NOTE TO REVIEWER: This is a revision request. This ICR is being submitted in association with the final rule "Additional Ambient Aerosol CNC Quantitative Fit Testing Protocols: Amendment to Respiratory Protection Standard." In this final rule, **OSHA is adding two modified PortaCount quantitative fit-testing protocols to its Respiratory Protection Standard (29 CFR 1910.134). The modified PortaCount protocols would be alternatives to the existing quantitative fit-testing protocols already listed in Part I.C of Appendix A of the Respiratory Protection Standard.**

This supporting statement has been revised to include the new protocols. OSHA is requesting a program change decrease of 201,640 hours, from 7,622,100 to 7,420,460 hours; all other burden hours and costs associated with the Respiratory Protection Standard ICR remain unchanged.

SUPPORTING STATEMENT FOR THE INFORMATION COLLECTION REQUIREMENTS OF THE RESPIRATORY PROTECTION STANDARD (29 CFR 1910.134)[1,2] Office of Management and Budget (OMB) Control No. 1218-0099 (April 2019)

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Occupational Safety and Health Act's (OSH Act) main objective is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources" (29 U.S.C. 651). To achieve this objective, the OSH Act specifically authorizes "the development and promulgation of occupational safety and health regulations" (29 U.S.C. 651).

To protect worker health, the OSH Act authorizes the Occupational Safety and Health Administration ("OSHA" or "Agency") to develop standards that provide for "monitoring or measuring employee exposure" to occupational hazards and "prescribe the type and frequency of medical examinations and other tests which shall be made available [by the employer] to

1 The purpose of this Supporting Statement is to analyze and describe the burden hours and costs associated with provisions of the Respiratory Protection Standard that contain paperwork requirements; this Supporting Statement does not provide information or guidance on how to comply with, or how to enforce, this Standard.

2 This Standard applies to general industry, construction, shipyard, longshoring, and marine-terminal workplaces.

employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure" (29 U.S.C. 655). In addition, the OSH Act mandates that "[e]ach employer shall make, keep and preserve, and make available to the Secretary [of Labor] . . . such records regarding [their] activities relating to this Act as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses" (29 U.S.C. 657). In addition, the OSH Act directs OSHA to "issue regulations requiring employers to maintain accurate records of employee exposure to potentially toxic materials or other harmful physical agents which are required to be monitored and measured," and further specifies that such regulations provide "for each employee or former employee to have access to such records as will indicate [their] own exposure to toxic materials or harmful physical agents" (29 U.S.C. 657). The OSH Act states further that "[t]he Secretary . . . shall . . . prescribe such rules and regulations as [he/she] may deem necessary to carry out [their] responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment" (29 U.S.C. 651).

The Respiratory Protection Standard, 29 CFR 1910.134, (the "Standard") assists employers in protecting the health of workers exposed to airborne contaminants, physical hazards, and biological agents. The Standard contains requirements for program administration; a written respiratory protection program with worksite-specific procedures; respirator selection; medical evaluations; fit testing; respirator use; respirator cleaning; maintenance, and repair; worker training; and other provisions. Items 2 and 12 below describe the specific information collection requirements of the Standard.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The following are the collection of information requirements as stated in the Standard, followed by discussions indicating how, by whom, and for what purpose the information is used for each of these requirements.

A. Respiratory protection program (29 CFR 1910.134(a) and (c))

§1910.134(a)(2) - A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in paragraph (c) of this section. The program shall cover each employee required by this section to use a respirator.

§1910.134(c)(1) - In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use. The employer shall include in the program the following provisions of this section, as applicable:

§1910.134(c)(1)(i) - Procedures for selecting respirators for use in the workplace;

§1910.134(c)(1)(ii) - Medical evaluations of employees required to use respirators;

§1910.134(c)(1)(iii) - Fit testing procedures for tight-fitting respirators;

§1910.134(c)(1)(iv) - Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;

§1910.134(c)(1)(v) - Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;

§1910.134(c)(1)(vi) - Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;

§1910.134(c)(1)(vii) - Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations;

§1910.134(c)(1)(viii) - Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance; and

§1910.134(c)(1)(ix) - Procedures for regularly evaluating the effectiveness of the program.

§1910.134(c)(2) - Where respirator use is not required:

§1910.134(c)(2)(i) - An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard. If the employer determines that any voluntary respirator use is permissible, the employer shall provide the respirator users with the information contained in Appendix D to this section ("Information for Employees Using Respirators When Not Required Under the Standard"); and

§1910.134(c)(2)(ii) - In addition, the employer must establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user. Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces (dust masks).

§1910.134(c)(3) - The employer shall designate a program administrator who is qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness.

§1910.134(c)(4) - The employer shall provide respirators, training, and medical evaluations at no cost to the employee.

Purpose: In developing and implementing written programs, employers must address the respiratory hazards in the workplace. This process requires employers to identify, measure, and document the hazardous atmospheres their workers may encounter during routine operations, as well as reasonably foreseeable emergencies that may occur in the workplace. When changes in atmospheric hazards or other workplace conditions affect respirator use, employers must update their written programs as appropriate.[3] Accordingly, a written program, properly updated, permits employers and OSHA compliance officers to assess the adequacy of the respiratory protection provided to workers.

B. Medical evaluation (29 CFR 1910.134(e))

Using a respirator may place a physiological burden on workers that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the worker. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the worker's ability to use a respirator.

§1910.134(e)(1) - General. The employer shall provide a medical evaluation to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace. The employer may discontinue an employee's medical evaluations when the employee is no longer required to use a respirator.

3 The burden for maintaining copies of written programs (see paragraph (m)(3) of the Standard) includes the requirement to update the programs.

Medical evaluation procedures (§1910.134(e)(2))

§1910.134(e)(2)(i) - The employer shall identify a physician or other licensed health care professional (PLHCP) to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire.

§1910.134(e)(2)(ii) - The medical evaluation shall obtain the information requested by the questionnaire in Sections 1 and 2, Part A of Appendix C of this section.

Purpose: The medical evaluation program ensures that any worker required to use a respirator can tolerate the: physiological burden associated with such use, including the burden imposed by the respirator itself (e.g., its weight and breathing resistance during both normal operation and under conditions of filter, canister, or cartridge overload); musculoskeletal stress; limitations on auditory, visual, and odor sensations; and physical and psychological isolation. Several job and workplace conditions also impose a physiological load on the worker who uses a respirator, including the duration and frequency of respirator use, the level of physical work effort, the use of protective clothing, and temperature extremes or high humidity. Job- and workplace-related stressors may interact with respirator characteristics to increase the physiological stress experienced by workers. For example, wearing protective clothing while performing heavy work can be highly stressful. Also, specific medical conditions can compromise a worker's ability to tolerate the physiological burdens imposed by respirator use, thereby placing the worker at increased risk of illness, injury, and even death. Such conditions include cardiovascular and respiratory diseases, reduced pulmonary function caused by factors such as smoking or prior exposure to toxic respiratory hazards, neurological or musculoskeletal disorders (e.g., ringing in the ears, epilepsy, lower back pain), and impaired sensory function (e.g., a perforated ear drum, reduced olfactory function). Psychological conditions, such as claustrophobia, also can impair respirator use and may cause significant elevations in heart rate that can jeopardize the health of workers who are at high risk for cardiopulmonary disease.

