60	5
	Attachment 20 - LRPL_Bitrex_Donning	38	1	1	38
	Attachment 21 – Performance Test	10	1	1	10
	Attachment 22 - Sound level STP-30_STP-111	25	2	6/60	5
	Attachment 23 – Stressors	10	1	1	10
	Attachment 24 – Test 118	10	25	30/60	125
	Attachment 25 – Test 147	10	4	9/60	6
	Attachment 26 – Wearability test	10	1	18/60	3
Total					131,060

Form	Total Burden Hours (from above)	Estimated Hourly Wage Rate	Total Cost of Hour Burden
Attachment 4 – Standard application form	128,240	$79.89	$10,245,093.60
Attachment 5 – Request manufacturing code	5.0	$79.89	$399.45
Attachment 7a – Site audits, Part 1	43	$79.89	$3,435.27
Attachment 7b – Site audits, Part 2	13	$79.89	$1,018.60
Attachment 7c – Site audits (completed for each corrective action)	2,240.0	$79.89	$178,953.60
Attachment 8 – Information sheet (initial participant visit only – contact info)	2.0	$50.00	$100.00
Attachment 9 – Informed consent (annually, all test participants)	10.0	$50.00	$500.00
Attachment 10 – Health and wellness screening (annually, all test participants)	10.0	$50.00	$500.00
Attachment 11 – Health and wellness screening (each test, fit testing)	80.0	$50.00	$4,000.00
Attachment 12 – Health and wellness screening (each test, man testing)	25	$75.00	$1875
Attachment 13 – Data collection form (man testing)	75	$75.00	$5,625
Attachment 14 – Capacity test	1	$50.00	$50.00
Attachment 15 – Communication Tests	20	$50.00	$1,000
Attachment 16 – Donning test	10	$50.00	$500.00
Attachment 17 – Fit test STP 5_5.1_6	42.0	$50.00	$2,100.00
Attachment 18 - Fit tests STP-9 and 10	42.0	$50.00	$2,100.00
Attachment 19 – Fogging test	5	$75.00	$375.00
Attachment 20 -	38.0	$50.00	$1,900.00

LRPL_Bitrex_Donning			
Attachment 21 – Performance Test	10	$50.00	$500.00
Attachment 22 - Sound level STP-30_STP-111	5.0	$50.00	$250.00
Attachment 23 – Stressors	10	$50.00	$500.00
Attachment 24 – Test 118	125	$50.00	$6,250.00
Attachment 25 – Test 147	6	$50.00	$300.00
Attachment 26 – Wearability test	3	$50.00	$150.00
Total			$10,457,475.52

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. For test participation, $50.00 was estimated as this is the dollar amount NIOSH has deemed is necessary to successfully recruit test participants to its NIOSH Pittsburgh facility - $75.00 and $100.00 was necessary for two tests as noted earlier in the document.

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

Since the last submission, NIOSH conducted an analysis that determined the current cost to operating the Program is far more than what is currently being collected under NIOSH's authority to collect fees. Thus, the cost framework has been updated to better align with a more

accurate reflection of the current cost – NIOSH is actively working to update its fee structure to collect fees more aligned with the actual cost.

Form	**Staff Hours**	**Estimated Hourly Wage Rate and Other Cost Factors**	**Total Cost of Hour Burden**
NIOSH staff time to review and process Attachment 4	560 applications x (15 hours for initial application review + 15 hours for quality assurance review + 1 hours for final review + 1 hour for concurrence review + 1 hours management oversight + 1 hours data management + 1 hours administrative management) = 19,600	$68.20 (assumes average hourly wage of $55.45 +23% benefits package)	$1,336,720.00
NIOSH staff time to review and process Attachment 5	10.0	$65.78 (assumes average hourly wage of $53.48 +23% benefits package)	$657.80
NIOSH staff time (includes contractor time) to review and process Attachments 7a and b	85 x 4 staff x 15 hours = 5,100	$180,000 (contract) + $65.78 hourly wage of NIOSH staff (assumes average hourly wage of $53.48 +23% benefits package)	$515,478.00
NIOSH staff time to review and process Attachment 7c	70 sites x 5 staff x 12 hours = 4,200 hours	$65.78 (assumes average hourly wage of $53.48 +23% benefits	$276,276.00