Follow-up medical examination (29 CFR 1910.134(e)(3))

§1910.134(e)(3)(i) - The employer shall ensure that a follow-up medical examination is provided for an employee who gives a positive response to any question among questions 1 through 8 in
Section 2, Part A of Appendix C or whose initial medical examination demonstrates the need for a follow-up medical examination.

§1910.134(e)(3)(ii) - The follow-up medical examination shall include any medical tests, consultations, or diagnostic procedures that the PLHCP deems necessary to make a final determination.

Purpose: The questionnaire and initial medical examination provide information about medical conditions and physical systems that may prevent or limit workers from using some types of respirators.

Supplemental information for the PLHCP (§1910.134(e)(5))

§1910.134(e)(5)(i) - The following information must be provided to the PLHCP before the PLHCP makes a recommendation concerning an employee's ability to use a respirator[4]:

§1910.134(e)(5)(i)(A) - (A) - The type and weight of the respirator to be used by the employee;

§1910.134(e)(5)(i)(B) - The duration and frequency of respirator use (including use for rescue and escape);

§1910.134(e)(5)(i)(C) - The expected physical work effort;

§1910.134(e)(5)(i)(D) - Additional protective clothing and equipment to be worn; and

§1910.134(e)(5)(i)(E) - Temperature and humidity extremes that may be encountered.

§1910.134(e)(5)(iii) - The employer shall provide the PLHCP with a copy of the written respiratory protection program and a copy of this section.

Purpose: This information is important to the PLHCP in making a recommendation regarding the worker's medical ability to use the respirator. Providing PLHCPs with information about the type of respirator and its use, as well as job and workplace, assists PLHCPs in determining if these factors may interact with preexisting medical conditions (identified through the medical questionnaire or medical examination) to impair a worker's ability to use the respirator. This information also allows the PLHCP to limit the conditions under which the worker uses a respirator.

Additional medical evaluations (29 CFR 1910.134(e)(7))

At a minimum, the employer shall provide additional medical evaluations that comply with the requirements of this section if:

4 In accordance with §1910.134(e)(5)(ii), any supplemental information provided previously to the PLHCP regarding a worker need not be provided for a subsequent medical evaluation if the information and the PLHCP remain the same.

§1910.134(e)(7)(i) - An employee reports medical signs or symptoms that are related to ability to use a respirator;

§1910.134(e)(7)(ii) - A PLHCP, supervisor, or the respirator program administrator informs the employer that an employee needs to be reevaluated;

§1910.134(e)(7)(iii) - Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for employee reevaluation; or

§1910.134(e)(7)(iv) - A change occurs in workplace conditions (e.g., physical work effort, protective clothing, temperature) that may result in a substantial increase in the physiological burden placed on an employee.

Purpose: This requirement ensures that a worker remains medically eligible to use a respirator during exposure to atmospheric contaminants in the workplace.

C. Fit testing (29 CFR 1910.134(f))

This paragraph requires that, before a worker may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the worker must be fit tested with the same make, model, style, and size of respirator that will be used. This paragraph specifies the kinds of fit tests allowed, the procedures for conducting them, and how the results of the fit tests must be used.[5]

§1910.134(f)(1) The employer shall ensure that employees using a tight-fitting facepiece respirator pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as stated in this paragraph.

§1910.134(f)(2) - The employer shall ensure that an employee using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter.

5 After a fit test, employers must record the worker's name, the date of the fit test, and the type, brand, and size of the respirator in accordance with paragraph (m)(3) of the Standard. These records ensure that: respirator users receive the proper fit test; the respirators selected are appropriate for the atmospheric hazards they encounter; and the respirator users receive annual retesting.

§1910.134(f)(3) - The employer shall conduct an additional fit test whenever the employee reports, or the employer, PLHCP, supervisor, or program administrator makes visual observations of, changes in the employee's physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.

Purpose: Respirators must fit properly to provide protection. If a tight seal is not maintained between the facepiece and the worker's face, contaminated air will be drawn into the facepiece and be breathed by the worker. The fit testing requirement of paragraph (f) seeks to protect the worker against breathing contaminated ambient air and is one of the core provisions of the respirator program required by this standard.

D. Maintenance and care of respirators (29 CFR 1910.134(h))

Storing and marking emergency-use respirators (§1910.134(h)(2)(ii)(B))

This paragraph requires the employer to provide for the cleaning and disinfecting, storage, inspection, and repair of respirators used by workers.

§1910.134(h)(2)(ii)(B) - Stored in compartments or in covers that are clearly marked as containing emergency respirators; and

§1910.134(h)(2)(ii)(C) - Stored in accordance with any applicable manufacturer instructions.

Certification of inspection records for emergency-use respirators - (§1910.134(h)(3)(iv)(A) and (h)(3)(iv)(B))

§1910.134(h)(3)(iv) - For respirators maintained for emergency use, the employer shall:

§1910.134(h)(3)(iv)(A) - Certify the respirator by documenting the date the inspection was performed, the name (or signature) of the person who made the inspection, the findings, required remedial action, and a serial number or other means of identifying the inspected respirator; and

§1910.134(h)(3)(iv)(B) - Provide this information on a tag or label that is attached to the storage compartment for the respirator, is kept with the respirator, or is included in inspection reports stored as paper or electronic files. This information shall be maintained until replaced following a subsequent certification.

Purpose: Marking compartments and covers permits ready access to the respirators in the event

of an emergency. Additionally, certification of inspection records provides assurance to workers that emergency-use respirators will operate properly when needed.

E. Breathing air quality and use (29 CFR 1910.134(i))

This paragraph requires the employer to provide workers using atmosphere-supplying respirators (supplied-air and SCBA) with breathing gases of high purity.

§1910.134(i)(4)(ii) - Cylinders of purchased breathing air have a certificate of analysis from the supplier that the breathing air meets the requirements for Grade D breathing air; and

§1910.134(i)(5)(iv) - Have a tag containing the most recent change date and the signature of the person authorized by the employer to perform the change. The tag shall be maintained at the compressor.

Purpose: The certificate of analysis assures workers and employers that the purchased breathing air used in atmosphere-supplying respirators is safe. In addition, the tag requirement provides assurance to workers and employers that sorbent beds and filters are functioning properly to remove hazardous substances from the air produced by compressors for atmosphere-supplying respirators.

F. Training and information (29 CFR 1910.134(k))

Upon further analysis, the requirement that employers provide training to workers under paragraph (k), with the exception of § 1910.134(k)(6), is not considered to be a collection of information.

Paragraph (k)(6) requires the employer to provide the basic information on respirators in Appendix D of this section to workers who wear respirators when not required by this section or by the employer to do so.[6]

§1910.134(k)(6) - The basic advisory information on respirators, as presented in Appendix D of this section, shall be provided by the employer in any written or oral format, to employees who wear respirators when such use is not required by this section or by the employer.

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6 Employers must provide Appendix D, "Information for Employees Using Respirators When Not Required Under the Standard" to workers using respirators voluntarily. Appendix D requires employees to: "Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators [*sic*] limitations."

Purpose: If an employer provides respirators to workers for voluntary use, or if a worker provides his/her own respirator, precautions need to be taken to be sure that the respirator itself does not present a hazard.

OSHA considers the requirement in § 1910.134(k)(6) that employers provide Appendix D to workers to be a public disclosure of information originally supplied by the Federal government to the employer for the purpose of disclosure to the public. Additionally, the Agency considers the requirement in Appendix D that workers engaged in voluntary respirator use "read and heed" instructions provided by the respirator manufacturer to be a usual and customary practice in these industries. Therefore, OSHA is taking no burden hours for this requirement.

G. Recordkeeping (29 CFR 1910.134(m))

This section requires the employer to establish and retain written information regarding medical evaluations, fit testing, and the respirator program. This information will facilitate worker involvement in the respirator program, assist the employer in auditing the adequacy of the program, and provide a record for compliance determinations by OSHA.

Medical evaluation (§1910.134(m)(1))

§1910.134(m)(1) - Records of medical evaluations required by this section must be retained and made available in accordance with 29 CFR 1910.1020.

Fit Testing (§1910.134(m)(2))

§1910.134(m)(2)(i) - The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee including:

§1910.134(m)(2)(i)(A) - The name or identification of the employee tested;

§1910.134(m)(2)(i)(B) - Type of fit test performed;

§1910.134(m)(2)(i)(C) - Specific make, model, style, and size of respirator tested;

§1910.134(m)(2)(i)(D) - Date of test; and

§1910.134(m)(2)(i)(E) - The pass/fail results for QLFTs or the fit factor and strip chart recording or other recording of the test results for QNFTs.

§1910.134(m)(2)(ii) - Fit test records shall be retained for respirator users until the next fit test is administered.

Respirator Program - *(§1910.134(m)(3))*

§1910.134(m)(3) – A written copy of the current respirator program shall be retained by the employer.

§1910.134(m)(4) - Written materials required to be retained under this paragraph shall be made available upon request to affected employees and to the Assistant Secretary or designee for examination and copying.

Upon further consideration, once a complaint is accepted by OSHA for investigation, information collected by the Agency during the inspection is not subject to the PRA under 5 CFR 1320.4(a)(2). Therefore, OSHA takes no burden or cost for disclosure of these records to OSHA during an inspection in Items 12 and 14 of this Supporting Statement.

Purpose: Employers may use a worker's fit-testing records to select specific respirator makes, models, and sizes for subsequent fit testings, thereby avoiding unnecessarily prolonged fit-testing sessions. These records also enable OSHA to determine if: the employer tested a worker prior to initial respirator use, administered the appropriate test, and performed the test correctly; and the worker passed the test and is using the proper respirator model and size.

A written program, properly updated, permits employers and OSHA compliance officers to assess the adequacy of the respiratory protection provided to workers.

Making the information available to workers ensures that workers have access to information they can use to identify workplace atmospheric hazards and to determine the effectiveness of their employer's respiratory protection program.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce the burden.

Employers may use improved information technology when making, keeping, or preserving the required records. OSHA wrote the Standard in performance language, i.e., it states what information to collect rather than how to collect it.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use of the purposes described in Item 2 above.

The information collection requirements in the Standard are specific to each employer and worker involved, and no other source or agency duplicates the requirements or can make the required information available to the Agency (i.e., the required information is available only from employers).

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information collection requirements of the Standard do not have a significant impact on a substantial number of small entities. As per the final rule FEA, this rule is not economically significant within the context of Executive Order 12866 (58 FR 51735), or a "major rule" under Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 804). The rule imposes no additional costs on any private- or public-sector entity and does not meet any of the criteria for a significant or major rule specified by Executive Order 12866 or other relevant statutes or executive orders.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The information collection frequencies specified by the Standard are the minimum OSHA believes necessary to allow it and employers to evaluate the effectiveness of respiratory protection programs, especially the health protection afforded by respirator use to workers who work in toxic atmospheres.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **Requiring respondents to report information to the agency more often than quarterly;**

- **Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

- **Requiring respondents to submit more than an original and two copies of any document;**

- **Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**

- **In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

· **Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

· **That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

· **Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No special circumstances exist that require employers to collect information in the manner or using the procedures specified by this item.

8. If applicable, provide a copy and identify the data and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every three years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

In accordance with the PRA, 44 U.S.C. 3506(c)(2), OSHA solicited public comments on proposed revisions to the Respiratory Protection Standard Information Collection Request (ICR) (paperwork burden hour and cost analysis) for the information collection requirements associated with the Additional PortaCount® Quantitative Fit-Testing Protocols: Amendment to Respiratory Protection Standard proposed rule (81 FR 69747). The Department submitted this ICR to OMB for review in accordance with 44 U.S.C. 3507(d) on October 7, 2016. A copy of the ICR for the proposed rule is available to the public at:

https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201511-1218-005.

On November 22, 2016, OMB issued a Notice of Action withholding its approval of the ICR. OMB requested that, "[p]rior to publication of the final rule, the agency should provide a summary of any comments related to the information collection and their response, including any changes made to the ICR as a result of comments. In addition, the agency must enter the correct burden estimates."

No public comments were received specifically in response to the proposed ICR submitted to OMB for review. However, a few public comments submitted in response to the NPRM minimally addressed provisions containing collections of information and included information relevant to the burden hour and costs analysis. These comments are addressed in the preamble (see the comment analysis in § II.F) of the final rule.

Subsequent to the close of the public notice and comment period for the proposed rule, on August 24, 2018, OMB approved OSHA's request to extend approval for the general Respiratory Protection Standard ICR (1218-0099) until August 31, 2021. (ICR Reference Number: 201803-1218-004.)

A discussion of the significant public comments related to the final rule information collection requirements and the agency response is provided below:

OSHA received a total of 27 comments from 25 separate individuals (with one individual OSHA received a total of 27 comments from 25 separate individuals (with one individual submitting three separate comments) in response to its request for comments in the proposal (OSHA-2015-0015-0015 to OSHA-2015-0015-0042). In addition, TSI submitted a comment several months after the close of the comment period (OSHA-2015-0015-0047). The agency decided to add this comment to the docket as a late submission in the interest of full disclosure. OSHA, however, did not take into account the information contained in the late submission, nor did it sway or affect the agency's final determination.

Of the 27 comments submitted to OSHA, six did not specifically address any of OSHA's questions for public comment, but were generally in favor of the proposed protocols (OSHA-2015-0015-0016, OSHA-2015-0015-0018, OSHA-2015-0015-0019, OSHA-2015-0015-0020, OSHA-2015-0015-0030, OSHA-2015-0015-0039). Their reasons for being in favor of the protocols included that abbreviated protocols would save time and resources and would increase the willingness of employers to follow safety and health regulations.

Of the 27 comments, 13 minimally addressed the ICR. Here the agency will address each of the specific questions posed by OSHA in the proposal that could address burden hours or cost analysis:

1. Were the three studies described in the peer-reviewed journal articles well controlled and conducted according to accepted experimental design practices and principles?

Concerns related to experimental design and methods revolved around the ambient and purge times being too short (OSHA-2015-0015-0022, OSHA-2015-0015-0026, OSHA-2015-0015-0027, OSHA-2015-0015-0032, OSHA-2015-0015-0033, OSHA-2015-0015-0036, OSHA-2015-0015-0038, OSHA-2015-0015-0041, OSHA-2015-0015-0042). For example, one commenter recommended that the proposed protocols "should provide for suitable ambient and respirator purge durations to address the full range of particle concentrations that the device is recommended for use in instead of selecting a duration based on the optimum conditions that were selected for the studies…" (OSHA-2015-0015-0026). Several commenters were concerned that there was only a 5-second ambient test conducted at the beginning and end of the new protocols (OSHA-2015-0015-0032, OSHA-2015-0015-0036, OSHA-2015-0015-0042).