		package)	
Attachment 8 – Information sheet (each visit, all tests)	2.0	$50.00 (test participant payment)	$100.00
Attachment 9 – Informed consent (annually, all test participants)	10.0	$50.00 (test participant payment)	$500.00
Attachment 10 – Health and wellness screening (annually, all test participants)	10.0	$50.00 (test participant payment)	$500.00
Attachment 11 – Health and wellness screening (each test, fit testing)	80.0	$50.00 (test participant payment)	$4,000.00
Attachment 12 – Health and wellness screening (each test, man testing)	7.5	$100.00 (test participant payment)	$750.00
Attachment 13 – Data collection form (man testing)	22.5	$100.00 (test participant payment)	$2,250.00
Attachment 14 – Capacity test	2.0	$50.00 (test participant payment)	$100.00
Attachment 15 – Communication Tests	16.0	$50.00 (test participant payment)	$800.00
Attachment 16 – Donning test	2.0	$50.00 (test participant payment)	$100.00
Attachment 17 – Fit test STP 5_5.1_6	42.0	$50.00 (test participant payment)	$2,100.00
Attachment 18 - Fit tests STP-9 and 10	42.0	$50.00 (test participant payment)	$2,100.00
Attachment 19 – Fogging test	1.0	$75.00 (test participant payment)	$75.00
Attachment 20 - LRPL_Bitrex_Donning	38.0	$50.00 (test participant payment)	$1,900.00
Attachment 21 – Performance Test	2.0	$50.00 (test participant payment)	$100.00
Attachment 22 - Sound level STP-30_STP-111	5.0	$50.00 (test participant payment)	$100.00

Attachment 23 – Stressors	2.0	$50.00 (test participant payment)	$100.00
Attachment 24 – Test 118	25.0	$75.00 (test participant payment)	$1,875.00
Attachment 25 – Test 147	1.2	$50.00 (test participant payment)	$60.00
Attachment 26 – Wearability test	0.6	$50.00 (test participant payment)	$30.00
CDC and NIOSH staff hours for Attachments 8 to 26	(309.75 hours x 2 NIOSH testing staff during test) + (100 hours x 2 staff for scheduling, set-up, etc.) + (275 hours x 1 administrative gift card manager) + (50 hours of CDC gift card compliance oversight x 1 compliance agent) = 1,144.5 hours	$65.78 (assumes average hourly wage of $53.48 +23% benefits package)	$75,285.21
NIOSH staff hours for laboratory accreditation and equipment maintenance, calibrations, etc.	2,000 x 2.5 NPPTL staff for calibrations, audits, procedure development, etc. = 5,000	$926,000 + $65.78 (assumes average hourly wage of $53.48 +23% benefits package)	$1,254,900.00
NIOSH staff hours (includes contractor hours) and costs for information system management ensuring information security	(1,500 hours x 3 project development staff) + (500 hours x 3 senior leaders) + (100 hours administrative time) = 6,100 hours	$500,000.00 (per year for next 3 years) + $92.89 hourly wage (assumes average wage of $75.16 +23% benefits package)	$1,066,629.00
NIOSH staff hours for oversight across all collection instruments	1,800 x (4 senior leaders + 6 frontline leaders) + (400 hours x 3 executive	$94.80 hourly wage (assumes average wage of $77.07 +23%	$1,820,160.00

	leaders) = 19,200	benefits package)	
Total			$6,363,646.01

Wage data for federal workers was determined as the average GS grade and step of the employees involved. Costs associated with contracts were based on the current contracted amount or estimates of the contracted amount.

15. Explanation for Program Changes or Adjustments

NIOSH submits this revision to improve its description of information collected to ensure that information collected from human participants while testing respirators to the required performance standards is sufficiently described. Previously, NIOSH included its non-research determination, clearly indicating the involvement of human participants. However, past information collection packages did not describe the data being collected from these human participants or the burden to them as individuals.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.