Regarding these comments, OSHA notes that for every exercise (except the grimace), the original OSHA-approved ambient aerosol CNC protocol involves a 4-second ambient purge, a 5-second ambient sample, and an 11-second mask purge, followed by a 40-second mask sample. A final 4-second ambient purge and 5-second ambient sample occur after the last 40-second exercise (normal breathing) mask sample. The proposed protocols employ the same 4-second ambient purge, 5-second ambient sample, and 11-second mask purge, followed by 4 consecutive 30-second mask samples during each of the 4 exercises, and a final 4-second ambient purge and 5-second ambient sample. Therefore, there are no differences in the ambient purge or sample times between the two proposed protocols. The new protocols differ from the original OSHA-approved sampling protocol in these ways: the ambient environment is measured only at the beginning and end of the exercises and not between each exercise, mask purging occurs just once (after the first ambient sample), and mask sampling time is 30 seconds rather than 40 seconds.

Thus, times for ambient purge and ambient sampling were not changed between the original OSHA-approved protocol and the proposed protocols. Requirements for conducting the fit test in an environment with an adequate particle concentration also did not change; they have been standard practice for the ambient aerosol CNC fit test method since its inception and approval by OSHA.

The time between the two ambient samples is 2 minutes 15 seconds in the proposed protocols, compared to 55 seconds between each ambient sample in the original protocol. This is not a large difference and is unlikely to introduce any significant errors if fit testers follow standard practice for the original protocol, i.e., an aerosol concentration between 1,000 and 30,000 particles/cm^3 (p/$cm^{3)}$ for filters with a NIOSH designation of N/R/P-99 or 100, and a concentration of 30 to 1,500 p/cm^3 for filters with a N/R/P-95 designation; no augmentation of

the ambient environment is recommended if the concentration exceeds 8000 p/cm^3 or 800 p/cm^3 for the 99/100 or the 95 filters, respectively.

8. Does the elimination of certain fit test exercises (e.g., normal breathing, deep breathing, talking) required by the existing OSHA-approved standard PortaCount® protocol impact the acceptability of the proposed protocols?

Several commenters expressed concern over removing certain fit test exercises (OSHA-2015-0015-0021, OSHA-2015-0015-0024, OSHA-2015-0015-0025, OSHA-2015-0015-0029, OSHA-2015-0015-0032, OSHA-2015-0015-0033, OSHA-2015-0015-0038, OSHA-2015-0015-0041), but did not provide any peer-reviewed data or published research to support their opinions. Three commenters (OSHA-2015-0015-0021, OSHA-2015-0015-0025, OSHA-2015-0015-0032) expressed concern about removing the talking exercise, because they had experienced fit test failures during the talking exercise when fit testing workers. Another commenter felt that "it doesn't make sense to eliminate [the talking] exercise simply because it wasn't the worst contributing exercise with poor fitting respirators" (OSHA-2015-0015-0033). A third suggested that the head side-to-side, head up-and-down, and talking exercises should be retained, because he believes they are currently the most rigorous exercises (OSHA-2015-0015-0024).

Another commenter suggested that "the conclusion to eliminate Normal Breathing 2 (NB2) from the Fast Full Protocol is extremely subjective" and questioned how "NB2 [normal breathing #2] could be eliminated and UD [moving head up and down] kept if there is no correlation with the study data?" (OSHA-2015-0015-0038). This commenter suggests that increasing the purge time would resolve the issue. Regarding this question, OSHA concluded that TSI's explanation for not considering a second normal breathing exercise following the bending over exercise made sense. TSI reasoned that the second normal breathing exercise had the lowest fit factor 19% of the time for poor-fitting respirators and 5% of the time for good-fitting respirators due to the fact that particles introduced during the preceding (bending over) exercise had a greater impact on the NB2 fit factor for poor-fitting respirators (OSHA-2015-0015-0008). Increasing the purge time to allow for all particles to clear from the facepiece would not, as the commenter suggests, improve the ability of the NB2 exercise to detect poor fits, but make its fit factor more similar to that measured during the first normal breathing exercise, which was never the lowest fit factor for any poor-fitting respirators. This is also supported by the fact that the NB1 and NB2 exercises were the lowest only 2 and 5% of the time, respectively, for good-fitting respirators.

12. Does OSHA's proposed regulatory text for the two new protocols offer clear instructions for implementing the protocols accurately?

One commenter was concerned about shortening the protocols to less than an eight-minute period, because she thought that symptoms of claustrophobia/panic attacks might not manifest before eight minutes (OSHA-2015-0015-0021). Although the agency agrees that claustrophobia/panic attacks are a potential concern for respirator wearers, this issue is addressed when the wearer is required, under 1910.134(e)(1) of the Respiratory Protection Standard, to undergo a mandatory medical evaluation "to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace." The mandatory medical questionnaire in Appendix C of the standard includes a question regarding claustrophobia. In addition, the agency is unaware of this having been an issue for respirator wearers who have been fit tested using the CNP REDON protocol (also an abbreviated quantitative fit testing protocol of less than eight minutes) since it was approved by OSHA on August 4, 2004.

Two commenters, while in favor of shorter protocols, expressed an interest in having the new protocols available on all ambient aerosol CNC-based fit testing instruments, particularly the older PortaCount® (model 8020) machines (OSHA-2015-0015-0028, OSHA-2015-0015-0030). OSHA notes that it only approves fit testing protocols, not specific fit testing machines. The agency has no authority to require which fit testing machines or models should or should not offer these new protocols. Employers must contact the manufacturers of CNC fit testing machines to determine which models are able to support the new protocols.

The public comments referenced above have also been uploaded into ROCIS.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

The Agency will not provide payments or gifts to the respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

OSHA considers the medical records required by the Standard to be confidential. To ensure that these records remain confidential, the Agency implemented 29 CFR1913.10, which governs its access to worker medical information.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be

given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

Perceived questions of a sensitive nature may be included in the medical questionnaires. Information from the medical questionnaire is necessary for the PLHCP, or employer, to determine what protections an employer must take to ensure that the employee will have minimal occupational exposure to hazards such as insufficient oxygen environments, harmful dusts, fogs, smokes, mists, gases, vapors, and sprays.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**

- **Provide estimates of annualized costs to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Respondent Burden Hour and Cost Burden Determinations

The following sections describe the methodology used for estimating the number of burden hours and costs resulting from the information collection requirements of the Standard. As part of the final rule, OSHA prepared a final economic analysis (FEA) as required by the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 et seq.) and Executive Orders 12866 (58 FR 51735 (Sept. 30, 1993)). New burden hours and costs for the fit-test protocols included in this ICR are based on the FEA. The total affected users identified in the FEA is 1,273,616. This number is representative of those who are potentially affected by the new fit-testing protocols, not the entire population of those covered by the respiratory standard.

On August 24, 2018, OMB approved OSHA's request to extend approval for the general Respiratory Protection Standard ICR (1218-0099) until August 31, 2021. (ICR Reference Number: 201803-1218-004.) For the ICR burden hours and costs not directly associated with

the final rule, OSHA applies updated wage rates consistent with the FEA to the burden hour assumptions approved under this ICR reference number. OSHA has determined that the previously approved burden hour assumptions already reflect the latest available establishment data associated with the final rule.

Wage Rates

The Agency determined the wage rate from mean hourly wage earnings to represent the cost of the employee time. For the relevant standard occupational classification category, OSHA used the wage rates reported in the Bureau of Labor Statistics (BLS), U.S. Department of Labor, Occupational Employment Statistics (OES), May 2016 [date accessed: September 12, 2017]. (OES data is available at: *https://www.bls.gov/oes/tables.htm*. To access a wage rate, select May 2016 "Occupational Profiles" and scroll down through the table to find the specific Standard Occupational Classification (SOC) code.)

To account for fringe benefits, the Agency used the BLS' *Occupational Employment Statistics (OES) (2017)*. Fringe markup is from the following BLS release: *Employer Costs for Employee Compensation* news release text; For release 10:00 AM (EDT), December 2017 (https://www.bls.gov/news.release/archives/ecec_12152017.htm). BLS reported that for private workers, fringe benefits accounted for 30.4 percent of total compensation and wages accounted for the remaining 69.6 percent. To calculate the loaded hourly wage for each occupation, the Agency divided the mean hourly wage by 1 minus the fringe benefits.

WAGE HOUR ESTIMATES				
Occupational Title	**Standard Occupational Code**	**Mean Hour Wage Rate (A)**	**Fringe Benefits (B)**	**Loaded Hourly Wage Rate (C) = (A)/((1-(B))**
Supervisory	11-1021	$58.70	30.4%	$84.34
Worker	00-0000	$23.86	30.4%	$34.28
Secretary	43-6010	$19.39	30.4%	$27.86
Occupational Health and	29-9010	$33.14	30.4%	$47.61

Safety Specialists and Technicians				

(A) Respiratory Protection Program (§1910.134(c))

The Standard requires employers to develop and maintain a written respiratory protection program. The Final Economic Analysis (FEA) for the Standard estimates that small and large firms take four and eight hours, respectively, to develop the written program. Of the estimated 631,607[7] employers covered by the Standard in 2012, OSHA believes that each year 10.3%[8] (65,056) are new employers who must develop new programs. The Agency assumes that 98% (63,755) of the new employers are small firms,[9] and that the remaining 2% (1,301) are larger employers. The Agency assumes a supervisor will develop the written program. Therefore, the total annual burden hours and cost for both employer groups to develop a written respiratory-protection program are:

Burden hours: (63,755 x 4 hours) + (1,301 x 8 hours) = 265,428 hours
Cost: 265,428 hours x $84.34 = $22,386,198

Existing employers[10] must update their programs to accommodate changes in workplace conditions that affect respirator use. OSHA assumes that 20% of existing employers (113,310) update their programs every year, and that supervisors for small firms (113,310 x 98% = 111,044 firms) would take two hours, and supervisors for larger firms (113,310 x 2% = 2,266 firms) would take four hours, to update the programs. The annual burden hour and cost estimates for existing employers to update their programs are:

Burden hours: (111,044 x 2 hours) + (2,266 x 4 hours) = 231,152 hours
Cost: 231,152 hours x $84.34 = $19,495,360

7 Source: *Respirator Usage in Private Sector Firms, 2001.* U.S. Department of Labor, Bureau of Labor Statistics (BLS) and the National Institute for Occupational Safety and Health (NIOSH). September 2003. Text Table 1: "Number and percent of establishments using respirators, by selected type of use and industry division." OSHA estimated the share of establishments using respirators in each sector by calculating the ratio of the number of establishments reported in Table 1 to total establishments reported by the 2001 County Business Patterns (CBP) and applying this same ratio to the 2012 County Business Patterns. OSHA adjusted the total 2001 CBP to represent only those industries covered by the regulation.

8 The U.S. Department of Labor, Bureau of Labor Statistics, Longitudinal Business Database (2012 establishment entry rate). Business Dynamics Statistics. https://www.census.gov/ces/dataproducts/bds/data_firm.html.

9 Small firms are defined as those employers employing less than 500 employees per facility.

10 Existing employers do not include the 65,056 employers who have developed new initial written respirator programs.

Total burden hours and costs for new and existing employers to develop their programs are:

Total Burden hours: 265,428 hours + 231,152 hours = 496,580 hours
Total cost: $22,386,198 + $19,495,360 = $41,881,558

(B) Medical Evaluation (§1910.134(e))

Paragraph (e)(2) of the Standard specifies that employers must medically evaluate workers prior to fit testing and initial respirator use. A PLHCP must perform medical evaluations using a medical questionnaire or an initial medical examination. The Agency estimates that a worker takes 15 minutes to complete the questionnaire. Based on the FEA and the change in employment in relevant industries from 2001 to 2015, it is estimated that in 2015 the Standard covered 5,849,542 workers.[11] The 2013 BLS Job Openings and Labor Turnover survey estimated an average total separations rate of 42.2%[12] in industries covered by the Standard. The burden hours and cost to administer the questionnaire to the 2,468,507 (5,849,542 x 42.2%) new workers (with an hourly wage rate of $34.28) each year are:

Burden hours: 2,468,507 questionnaires x 15/60 minutes = 617,127 hours
Cost: 617,127 x $34.28= $21,155,114

According to paragraph (e)(3) of the Standard, employers must provide follow-up medical examinations to workers who respond positively to specific items in the questionnaire (or to the initial medical examination). OSHA estimates that 23%[13] of the 2,468,507 new workers (567,757) require follow-up medical examinations each year, and that it takes one hour for them to receive a follow-up medical examination. Therefore, the annual burden hours and cost of this provision are:

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11 OSHA calculated the change in total employment for each industry division by comparing the employment numbers in the 2015 CBP to the 2001 CBP. OSHA then applied the aggregate percent change to the number of employees reported in OSHA's Supporting Statement for the Information–Collection Requirements of the Respiratory Protection (29 CFR 1910.134), 1218-0099 (April 2001). The results showed a 17% (1.16990836032495) overall increase in respirator users covered by the Standard. This 17% increase represents the change in employment for the relevant respirator-using industries between 2001 and 2015. Thus, it was applied to the estimate of affected workers contained in the 2001 ICR to determine updated employment figures (5,000,000 x (1+.16990836032495) = 5,849,542).

12 Source: Bureau of Labor Statistics, U.S. Department of Labor. 2013. Job Openings and Labor Turnover Survey. Separations rate for Private Industry. http://www.bls.gov/jlt/#data

13 The FEA estimated that 23% of the employees receiving an initial medical evaluation would need a follow-up medical examination. Accordingly, OSHA is applying this percentage to the total number of new employees covered by the Standard.

Burden hours: 567,757 workers x 1 hour = 567,757 hours
Cost: 567,757 hours x $34.28 = $19,462,710

Paragraph (e)(5) of the Standard requires employers to provide PLHCPs with information about a worker's respirator and work conditions before the PLHCP makes a recommendation concerning a worker's eligibility to use the respirator. Employers provide this information to PLHCPs prior to a worker's initial medical evaluation and any additional medical examination.[14] OSHA estimates that employers provide 2,468,507 initial medical evaluations and 292,477 additional medical (see paragraph (e)(7) below) evaluations each year and that, for each medical evaluation, a secretary takes 15 minutes to compile the required information and provide it to the PLHCP. Accordingly, each year the burden hours and cost of this requirement are:

Burden hours: 2,760,984 evaluations x 15/60 minutes = 690,246 hours
Cost: 690,246 hours x $27.86 = $19,230,254

Paragraph (e)(7) of the Standard requires employers to provide an additional medical evaluation to workers under specific conditions. However, the Agency believes that most workers who use respirators do not need additional medical evaluations. Therefore, OSHA assumes that 5% of all workers (5% x 5,849,542 = 292,477) will require additional medical evaluations each year, and that each of these workers takes half an hour to undergo the additional medical evaluation. The yearly burden hours and cost of this provision are:

Burden hours: 292,477 workers x 30/60 minutes = 146,239 hours
Cost: 146,239 hours x $34.28 = $5,013,073

Total burden hours and costs for administering the initial medical evaluations, follow-up medical examinations, and additional medical evaluations, as well as providing supplemental information to the PLHCPs, are:

Total Burden hours: 617,127 hours + 567,757 hours + 690,246 hours + 146,239 hours = 2,021,369 hours
Total cost: $21,155,114 + $19,426,710 + $19,230,254 + $5,013,073 = $64,861,151

C. Fit testing (§1910.134(f))

Based on percentages used in the FEA, of the 5,849,542 workers currently covered by this

14 Employers do not need to provide supplemental information regarding a worker to the PLHCP for subsequent medical evaluations when the information and the PLHCP are the same. Therefore, employers would rarely provide this information to a PLHCP when a worker receives a follow-up examination because the PLHCP usually receives the information prior to the initial medical evaluation.

provision, 13% (760,441) received annual fit tests when the standard became effective. Therefore, the additional paperwork requirement associated with annual fit testing applies only to the remaining 87% (5,089,102). From percentages used in the FEA, OSHA finds that outside contractors provide quantitative fit tests to 8% (407,128) of the remaining workers while respirator manufacturers administer qualitative fit tests to about 20% (1,017,820) of these workers at no cost to their employers, and employers conduct in-house fit testing on the final group of 3,664,154 workers.

In the 2018 ICR extension, OSHA revised the estimated time for employees to receive fit testing. The Agency estimated that, where applicable, approved abbreviated quantitative fit testing protocols (i.e., REDON) would take employers approximately 25 minutes to administer to employees. The Agency estimated that this situation currently applies to 1,032,972[15] respirator wearers.

For this rulemaking and associated ICR, OSHA is adding two modified PortaCount® quantitative fit-testing protocols to the Respiratory Protection Standard (29 CFR 1910.134); these proposed changes are termed "Program Changes" under PRA. These protocols are estimated to take 25 minutes (25/60) per fit-test, five minutes less than the current protocol procedures. The equations below estimate the burden hour and cost savings when employers use the proposed PortaCount® quantitative fit-testing protocols.

Summary of Burden Hour Changes -Program Changes			
Fit-Testing (§1910.134(f))	Adjusted Total Hours	Program Change	Total Burden Hours
Quant. Fit-Test by Outside contractors	169,636	-16,964	186,600
Qualitative Fit Testing by Respirator Manufacturers	508,910	0	508,910
In-House Fit Testing by OSH Technician	3,363,626	-184,676	3,548,302
Totals	4,042,172	-201,640	4,243,812

1. Quantitative Fit Testing by Outside Contractors

The Agency estimates approximately half of the fit tests to be conducted by outside contractors would use these new procedures.

***Burden hours**: 203,564 (REDON tests) x 25/60 (worker time) = 84,818 hours*

15 Tab Input and Parameters REDON, cell H81

***Cost**: 84,818 hours x $34.28 = $2,907,561*

***Burden hours**: 203,564 (Modified PortaCount® tests) x 25/60 hour (worker time) = 84,818 hours*

***Cost**: 84,818 hours x $34.28 = $2,907,561*

Total Burden hours: (84,818 REDON) + (84,818 Modified PortaCount) = 169,636 hours

Cost: ($2,907,561 REDON) + ($2,907,561 Modified PortaCount) = $5,815,122

2. Qualitative Fit Testing by Respirator Manufacturers

The new protocols would not change the burden hours for the qualitative fit tests that are provided by respirator manufacturers.

***Burden hours**: 1,017,820 tests x 30/60 hour (worker time) = 508,910 hours*

***Cost**: 5 hours x $34.28 = $17,445,435*

3. In-House Fit Testing by OSH Technicians

Employers conduct in-house fit testing for 3,664,152 workers. Of these, 695,121 workers will receive REDON in-house fit-testing, taking an OSH technician and employee 25 minutes. Also, OSHA estimates that in-house OSH technicians would administer 1,108,046 fit-tests using the proposed new PortaCount® protocols. Each new PortaCount® protocol test takes 25 minutes (25/60) to administer. The remaining in-house fit-tests using other (qualitative fit testing) protocols will take 30 minutes to administer. The remaining 1,860,985 workers will receive qualitative or other protocol fit-testing taking 30 minutes.

In addition, as modification to the wage analysis of the Respiratory Protection ICR, in order to match the accompanying Final Economic Analysis, the Agency is substituting an OSH Technician wage for in-house fit testing in place of the supervisor wage previously used. (The supervisor wage continues to apply to all other categories as used in the previous ICRs.)

REDON
OSH Technician: 695,121 tests x 25/60 hour = 289,634
Workers: 695,121 tests x 25/60 hour = 289,634
*Total: **579,268 hours***

Cost
OSH Technician: 289,634 hours x $47.61 = $13,789,475
Workers: 289,634 hours x $34.28 = $9,928,654

*Total: **$23,718,129***

PortaCount® protocols (Program change)
OSH Technician: 1,108,046 tests x 25/60 hour = 461,686
Workers: 1,108,046 tests x 25/60 hour = 461,686
*Total: **923,372 hours***

Cost
OSH Technician: 461,686 hours x $47.61 = $21,980,870
Workers: 461,686 hours x $34.28 = $15,826,596
*Total: = **$37,807,466***

***Other (Qualitative Fit Testing)**:*

OSH Technician: 1,860,985 x 30/60 hour = 930,493
Workers: 1,860,985 x 30/60 hour = 930,493
*Total**: 1,860,986 hours***

OSH Technician: 930,4937 hours x $47.61 = $44,300,772
Workers: 930,493 hours x $34.283 = $31,897,300
*Total: = **$76,198,072***

Total Burden hours: REDON (*579,268 hours)* + PortaCount® protocols *(923,372 hours*) + Other (Qualitative Fit Testing) (*1,860,986 hours) = 3,363,626 hours*
Total cost: REDON (*$23,718,129)* + PortaCount® protocols *($37,807,466)* + Other (Qualitative Fit Testing) (*$76,198,072) = $137,723,667*

D. Maintenance and care of respirators (§1910.134(h))

Storing and marking emergency-use respirators (§1910.134(h)(2)(ii)(B))

This provision requires employers to store emergency-use respirators in compartments or protective covers and clearly mark the compartments or covers to indicate that they contain emergency-use respirators. The FEA estimated that approximately 2% of the employers who use respirators must comply with this marking requirement; hence, out of the total number of employers who use respirators (631,607) 12,632 would be affected by the provision. OSHA assumes that 10% of these employers (1,263) are new employers who are complying with this provision for the first time, and that each of these employers marks an average of two emergency-use respirators, for a total of 2,526 respirators. In addition, the Agency estimates that a worker takes 5 minutes to mark a storage compartment or protective cover for each respirator. Therefore, the annual burden-hour and cost estimates for this requirement are:

Burden hours: 2,526 respirators x 5/60 minutes = 211 hours
Cost: 211 hours x $34.28 = $7,233

Certification of inspection records for emergency-use respirators (§1910.134(h)(3)(iv)(A) and (h)(3)(iv)(B))

Employers must inspect emergency-use respirators at least monthly and then certify, in writing, the inspection records for these respirators. OSHA estimates that a worker takes 10 minutes to perform the inspection and to complete the written certificate (e.g., enter the required inspection information on a tag or label attached to the compartment used to store the respirator). As noted in the previous section, the Agency determined that 12,632 employers each have 2 emergency-use respirators (for a total of 25,264 respirators). Accordingly, the yearly burden-hour and cost estimates for this provision are:

Burden hours: 25,264 respirators x 12 inspections/year x 10/60 minutes = 50,528 hours
Cost: 50,528 hours x $34.28 = $1,732,100

E. Breathing air quality and use (§1910.134(i))

Certificate of analysis for cylinders (§1910.134(i)(4)(ii))

The Agency believes that it is the usual and customary practice among suppliers of purchased breathing air to provide employers with the required certificate when they purchase the breathing air. Therefore, OSHA is taking no burden for this requirement.

Sorbent beds and filters (§1910.134(i)(5)(iv))

The Agency assumes that employers make three sorbent-bed and filter changes on each air compressor annually. OSHA estimates that the requirement to maintain a tag on each compressor displaying the required change information applies to 26,931 compressors[16], and that a worker takes five minutes to enter this information on a tag. Therefore, the annual burden hours and cost of this provision are:

Burden hours: 26,931 compressors x 3 changes/year x 5/60 minutes = 6,733 hours
Cost: 6,733 hours x $34.28 = $230,807

16 OSHA assumes that compressors are used in supplied air respirators and that the number of compressors declined at the same rate as total employment. The decline in total employment was calculated by comparing the 2001 CBP data to the 2015 CBP data. Hence, the 8.91% change is the change from 2001 to 2015 (see footnote 11). OSHA has updated the value contained in the 2001 ICR to update this 8.91% increase (24,727 x (1+.0891) = 26,931).

(F) Training and information (§1910.134(k))

Upon further analysis, the requirement that employers provide training to workers under paragraph (k), with the exception of § 1910.134(k)(6), is not considered to be a collection of information. OSHA considers the requirement in § 1910.134(k)(6) that employers provide Appendix D to workers to be a public disclosure of information originally supplied by the Federal government to the employer for the purpose of disclosure to the public. Additionally, the Agency considers the requirement in Appendix D that workers engaged in voluntary respirator use "read and heed" instructions provided by the respirator manufacturer to be a usual and customary practice in these industries. Therefore, OSHA is taking no burden hours for this requirement.

(G) Recordkeeping (§1910.134(m))

Medical-Evaluation Records (§1910.134(m)(1))

Employers must maintain the medical-evaluation records required by the Standard in accordance with 29 CFR 1910.1020. For purposes of estimating the burden hours and cost imposed by this recordkeeping provision, the Agency assumed that each medical procedure (i.e., initial medical evaluation, follow-up medical examination, and additional medical evaluation) resulted in a record. Based on the determinations made under section (B) above, OSHA finds that employers must maintain 33,328,741 medical records each year (i.e., 2,468,507 initial medical evaluations + 567,757 follow-up medical examinations + 292,477 additional medical evaluations). In addition, the Agency estimates that a secretary takes 5 minutes to maintain each medical record. Accordingly, the annual burden hours and cost of this recordkeeping requirement are:

Burden hours: 3,328,741 records x 5/60 minutes = 277,395 hours
Cost: 277,395 hours x $27.86 = $7,728,225

Respirator Fit-Testing Records (§1910.134(m)(2))

The fit-testing provisions of the Standard require employers to establish and maintain a record of the qualitative and quantitative fit tests administered to workers. As noted under section (C) above, employers collect 5,089,101 fit-testing records annually. OSHA estimates that a secretary spends 5 minutes annually establishing and maintaining each of these records. The burden hours and cost associated with this provision are:

Burden hours: 5,089,101 records x 5/60 minutes = 424,092 hours
Cost: 424,092 hours x $27.86 = $11,815,203

Written Respiratory Protection Program Records (§1910.134(m)(3))

In Paragraph A of Item 12 of this Supporting Statement, OSHA estimates the costs for employers to develop and update a written respiratory protection program. The Agency believes that, for each affected employer, a secretary takes 5 minutes to maintain the program record. Therefore, this provision results in the following burden hours and cost:

Burden hours: 631,607 records x 5/60 minutes = 52,634 hours
Cost: 52,634 hours x $27.86 = $1,466,383

Employee Access (§1910.134(m)(4))

OSHA assumes that each year 10% of the 5,849,542 workers subject to the medical-evaluation provisions of the Standard make a request to review their medical records. The Agency believes that a secretary takes 5 minutes to process each of these requests. Therefore, this provision results in the following burden hours and cost:

Burden hours: 584,954 workers x 5/60 minutes = 48,746 hours
Cost: 48,746 hours x $27.86 = $1,358,064

Estimated Annualized Respondent Hour and Cost Burden Table

***** The "*Additional PortaCount® Quantitative Fit-Testing Protocols: Amendment to Respiratory Protection Standard"* final rule impacts the highlighted rows only.

Information Collection Requirement (Across Top of Rows)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (In Hrs.)	Total Burden Hours (rounded)	Avg. Hourly Wage Rate*	Total Burden Costs (rounded)
A. Respiratory Protection Program								
	Supervisor	63,755	1	63,755	4	255,020	$84.34	$21,508,387
	Supervisor	1,301	1	1,301	8	10,408	$84.34	$877,811
	Supervisor	111,044	1	111,044	2	222,088	$84.34	$18,730,902
	Supervisor	2,266	1	2,266	4	9,064	$84.34	$876,458
Subtotal (A.)				***178,366***		***496,580***		***$41,881,558***
B. Medical Evaluation								
	Worker	2,468,507	1	2,468,507	15/60	617,127	$34.28	$21,155,114
	Worker	567,757	1	567,757	1	567,757	$34.28	$19,462,710
	Secretary	2,760,984	1	2,760,984	15/60	690,246	$27.86	$19,230,254
	Worker	292,477	1	292,477	30/60	146,239	$34.28	$5,013,073
Subtotal (B.)				***6,089,725***		***2,021,369***		***$64,861,151***
C. Fit Testing								
1. Quantitative Fit Testing by Outside								

Contractors								
REDON	Worker	203,564	1	203,564	25/60	84,818	$34.28	$2,907,561
*PortaCount protocols (Program Change)**	Worker	203,564	1	203,564	25/60	84,818	$34.28	$2,907,561
Subtotal (C.1.)				407,128		169,636		$5,815,122
2. Qualitative Fit testing by Respirator manufacturers	Worker	1,017,820	1	1,017,820	30/60	508,910	$34.28	$17,445,435
3. In-House Fit Testing by Supervisors								
REDON	OSH Technician	695,121	1	695,121	25/60	289,634	$47.61	$13,789,475
REDON	Worker	695,121	1	695,121	25/60	289,634	$34.28	$9,928,654
*PortaCount protocols (Program Change)**	OSH Technician	1,108,046	1	1,108,046	25/60	461,686	$74.61	$21,980,870
*PortaCount protocols (Program Change)**	Worker	1,108,046	1	1,108,046	25/60	461,686	$34.28	$15,826,596
Other (Qualitative Fit	OSH Technician	1,860,985	1	1,860,985	30/60	930,493	$47.61	$44,300,772

Testing)								
Other (Qualitative Fit Testing)	Worker	1,860,985	1	1,860,985	30/60	930,493	$34.28	$31,897,300
Subtotal (C.3)				7,328,306		3,363,626		$ 137,723,667
Subtotal (C.)				***8,753,254***		***4,042,172***		***$160,984,224***
D. Maintenance and Care of Respirators								
Storing and Marking Emergency-Use Respirators	Worker	2,526	1	2,526	5/60	211	$34.28	$7,233
Certification of Inspection Records for Emergency-Use Respirators	Worker	25,264	12	303,168	10/60	50,528	$34.28	$1,732,100
Subtotal (D.)				***305,694***		***50,739***		***$1,739,333***
E. Breathing Air Quality and Use								
Certificate of Analysis for Cylinders		-	-	-	-	-	-	-

Sorbent Beds and Filters	Worker	26,931	3	80,793	5/60	6,733	$34.28	$230,807
Subtotal (E.)				***80,793***		***6,733***		***$230,807***
F. Training and Information								
		-	-	-	-	-	-	-
G. Recordkeeping								
Medical-Evaluation Records	Secretary	3,328,741	1	3,328,741	5/60	277,395	$27.86	$7,728,225
Respirator Fit-Testing Records	Secretary	5,089,101	1	5,089,101	5/60	424,092	$27.86	$11,815,203
Written Respiratory Protection Program Records	Secretary	631,607	1	631,607	5/60	52,634	$27.86	$1,466,383
Employee Access	Secretary	584,954	1	584,954	5/60	48,746	$27.86	$1,358,064
Subtotal (G.)				***9,634,403***		***802,867***		***$22,367,875***
TOTAL		**24,710,469**		**25,042,236**		**7,420,460**		**$ 292,064,948**

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14.)

· **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life on capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

· **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

· **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

The fit-testing rule allows employers increased flexibility in choosing fit-testing methods for employees. It does not require an employer to update or replace its current fit-testing method(s).

OSHA requests that the existing approved operation and maintenance costs for the ICR be maintained. The estimates included in the previously approved ICR (ICR Reference Number: 201803-1218-004) are unchanged by the exposure profile for the final rule.

	Current Cost	Requested Cost	Change in Cost
Medical Examinations	$279,214,752	$279,214,752	$0
Fit-Testing	$4,470,268	$4,470,268	$0

Materials			
Quantitative Fit-Test	$33,221,645	$33,221,645	$0
Total	$316,906,665	$316,906,665	$0

Medical Examinations

Assuming that each medical examination costs $324.58[17], the total cost of administering the medical examinations (see section (B) above (§1910.134(e)(3) and (e)(7)) is $279,214,752 (567,757 follow-up + 292,477 additional = 860,234 medical examinations). As noted above, the fit-testing rule is designed to give employers increased options and flexibility and does not impose any new requirements. Specifically, it would not affect medical requirements for respirators. As such, there would be no new medical costs as a result of the rule.

Fit-Testing Materials

As noted under section (C) above, employers administer in-house fit tests to 3,644,154 workers each year. Estimating that the materials for each fit test cost $1.22[18], the total cost of these materials is $4,470,268.[19] This cost is related to qualitative fit testing, which is not affected by this rulemaking.

Quantitative Fit Tests

Section (C) above shows that contractors administer quantitative fit tests to 407,128 workers. Having determined that the price of each of these fit tests is $81.60[20], the total cost of this testing was $33,221,645. The Agency is estimating the reduction in burden hours associated with quantitative fit testing; however, it is not assuming a reduction in the contractor's unit price, therefore there is no estimated change to the cost of testing.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff),

17 The previous ICR assumed that each medical examination cost $294.75. The Consumer Price Index (CPI) indicated a 10.12% increase in the price of medical services from December 2010 to December 2013; the cost of a medical examination was assumed to have increased by 10.12% as well.

18 The previous ICR assumed that materials for each fit test cost $1.15. Given an increase in the overall CPI of 6.42% from 2010 to 2013, it was assumed that the cost of materials increased by 6.42% as well.

19 OSHA is not including the cost of administering qualitative fit tests as a capital expense because respirator manufacturers provide this service at no cost to employers with the purchase of their respirators.

20 The previous ICR determined that the price of quantitative fit test was $76.68. Given an increase in the overall CPI of 6.42% from 2010 to 2013, it was assumed that the cost of quantitative fit tests increased by 6.42% as well.

and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

The disclosure of records during an inspection is not subject to the PRA under 5 CFR 1320.4(a)(2). OSHA would only review records in the context of an open investigation of a particular employer to determine compliance with the standard. Therefore, OSHA takes no burden or cost in this supporting statement for disclosing information during an inspection.

15. Explain the reasons for any program changes or adjustments.

The Agency requests a program change decrease of 201,640 hours, from 7,622,100 to 7,420,460 hours, to incorporate the new fit-testing protocols associated with the final rule into this ICR.

There are no new operation or maintenance costs for the new fit-testing protocols associated with the final rule. Therefore, the Agency requests approval to maintain the existing operation and maintenance costs, $316,906,665, for the ICR.

16. For collection of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

OSHA will not publish the information collected under the Standard.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

OSHA lists current valid control numbers in 29 CFR 1910.8, 1915.8, 1917.4, 1918.4, and 1926.5 and publishes the expiration date in the Federal Register notice announcing OMB approval of the information-collection requirement. (See 5 CFR 1320.3(f)(3)) OSHA believes that this is the most appropriate and accurate mechanism to inform interested parties of these expiration dates.

18. Explain each exception to the certification statement.

OSHA is not seeking such an exception.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This Supporting Statement does not contain any collection of information requirements that employ statistical methods.

Table 1

Description of Requested Burden-Hour

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Burden Hour Change	Estimated Cost	Responses	Description of Change Adjustment or Program Change
Respiratory Protection Program	496,580	496,580	0	$41,881,558	178,366	
Medical Evaluation						
Medical Evaluation: Initial Medical Evaluations, Follow-up Medical Examinations, Additional Medical Evaluations, and Information Provided to the PLHCP	2,021,369	2,021,369	0	$64,861,151	6,089,725	
Fit Testing	4,243,812	4,042,172	-201,640	$160,984,224	8,753,254	Program Change: The FEA for the Final Rule determined that the number of responses decrease from 9,332,524 to 8,753,254.
Maintenance and Care of Respirators:						

Information Collection Requirement	Current Burden Hours	Requested Burden Hours	Burden Hour Change	Estimated Cost	Responses	Description of Change Adjustment or Program Change
Storing and Marking Emergency-Use Respirator	211	211	0	$7,233	2,526	
Certification of Emergency-Use Respirator	50,528	50,528	0	$1,732,100	303,168	
Breathing air quality and use						
Certificate of Analysis of Cylinders	-	-	-	-	-	
Sorbent Beds and Filters	6,733	6,733	0	$230,807	80,793	
Training and Information	-	-	-	-	-	
Recordkeeping						
Medical-Evaluation Records	277,395	277,395	0	$7,728,225	3,328,741	
Fit-Testing Records	424,092	424,092	0	$11,851,203	5,089,101	
Written Program Record	52,634	52,634	0	$1,466,383	631,607	
Employee Access	48,746	48,746	0	$1,358,064	584,954	
TOTALS	**7,622,100**	**7,420,460**	**-201,640**	**$292,064,948**	**25,042,236**	